GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. R. 352 **8 May 2014**

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

SCHEDULES: AMENDMENT

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.104 (Medicines and Related Substances Act, 1965 (Act 101 of 1965): Schedules), Government Gazette 37318, 11 February 2014 using the following convention:

- Words in bold and in square brackets (e.g. **[Gamma benzene hexachloride]** in Schedule 1), indicate omission from a Schedule; and
- 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.

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)

Loratidine,

[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.]**

Schedule 1

[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.]**

- END SCHEDULE 1 -

SCHEDULE 2

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –

   (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

   (ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

   (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

   (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 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.

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)

Estradiol,

a. when intended for human vaginal use;

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

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

[Retapamulin, when intended for topical application to the skin, nares and external ear. (S4)]

- 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.

Estradiol,

a. when intended for oral contraception;

b. except when intended for human vaginal use; (S2)

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

Gelatine succinylated.

Mirabegron.

- END SCHEDULE 3 -

SCHEDULE 4

a. All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –

   (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and

   (ii) analytical laboratory purposes.

b. All preparations of substances or mixtures of such substances containing or purporting to contain any substance referred to in this Schedule and includes the following:

   (i) The salts and esters of such substances, where the existence of such salts and esters is possible; and

   (ii) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

c. In terms of section 22A(5)(f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 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.

Afatinib.

Certoparin.

Crizotinib.

Dapagliflozin.

Estradiol,

a. when intended for hormone replacement therapy;

b. except when intended for human vaginal use; (S2)

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

Fampridine.

Lenalidomide.

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:

Schedule 4

(viii) Radium – 223;

Retapamulin.[**except when intended for topical application to the epidermis, nares and external ear. (S2)]**

Telaprevir.

Vismodegib.

– END SCHEDULE 4 –

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

Schedule 6

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

[Phenylbutazone and its derivatives.]

– END SCHEDULE 6 –

SCHEDULE 7

All preparations or mixture of such substances containing or purporting to contain substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of isomers of such esters, or ethers is possible;

(iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;

(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;

(v) all preparations and mixtures of any of the above.

(vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

Phenylbutazone and its derivatives.

– END SCHEDULE 7 –

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

DR A MOTSOALEDI, MP

MINISTER OF HEALTH

DATE: 16/4/2014