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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 104 **11 February 2014**

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.690 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 36850, 20 September 2013 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 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.

Ascorbic Acid –see Vitamin C.

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 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 56 of 1974) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Schedule 1

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 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 56 of 1974) 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 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 56 of 1974) 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 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 56 of 1974) 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);

Schedule 1

b. except in pharmaceutical preparations and mixtures 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 56 of 1974) 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 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 56 of 1974) 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 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 56 of 1974) 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 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)

Schedule 1

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 56 of 1974) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Boron, in oral preparations or mixtures containing more than 3 mg of Boron per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Calcium,

a. in oral preparations or mixtures containing more than 1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection; (S3)

c. except when indicated for the treatment of hyperphosphataemia; (S4)

d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Carbamoyl benzamide phenyl isoxazoline, except when intended and registered as a stock remedy in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

Copper,

a. 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; (S0)

b. except in preparations thereof for injection. (S3)

Cyanocobalamin –*see* Vitamin B12.

Ephedrine, 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. (**[S2;]** S6)

Folic Acid, in oral preparations or mixtures containing more than 500 µg of Folic Acid per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Fluorides,

a. in oral medicinal preparations or mixtures intended for ingestion containing 0,25 milligrams or less of fluorine per dosage unit; **[S0]** *Schedule 0 inscription removed*

b. except in **[excluding]** toothpaste containing less than 0,15 percent fluoride; (S0) and

c. except in **[excluding]** mouth rinses containing less than 0,15 percent fluoride; (S0)

d. except in oral medicinal preparations or mixtures intended for ingestion containing more than 0,25 milligrams of fluorine per dosage unit. (S4)

Schedule 1

Flurbiprofen,

a. when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:

(i) a maximum of 8,75 milligrams per lozenge;

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

(iii) a maximum pack size of 15 lozenges.(S3)

b. when intended for application to the skin, provided that in the case of application by transdermal patch:

(i) use is restricted to adults and children 12 years and older; and

(ii) the treatment period is limited to a maximum of 4 weeks.

c. except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)

d. except when intended for ophthalmic use. (S4)

[**Gamma benzene hexachloride**].

Hyaluronic acid and its salts,

a. when intended for topical application to the skin; (S4)

b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)

c. except when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent; (S2)

d. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972),

Indometacin,

a. when intended for application to the skin; (S3)

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

Iron,

a. in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection; (S3)

c. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Schedule 1

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 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 56 of 1974) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacilius 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 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 56 of 1974) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus bulgaricus,

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 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 56 of 1974) 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);

Schedule 1

b. except in pharmaceutical preparations and mixtures 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 56 of 1974) 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 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 56 of 1974) 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 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 56 of 1974) 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 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)

Schedule 1

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 56 of 1974) 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 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 56 of 1974) 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 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 56 of 1974) 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 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 56 of 1974) 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 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 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 56 of 1974) 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 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 56 of 1974) 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 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 56 of 1974) 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);

Schedule 1

b. except in pharmaceutical preparations and mixtures 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 56 of 1974) 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 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 56 of 1974) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Magnesium, in oral preparations or mixtures containing more than 250 mg of Magnesium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Manganese,

a. in oral preparations or mixtures containing more than 4 mg of Manganese per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. in preparations thereof for injection when intended for veterinary use.

Molybdenum and derivatives thereof in oral preparations or mixtures containing more than 230 µg of Molybdenum per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Niacin (Nicotinic Acid, Vitamin B3) and derivatives thereof,

a. in oral preparations or mixtures containing more than 35 mg of Niacin per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except when intended for hypercholesterolaemia and for the management of dyslipidaemias. (S4)

Nicotinamide and derivatives thereof, in oral preparations or mixtures containing more than 500 mg of Nicotinamide per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Schedule 1

Nicotine,

a. when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to an including 21mg/ 24 hours;

b. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing not more than 4 mg nicotine per piece; (S0)

c. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4 mg nicotine per piece; (S2)

d. except when registered as metered sprays containing not more than 1 mg per dose; (S2)

e. except when registered as oral solid dosage forms containing not more than 2 mg; (S2)

f. except when registered as inhalers containing not more than 10 mg per cartridge; (S2)

g. except when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended). (S3)

Nystatin,

e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Pantothenic Acid –*see* Vitamin B5.

