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From: **Neil Kirby** <NKirby@werksmans.com>
Date: Sun, Nov 19, 2017 at 11:58 PM
Subject: RE: Gazette
To: info@protextm.co

I confirm that the publication of the amendments to the Schedules to the Medicines & Related Substances Act No. 101 of 1965, as amended, brings the amendments into law with effect from 17 November 2017.

Based on the amended Schedules, Cannabidiol is to be treated as a Schedule 4 substance when intended for therapeutic purposes. When the "therapeutic purpose" is absent from the intended use of Cannabidiol, the substance is to be considered as a Schedule 7 substance.

Kind regards

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DEPARTMENT OF HEALTH

NO. 1261 **17 NOVEMBER 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; Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 40041, 03 June 2016; and Government Notice R.748 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 41009, 28 July 2017 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 14 **[5]** days;
b. except when intended for injection or for the management of paracetamol overdosage. (S3)

Diclofenac,

a. when intended for application to the skin and containing more than 1 % m/m of diclofenac;
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 human use only in 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)
e. except when intended for veterinary use. (S3)

Fluorides,

a. in oral medicinal preparations or mixtures intended for ingestion containing not more than 0,25 milligrams **[or less]** of fluorine per dosage unit;
b. except in toothpaste containing **[less than]** not more than 0,15 percent fluoride; (S0) and
c. except in mouth rinses containing **[less than]** not more 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)

5-Hydroxy Tryptophan,

a. in oral preparations with a maximum daily dose not exceeding 220 mg of **[L]** 5-Hydroxy tryptophan, alone or in combination with other active pharmaceutical ingredients; (S5)

b. except in oral preparation with a maximum daily dose not exceeding 220 mg of **[L]** 5-Hydroxy alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0)

Ibuprofen

a. when contained in preparations intended for application to the skin; (S2, S3, S4).

b. when contained in oral medicinal preparations, intended for human use only, supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight. (S2, S3).

c. except when intended for veterinary use. (S3)

Indometacin,

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

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

c. except when intended for veterinary use. (S3)

Iodine,

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

Naproxen

a. when contained in preparations intended for application to the skin; (S2, S3)

b. when contained in oral medicinal preparations, intended for human use only containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period; (S2, S3)

c. except when intended for veterinary use. (S3)

Vanadium,

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

– 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.

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 human use only in 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;

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)

e. except when intended for veterinary use. (S3)

Ibuprofen,

a. when contained in oral medicinal preparations, intended for human use only **[containing ibuprofen]** in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight.

b. when contained in oral medicinal preparations, intended for human use only **containing ibuprofen]** as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight;

c. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S3)

d. except when contained in preparations intended for application to the skin; (S1)

e. except when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the

recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

f. except when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)

g. except when intended for veterinary use. (S3)

Hyoscine; substances, preparations and mixtures thereof-

a. when intended for oral administration; and

b. **[including]** transdermal preparations when intended for the prevention of the symptoms of motion sickness.(S3)

Indometacin,

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

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

c. except when intended for veterinary use. (S3)

[Insulin glargine.]

Mefenamic acid,

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

b. preparations containing mefenamic acid as the only therapeutically active substance, when intended for human use only in the treatment of primary dysmenorrhoea, subject to a maximum daily dose of 500 milligrams 3 times a day and a maximum treatment period of 3 days; (S3)

c. except when intended for veterinary use. (S3)

Naproxen

a. when intended for the treatment of acute gout attacks, for a maximum treatment period of 5 days in patients over 16 years of age; (S3)

b. except when contained in preparations intended for application to the skin; (S1) and

c. except when contained in oral medicinal preparations, intended for human use only containing naproxen as the only active therapeutic substance intended for patients over

16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period; (S1, S3)

d. except when intended for veterinary use. (S3)

Pholcodine, when prepared, mixed or compounded **[preparations and mixtures when compounded with one or more therapeutically active substances, and]**

a. containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit; or **[and]**

b. **[liquid oral preparations and mixtures]** containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitre dosage unit in the case of liquid oral preparations and mixtures. (S6)

Ulipristal.

