No. R. 1230 **31 December 2009**

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 935 (medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 31397, 5 September 2008 using the following convention:

- Words 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 in Schedule 2), 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 0

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 which are intended to be ingested by man or animals as a food or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and

Disinfectants Act, 1972 (Act 54 of 1972) or that are registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947); and

(ii) analytical laboratory purposes.

b. This Schedule shall include all substances or mixtures of such substances containing or purporting to contain substances referred to, including the salts and esters of such substances, where the existence of such salts and esters is possible, except where such substances or mixtures of substances are expressly excluded.

This Schedule includes all substances or mixtures of substances subject to registration in terms of the Act and which are not listed in any of the other Schedules.

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. This Schedule shall include 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.

Bee venom, preparations intended for application to the skin. (S4)

[Gamma benzene hexachloride] *delete inscription. See inscription in S2.*

Hyaluronic acid and its salts, when intended for topical application to the skin. (S0, S2, S4)

Normal Saline (Sodium chloride 0,9 % m/v) when intended for injection, in a dosage form not exceeding 20 millilitres in volume. (S0, S3)

Zinc salts, when intended for veterinary use as an injection, except

a. when intended for oral ingestion, where the daily dose is less than 50 milligrams of elemental zinc, or when intended for topical use by humans; (S0), or

b. 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. This Schedule shall include 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.

BCG vaccine – see *Mycobacterium bovis*.

Bismuth, when intended for oral use.

Diphtheria toxoid vaccine.

Gamma benzene hexachloride when intended to be used for the second line treatment of lice in a pack size not exceeding 60ml. (S4)

Haemophilus influenzae vaccine (Hib).

Hepatitis B vaccine

Rotavirus, live attenuated.

Metronidazole, when intended for human vaginal use, specifically for the treatment of recurrent bacterial vaginosis and except when intended and registered for use in pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947). (S4)

Mycobacterium bovis vaccine (BCG).

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

a. maximum daily dose of 20 milligrams

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

Pertussis toxoid vaccine.

Pholcodine, [oral solid] preparations and mixtures when compounded [in combination] with one or more therapeutically active substances, and containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit and liquid oral preparations and mixtures [in combination with one or more therapeutically active substances] and containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitres dosage unit. (S6)

Pneumococcal vaccine, conjugated.

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. This Schedule shall include 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.

Beclomethasone – see corticosteroids.
Budesonide, when intended for inhalation and for nasal administration. (S4)
Butecosone, when intended for inhalation and for nasal administration.
Dienogest.

Estradiol.

Flunisolide – see corticosteroids.

Fluticasone – see corticosteroids.

Ibuprofen, except for application to the skin (S1), and except when used in oral medicinal preparations –

a. for the treatment of post-traumatic conditions for a maximum treatment period of 5 days, where the recommended daily dose for adults does not exceed 1,2 g and the dose for children up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

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

c. for the treatment of a haemodynamically significant patent ductus arterious in infants less than 34 weeks of gestational age. (S4)

Ivabradine

Macrogol (polyethylene glycol), when used for faecal impaction, or for the purposes of bowel cleansing prior to surgery or diagnostic procedures. (S0)

Normal Saline (Sodium chloride 0,9 % m/v) when intended for injection, except when intended for injection in a dosage form not exceeding 20 millilitres in volume. (S0, S1)

Strontium, except when contained in toothpaste. (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. This Schedule shall include 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.

Anidulafungin.

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

Biological medicines, injectable preparations thereof, when intended for human use and unless listed elsewhere in the Schedules,

a. except vaccines, when listed elsewhere in the Schedules and vaccines registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

b. but specifically including the following -

   (i) Equine anti-human thymocyte globulin;

   (ii) Equine gamma globulin;

   (iii) Human anti-D immunoglobulin;

   (iv) Human anti-thymocyte rabbit immunoglobulin;

   (v) Hepatitis A vaccine;

   (vi) Hepatitis B immunoglobulin;

(vii) Human normal immunoglobulin, possibly polyvalent or possibly including IgG, IgA, or IgM;

(viii) Human plasma albumin;

(ix) *Neiserria meningitides* polysaccharide vaccine;

(x) Pneumococcal vaccine, polysaccharide;

(xi) Rabies immunoglobulin;

(xii) Rabies vaccine;

(xiii) Recombinant cholera toxin B subunit;

(xiv) rhDNase-dornase alfa;

(xv) Tetanus immunoglobulin;

(xvi) Varicella immunoglobulin;

(xvii) Varicella-zoster virus vaccine;

(xviii) Yellow Fever virus, attenuated.

Budesonide, except when intended for inhalation and for nasal administration. (S3)
Cefovecin.
Ceftobiprole.
Chlormadinone.

Enramycin, except when intended and registered to promote growth as a feed additive in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Epoetin beta, polyethylene glycol.
Florfenicol.
[Fusafungine] *delete inscription. See inscription in S2.*
Fosaprepitant.
Fluticasone.
Gamma benzene hexachloride, except when intended to be used for the second line treatment of lice in a pack size not exceeding 60ml. (S2)

[Injections, unless listed elsewhere in the Schedules] *delete inscription. See inscription in S3*
[Ivabradine] *delete inscription. See inscription in S3*

Maraviroc.

Metronidazole, except when

a. intended and registered for use in pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947) and

b. intended for human vaginal use, specifically for the treatment of recurrent bacterial vaginosis. (S2)

Methylnaltrexone.

Monensin except when listed elsewhere in the Schedules and except when intended and registered as an anti-coccidial preparation and as a feed additive for growth promotion in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Natalizumab.
Niacin when intended for hypercholesterolaemia. (S0)

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

a. a maximum daily dose of 20 milligrams (S2); and

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

Phospholipids when intended for parenteral administration. (S0)
Pimobendan.
Raltegravir.
Rifaximin.
Rivaroxaban.
Robenacoxib.

Trimethoprim, except when specifically intended and registered in combination with sulphonamides for the treatment of gastro-enteritis and pneumonia in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Urofollitropin.

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

a. All preparations or mixtures of such substances containing or purporting to contain substances 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.

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 **

Atomoxetine.

Paliperidone.

SCHEDULE 6

a. All preparations or mixtures 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.

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.

[Atomoxetine] *delete inscription. See inscription in S5*

Pholcodine, except [oral solid] preparations and mixtures when compounded [in combination] with one or more therapeutically active substances, and containing 20 milligrams or less of pholcodine (calculated as base) per dosage unit and liquid oral preparations and mixtures [in combination with one or more therapeutically active substances, and] containing 20 milligrams or less of pholcodine (calculated as base) per 5 millilitre dosage unit. (S2).

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

DR A MOTSOALEDI
MINISTER OF HEALTH