GOVERNMENT NOTICES
GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH
DEPARTEMENT VAN GESONDHEID

No. R. 690 **20 September 2013**

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.227 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 35149, 15 March 2012 using the following convention:

- Words in bold and in square brackets (e.g. **[Gamma benzene hexachloride]**), 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.

Amethocaine - *see* Tetracaine.

Benzocaine,

a. when intended for topical use;

b. in oral preparations containing 2 % or less of benzocaine;

c. in lozenges containing 30 mg or less of benzocaine, per dosage unit;

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

Collagenase clotridiopeptidase, when intended for application to the skin.

Ethyl chloride.

Lidocaine,

a. when intended for topical use;

b. in oral preparations containing 2 % or less of lidocaine, per dosage unit;

c. except when intended for ophthalmic or parenteral use; (S4)

d. except when intended for the treatment of neuropathic pain associated with previous herpes zoster infection. (S4)

Lignocaine,- *see* Lidocaine.

Naproxen

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

b. when contained in oral medicinal preparations 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 peroid. (S2, S3)

Oxetacaine (Oxethazaine),

a. in oral preparations containing an antacid;

b. except when intended for ophthalmic or parenteral use. (S4)

Pramoxine.

Prilocaine,

a. in topical preparations containing 10 % or less of prilocaine;

b. except when intended for ophthalmic or parenteral use. (S4)

Tetracaine,

a. when intended for topical use;

b. in oral preparations containing 2 % or less of tetracaine, per dosage unit;

c. except when contained in eye drops intended for the emergency treatment of "arc eyes"; (S2)

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

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.

Amethocaine,- *see* Tetracaine.

Antazoline.

Ergotamine.

Influenza virus vaccine.

[Iopromide].

Ketotifen

Levonorgestrel.

a. when intended for emergency post coital contraception;

b. except when intended for oral contraception; (S3)

c. except when administered via an Intra Uterine System. (S4)

Schedule 2

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 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)

Rabeprazole, when intended for the temporary short term relief of heartburn and hyperacidity, subject to-

a. maximum daily dose of 10 milligrams;

b. maximum treatment period of 14 days. (S4)

Sul**[ph]**fadiazine.

Tetracaine,

a. when contained in eye drops intended for the emergency treatment of "arc eyes"

b. except when intended for topical use; (S1)

c. except in oral preparations containing 2 % or less of tetracaine, per dosage unit; (S1)

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

Vitamin A and derivatives thereof and including retinol, retinal, retinoic acids and beta-carotene (but excluding isotretinoin) and not listed elsewhere in the Schedules, contained in preparations or mixtures containing more than 5 000 I.U (or 1 500 mg of the retinol equivalent or 3 000 mg of the beta-carotene equivalent) but not more than 10 000 I.U (or 3 000 mg of the retinol equivalent or 6 000 mg of the beta-carotene equivalent) of Vitamin A per recommended daily dose alone or in combination with other active pharmaceutical ingredients, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agriculture Remedies and Stock Remedies Act, 1947 (Act 36 of 1947. (S0, S3)

Vitamin E and derivatives thereof, including *dl*-alpha-tocopherol and not listed elsewhere in the Schedules, contained in preparations or mixtures containing more than 400 I.U. of Vitamin E per recommended daily dose.(S0)

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.

Bowel cleansers, preparations intended for the management of faecal impaction, or for the purpose of bowel cleansing prior to surgical or diagnostic procedures, unless listed elsewhere in the Schedules. (S0)

Cholecalciferol,- *see* Vitamin D.

Drospirenone,

a. when intended for oral contraception;

b. except when intended for hormone replacement therapy. (S4)

Estradiol.

a. when intended for oral contraception;

b. except when intended for hormone replacement therapy. (S4)

Gestodene.

[influenza virus vaccine]

Ketorolac **[trometamol]** when intended for ophthalmic use. S4)

Schedule 3

Linagliptin.

Liothyronine sodium.

Levonorgestrel,

a. when intended for oral contraception

b. except when intended for emergency post coital contraception; (S2)

c. except when administered via an Inta Uterine System. (S4)

Naproxen, except

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

b. when contained in oral medicinal preparations 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 peroid. (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)

Noradrenaline theophylline – *see* Theodrenaline.

Norelgestromin.

Norethisterone,

a. when intended for oral contraception;

b. except when intended for parenteral use as a contraceptive; (S4)

c. except when intended for hormone replacement therapy. (S4)

Norgestrel,

a. when intended for oral contraception;

b. except when intended for hormone replacement therapy. (S4)

Sitagliptin phosphate.

Sodium phosphate, in preparations intended for the management of faecal impaction or for bowel cleansing prior to surgical and diagnostic procedures. (S0)

Sodium picosulphate, in preparations intended for the management of faecal impaction or for bowel cleansing prior to surgical and diagnostic procedures. (S0)

Silimarin – *see* Silymarin.

Schedule 3

S**[il]**ylimarin - *see* (Silimarin).