– 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 14 **[5]** days. (S2)

Aclidinium.

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)

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 human use only in 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)

Hyoscine; substances, preparations and mixtures thereof-

a. except when intended for oral administration; and

b. except transdermal preparations when intended for the prevention of the symptoms of motion sickness.(S2)

Ibuprofen, except

a. when contained in preparations intended for application to the skin; (S1)

b. when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

c. when contained **[used]** in oral medicinal preparations intended for human use only, **[containing ibuprofen]** in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

d. when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100

millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

e. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

f. when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S4)

Insulin Glargine.

Mefenamic acid, except -

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

b. preparations containing mefenamic acid as the only therapeutic active substance, when intended for human use only in the treatment of primary dysmenorrhoea subject to a maximum daily dose of 500 milligrams mefenamic acid 3 times a day and a maximum treatment period of 3 days. (S2)

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

Naproxen, except

a. when contained in preparations intended for application to the skin; (S1, S2)

b. when contained in oral medicinal preparations, intended for human use only containing naproxen as the only active therapeutic substance intended for patients over 16 years of age, for the treatment of mild to moderate pain or fever of inflammatory origin at a maximum dose of 600 milligrams naproxen base (660 milligrams naproxen sodium) in a 24 hour period for a maximum treatment period of 5 days and supplied in a solid dose form as divided doses contained in packs not exceeding the stated maximum treatment period. (S1, S2)

c. when intended for the treatment of acute gout attacks, for a maximum treatment period of 5 days in patients over 16 years of age. (S1, S2)

V. cholera.

– 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.

Apremilast.

Cannabidiol, when intended for therapeutic purposes. (S7)

Ceftolozane.

Ceritinib.

Dabrafenib.

Dexlansoprazole.

Efraloctocog alfa.

Etelcalcetide.

Fluorides,

a. except in oral medicinal preparations or mixtures intended for ingestion containing not more than 0,25 milligrams **[or less]** of fluorine per dosage unit; (S1)

b. except in toothpaste containing **[less than]** not more than 0,15 percent fluoride; (S0) and

c. except in mouth rinses containing **[less than]** not more than 0,15 percent fluoride. (S0)

Human coagulation factors.

Ibuprofen,

a. when intended for the treatment of a haemodynamically significant patent ductus arterious in infants less than 34 weeks of gestational age;

b. except when contained in preparations intended for application to the skin; (S1)

c. except when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

d. except when contained **[used]** in oral medicinal preparations intended for human use only, **[containing ibuprofen]** in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

e. except when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children

over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

f. except for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

g. except when intended for veterinary use. (S3)

Lesinurad.

[Meloxicam, when intended for veterinary use. (S3)]

Osimertinib.

Pomalidomide.

Ribociclib.

Rifapentine.

R-salbutamol, 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).

Trametinib.

Velaglucerase alfa.

– END SCHEDULE 4 –

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]** 5-Hydroxy tryptophan, alone or in combination with other active pharmaceutical ingredients; (S1)

b. except in oral preparation with a maximum daily dose not exceeding 220 mg of **[L]** 5-Hydroxy tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0)

Paliperidone.

– 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, 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.]

Lisdexamfetamine (Lisdexamphetamine), in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder. (S7)

Pholcodine, except when prepared, mixed or compounded **[preparations and mixtures when compounded with one or more therapeutically active substances, and]**

a. containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit; or **[and]**
b. **[liquid oral preparations and mixtures]** containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitre dosage unit in the case of liquid oral preparations and mixtures. (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.

Cannabidiol, except when intended for therapeutic purposes. (S4)

Lisdexamfetamine (Lisdexamphetamine), except in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder. (S7)

– END SCHEDULE 7 –

SCHEDULE 8

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 such isomers of esters and 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.

[Lisdexamfetamine (Lisdexamphetamine). (S7)]

- END SCHEDULE 8 -

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

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 24/10/2017