Phosphorus, in oral preparations or mixtures containing more than 250 mg of Phosphorus per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Pyridoxine –*see* Vitamin B6.

Riboflavin –*see* Vitamin B2.

Selenium,

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

b. in preparations thereof for injection when intended for veterinary use.

Streptococcus thermophilus,

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 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 56 of 1974) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Thiamine –*see* Vitamin B1.

Thiomersal.

Vitamin B1 (Thiamine) and derivatives thereof,

a. in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection. (S3)

Vitamin B2 (Riboflavin) and derivatives thereof,

a. in oral preparations or mixtures containing more than 100 mg of Vitamin B2 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection. (S3)

Vitamin B5 (Pantothenic Acid) and derivatives thereof,

a. in oral preparations or mixtures containing more than 200 mg of Vitamin B5 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection. (S3)

Vitamin B6 (Pyridoxine) and derivatives thereof,

a. in oral preparations or mixtures containing more than 100 mg of Vitamin B6 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection. (S3)

Vitamin B12 (Cyanocobalamin) and derivatives thereof,

a. in oral preparations or mixtures containing more than 100 µg of Vitamin B12 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection. (S3)

Vitamin C (Ascorbic Acid),

a. in oral preparations or mixtures containing more than 1000 mg of Vitamin C per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in preparations thereof for injection. (S3)

Vitamin H (Biotin) and derivatives thereof, in oral preparations or mixtures containing more than 500 µg of Vitamin H per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Schedule 1

Vitamin K and derivatives thereof,

a. in oral preparations or mixtures containing more than 120 µg of Vitamin K per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

b. except in injection preparations; (S3)

c. except when used in infant milk feeds or formulae in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Zinc and derivatives thereof,

a. in injection preparations when intended for veterinary use;

b. except in oral preparations or mixtures containing not more than **[50 mg]** 25 mg of Zinc per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

c. except when intended for topical use; (S0)

d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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 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.

Atropine, except

a. when intended for use in ophthalmic preparations; (S3)

b. when intended for use in injections. (S4)

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

a. oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, 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)

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

Flurbiprofen,

a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S3)

Schedule 2

b. except when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:

(i) a maximum of 8,75 milligrams per lozenge;

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

(iii) a maximum pack size of 15 lozenges. (S1)

c. except when intended for application to the skin, provided that in the case of application by transdermal patch:

(i) use is restricted to adults and children 12 years and older; and

(ii) the treatment period is limited to a maximum of 4 weeks. (S1)

d. except when intended for ophthalmic use; (S4)

[Glycopyrronium].

Hyaluronic acid and its salts,

a. when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent; (S4)

b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)

c. except when intended for topical application to the skin; (S1)

d. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Indometacin,

a. when intended for the emergency treatment of acute gout attacks; (S3)

b. except when intended for application to the skin. (S1)

Monoethanolamine.

Nicotine,

a. when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4mg nicotine per piece;

b. when registered as metered sprays containing 1mg per dose or less;

c. when registered as oral solid dosage forms containing 2mg or less;

d. when registered as inhalers containing 10mg or less per cartridge;

e. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing not more than 4mg nicotine per piece; (S0)

Schedule 2

f. except when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to an including 21mg/ 24 hours; (S1)

g. except when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended). (S3)

Nystatin,

e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Potassium, **[chloride]**

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

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

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

Rupatidine.

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.

Ascorbic Acid –*see* Vitamin C.

Atropine,

a. when intended for use in ophthalmic preparations; (S2)

b. except when intended for use in injections. (S4)

Calcium,

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)

c. except when indicated for the treatment of hyperphosphataemia; (S4)

d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Copper,

Schedule 3

a. in preparations thereof for injection; (S0)

b. 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)

Cyanocobalamin –*see* Vitamin B12.

Ergocalciferol – *see* Vitamin D.

Flurbiprofen, except

a. when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:

(i) a maximum of 8,75 milligrams per lozenge;

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

(iii) a maximum pack size of 15 lozenges. (S1)

b. when intended for application to the skin, provided that in the case of application by transdermal patch:

(i) use is restricted to adults and children 12 years and older; and

(ii) the treatment period is limited to a maximum of 4 weeks. (S1)

c. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)

d. when intended for ophthalmic use; (S4)

Glycopyrronium.