Theodrenaline – *see* Noradrenaline theophylline.

Vildagliptin.

[Vitamin A; preparations thereof for injection and oral preparations and mixtures thereof containing more than 10 000 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)].

Vitamin A and derivatives thereof and including retinol, retinal, retinoic acids and beta-carotene (but excluding isotretinoin) and not listed elsewhere in the Schedules, contained in preparations or mixtures containing more than 10 000 I.U (or 3 000 mg of the retinol equivalent or 6 000 mg of the beta-carotene equivalent) of Vitamin A per recommended daily dose alone or in combination with other active pharmaceutical ingredients, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agriculture Remedies and Stock Remedies Act, 1947 (Act 36 of 1947. (S0, S2)

Vitamin K and derivatives therof for injection (S0)

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.

Abciximab.

A**[l]**galsidase Alfa.

Amethocaine,- *see* Tetracaine.

Bendamustine.

Bedaquiline.

Benzocaine,

a. when intended for ophthalmic or parenteral use;

b. except in lozenges containing 30 mg or less of benzocaine, per dosage unit; (S1)

c. except when intended for topical use; (S1)

d. except in preparations containing 2 % or less of benzocaine. (S1)

[Blood collection bags, when intended for the collection and preservation of blood for subsequent use].

Botulinum toxin.

Bupivicaine.

Schedule 4

[Colecalciferol see Vitamin D]

Denosumab.

Desmopressin.

Dexamethasone.

Doripenem.

Drospirenone,

a. when intended for hormone replacement therapy;

b. except when intended for oral contraception. (S3)

Dydrogesterone.

Eptifibatide.

Ergometrine maleate.

Eribulin.

Estradiol,

a. when intended for hormone replacement therapy;

b. except when intended for oral contraception; (S3)

Exemestane.

Fludrocortisone acetate.

Fluorometholone.

Human fibrinogen, when indicated for use as a haemostatic.

Human thrombin, when indicated for use as a haemostatic.

Ifosfamide.

Ipilimumab.

[Ketorolac tromethamine].

Ketorolac **[trometamol],** excepted when intended for ophthalmic use. (S3)

Laropiprant.

Leuprolide acetate.

Levonorgestrel,

a. when administered via an Intra Uterine System;

b. except when intended for oral contraception; (S3)

Schedule 4

c. except when intended for emergency post coital contraception. (S2)

Lidocaine,

a. when intended for ophthalmic or parenteral use;

b. when intended for the treatment of neuropathic pain associated with previous herpes zoster infection;

c. except when intended for topical use; (S1)

d. except in oral preparations containing 2 % or less of lidocaine per dosage form. (S1)

Lignocaine, *see* Lidocaine.

[Linagliptin].

Mavacoxib.

Medroxyprogesterone.

Mepivicaine.

Nilotinib.

Norethisterone,

a. when intended for parenteral use as a contraceptive;

b. when intended for hormone replacement therapy;

c. except when intended for oral contraception. (S3)

Norgestrel,

a. when intended for hormone replacement therapy;

b. except when intended for oral contraception. (S3)

Ornipressin.

Oxetacaine (Oxethazaine),

a. when intended for ophthalmic or parenteral use;

b. except in oral preparations containing an antacid. (S1)

Oxybuprocaine,

a. when intended for ophthalmic or parenteral use;

b. except when contained in eye drops intended for the emergency treatment of "arc eyes". (S2)

Oxytocin.

Prilocaine,

a. when intended for ophthalmic or parenteral use; (S4)

Schedule 4

b. except in topical preparations containing 10 % or less of prilocaine. (S1)

Progesterone.

Quinagolide.

Rabeprazole,except when intended for the temporary short term relief of heartburn and hyperacidity, subject to-

a. maximum daily dose of 10 milligrams;

b. maximum treatment period of 14 days. (S2)

Regorafenib.

Rilpivirine.

Ropivacaine.

Sevelamer.

[Sitagliptin phosphate].

Sulfasalazine.

Tetracaine,

a. when intended for ophthalmic or parenteral use;

b. except when intended for topical use; (S1)

c. except in oral preparations containing 2 % or less of Tetracaine; (S1)

d. except when contained in eye drops intended for the emergency treatment of "arc eyes". (S2)

Tetracosactrin (Tetracosactide).

Vemurafenib.

[Vildagliptin].

Ziv-aflibercept.

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 **

Chlorpromazine.

Fluphenazine.

Mirtazapine.

Prochlorperazine maleate.

Sulp**[y]**iride.

Trifluoroperazine.

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.

1,3 Dimethylamylamine *also known as* (1,3 DMAA/ 1,3 dimethylpentylamine/ 2-amino-4-methylhexane/ 2-hexanamine/ 4-methylhexane-2-amine/ 4-methyl-2-hexanamine/ 4-methyl-2-hexylamine/ 4-methyl-(9CI)/ dimethylamylamine/ geranamine/ methylhexeanamine/ methylhexaneamine)

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

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 9/9/2013