Iron,

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)

c. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Nicotine,

a. when intended for human medicinal use as an aid to smoking cessation or as a substitute for a tobacco product (as defined in the Tobacco Products Control Act, 1993, as amended);

b. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing not more than 4 mg nicotine per piece; (S0)

c. except when intended for human medicinal use as an aid to smoking cessation, when registered and presented as nicotine transdermal patches for continuous application to the skin in strengths up to an including 21mg/ 24 hours; (S1)

d. except when registered for human medicinal use as an aid to smoking cessation and presented as nicotine gum or lozenges containing more than 4 mg nicotine per piece; (S2)

e. except when registered as metered sprays containing not more than 1 mg per dose; (S2)

f. except when registered as oral solid dosage forms containing not more than 2 mg; (S2)

g. except when registered as inhalers containing not more than 10 mg per cartridge. (S2)

Pantothenic Acid –*see* Vitamin B5.

Pyridoxine –*see* Vitamin B6.

Riboflavin –*see* Vitamin B2.

Thiamine –*see* Vitamin B1.

Vitamin B1 (Thiamine) and derivatives thereof,

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin B2 (Riboflavin) and derivatives thereof,

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B2 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin B3 – *See* Niacin.

Vitamin B5 (Pantothenic Acid) and derivatives thereof,

a. in preparations thereof for injection; (S0)

b. in oral preparations or mixtures containing more than 200 mg of Vitamin B5 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin B6 (Pyridoxine) and derivatives thereof,

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B6 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin B12 (Cyanocobalamin) and derivatives thereof,

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than 100 µg of Vitamin B12 per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Schedule 3

Vitamin C (Ascorbic Acid),

a. in preparations thereof for injection; (S0)

b. except in oral preparations or mixtures containing more than 1000 mg of Vitamin C per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

Vitamin D (cholecalciferol), preparations thereof for injection and oral preparations and mixtures thereof containing more than **[500 I.U.]** 1 000 I.U. per recommended daily dose, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).(S0)

Vitamin K and derivatives thereof,

a. in injection preparations; (S0)

b. except in oral preparations or mixtures containing more than 120 µg of Vitamin K per recommended daily dose alone or in combination with other active pharmaceutical ingredients, (S1)

c. except when used in infant milk feeds or formulae in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

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 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.

Abiraterone.

Atropine,

a. when intended for use in injections. (S2)

b. except when intended for use in ophthalmic preparations. (S3)

Calcium,

a. when indicated for the treatment of hyperphosphataemia; (S0)

b. except in oral preparations or mixtures containing more than1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)

c. except in preparations thereof for injection; (S3)

d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Schedule 4

Cefquinome.

Fluorides,

a. except in oral medicinal preparations or mixtures intended for ingestion containing 0,25 milligrams or less of fluorine per dosage unit; (S1)

b. except in toothpaste containing less than 0,15 percent fluoride; (S0) and

c. except in mouth rinses containing less than 0,15 percent fluoride. (S0)

Flurbiprofen,

a. when intended for ophthalmic use; (S3)

b. except when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:

(i) a maximum of 8,75 milligrams per lozenge;

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

(iii) a maximum pack size of 15 lozenges. (S1)

c. except when intended for application to the skin, provided that in the case of application by transdermal patch:

(i) use is restricted to adults and children 12 years and older; and

(ii) the treatment period is limited to a maximum of 4 weeks. (S1)

d. except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2).

Hyaluronic acid and its salts,

a. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)

b. except when intended for topical application to the skin; (S1)

c. except when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent;(S2)

d. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Niacin (Nicotinic Acid) and derivatives thereof,

a. when intended for hypercholesterolaemia and for the management of dyslipidaemias; (S0)

Schedule 4

b. except in oral preparations or mixtures containing more than 35 mg of Niacin per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S1)

[Nicotinic Acid, when intended for the management of dydlipidaemias. (S0)]

Nystatin,

e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Osaterone, when intended for veterinary use.

Radiopharmaceuticals, being radioactive compounds and radio-active labelled compounds when used for diagnostic or therapeutic purposes, unless listed elsewhere in the Schedules, and including the following radioisotopes:

(xiii) Gold – 198.

Riociguat.

Triflusal.

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.

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 **

[Nefopam]

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.

Ephedrine,

[except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, when in combination with another pharmacologically active substance and intended for the

Schedule 6

symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S2)]

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

Nefopam.

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

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 9/12/2013

Schedule 6

symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S2)]

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

Nefopam.

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

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 9/12/2013

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