



# Government Gazette Staatskoerant

REPUBLIC OF SOUTH AFRICA  
REPUBLIEK VAN SUID AFRIKA

Vol. 609

15 March  
Maart 2016

No. 39815

N.B. The Government Printing Works will not be held responsible for the quality of "Hard Copies" or "Electronic Files" submitted for publication purposes

ISSN 1682-5843



**AIDS HELPLINE: 0800-0123-22 Prevention is the cure**

# Government Printing Works

## Notice submission deadlines

Government Printing Works has over the last few months implemented rules for completing and submitting the electronic Adobe Forms when you, the customer, submit your notice request.

In line with these business rules, GPW has revised the notice submission deadlines for all gazettes. Please refer to the GPW website [www.gpwnonline.co.za](http://www.gpwnonline.co.za) to familiarise yourself with the new deadlines.

### CANCELLATIONS

Don't forget!

Cancellation of notice submissions are accepted by GPW according to the deadlines stated in the table above.

Non-compliance to these deadlines will result in your request being failed. **Please pay special attention to the different deadlines for each gazette.**

**Please note that any notices cancelled after the cancellation deadline will be published and charged at full cost.**

Requests for cancellation must be sent by the original sender of the notice and must be accompanied by the relevant notice reference number (N-) in the email body.

### AMENDMENTS TO NOTICES

take note!

With effect from 01 October, GPW will not longer accept amendments to notices. The cancellation process will need to be followed and a new notice submitted thereafter for the next available publication date.

### CUSTOMER INQUIRIES



Many of our customers request immediate feedback/confirmation of notice placement in the gazette from our Contact Centre once they have submitted their notice – While GPW deems it one of their highest priorities and responsibilities to provide customers with this requested feedback and the best service at all times, we are only able to do so once we have started processing your notice submission.

GPW has a **2-working day turnaround time for processing notices** received according to the business rules and deadline submissions.

Please keep this in mind when making inquiries about your notice submission at the Contact Centre.

### PROOF OF PAYMENTS



GPW reminds you that all notice submissions **MUST** be submitted with an accompanying proof of payment (PoP) or purchase order (PO). If any PoP's or PO's are received without a notice submission, it will be failed and your notice will not be processed.

When submitting your notice request to [submit.egazette@gpw.gov.za](mailto:submit.egazette@gpw.gov.za), please ensure that a purchase order (GPW Account customer) or proof of payment (non-GPW Account customer) is included with your notice submission. All documentation relating to the notice submission must be in a single email.

A reminder that documents must be attached separately in your email to GPW. (In other words, your email should have an Adobe Form plus proof of payment/purchase order – 2 separate attachments – where notice content is applicable, it should also be a 3rd separate attachment).

### REMINDER OF THE GPW BUSINESS RULES

- Single notice, single email – with proof of payment or purchase order.
- All documents must be attached separately in your email to GPW.
- 1 notice = 1 form, i.e. each notice must be on a separate form
- Please submit your notice **ONLY ONCE**.
- Requests for information, quotations and inquiries must be sent to the Contact Centre **ONLY**.
- The notice information that you send us on the form is what we publish. Please do not put any instructions in the email body.



## Contents

<i>No.</i>		<i>Gazette No.</i>	<i>Page No.</i>
<b>GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS</b>			
<b>Health, Department of/ Gesondheid, Departement van</b>			
254	Medicines and Related Substances Act (101/1965): Updating of Schedules on the recommendation of the Medicines Control Council .....	39815	4

---

**GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS**

---

**DEPARTMENT OF HEALTH****NO. 254****15 MARCH 2016****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 and Government Notice R.234 (Medicines and Related Substances Act, 1965: Schedules) in Government Gazette 38586, 20 March 2015 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.

## 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 or 25 mg/ 16 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 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 containing more than 21mg/ 24 hours or 25 mg/ 16 hours; (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)
- h. 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)

- 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.
- (i) Annexure 1A: Emergency Care Provider (Paramedic);
  - (ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner);
  - (iii) Annexure 2: Dental Therapist.

Acetylcysteine, except when intended for injection or for the management of paracetamol overdose. (S3)

**[Acetyldihydrocodeine:**

- a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit; and

- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S6)]

Codeine (methylnorphine),

- a. oral solid preparations, in combination with one or more therapeutically active substances, [and] containing [20 milligrams or less]not more than 10 milligrams of codeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, [and] containing [20 milligrams or less]not more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres;
- c. except oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per dosage unit. (S3)
- d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit ; (S3)
- e. except single component codeine preparations. (S6)

Dihydrocodeine,

- a. oral solid preparations, in combination with one or more therapeutically active substances, [and] containing [20 milligrams or less]not more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, [and] containing [20 milligrams or less]not more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres;



- c. except oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit; (S3)
- d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit; (S3)
- e. except single component dihydrocodeine preparations. (S6)

Doxycycline,

- a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older, for periods not exceeding 4 months of continuous use; (S4)
- b. except in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), excluding when intended for administration in animal feed.

Human papillomavirus vaccine.

Ipratropium, except when contained in respirator solutions. (S3)

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. 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 containing more than 21mg/ 24 hours or 25 mg/ 16 hours;
- f. 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)

- g. 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 and including 21mg/ 24 hours or 25 mg/ 16 hours: (S1)
- h. 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)

**[Norcodeine,**

- a. oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit; (S6) or
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S6)]

**- 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).

Acetylcysteine, when intended for injection or for the management of paracetamol overdose.  
(S2)

Codeine (methymorphine)

- a. oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per dosage unit;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit;

- c. except oral solid preparations, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days (S2);
- d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of codeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres; (S2)
- e. except single component codeine preparations. (S6)

Dihydrocodeine.

- a. oral solid preparations, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit;
- b. liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit;
- c. except oral solid preparations, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of dihydrocodeine (calculated as base) per dosage unit, with a maximum daily dose not exceeding 80 milligrams, and in packs containing sufficient dosage units for a maximum treatment period of 5 days; (S2)
- d. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, containing not more than 10 milligrams of dihydrocodeine (calculated as base) per 5 millilitre dosage unit, with a maximum daily dose not exceeding 80 milligrams, and with a pack size not exceeding 100 millilitres; (S2)
- e. except single component dihydrocodeine preparations. (S6)

Ipratropium, [except] when contained in respirator solutions. (S2)

## 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 or 25 mg/ 16 hours; (S1)
- d. 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 containing more than 21mg/ 24 hours or 25 mg/ 16 hours; (S2)
- e. 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)
- f. except when registered as metered sprays containing not more than 1 mg per dose; (S2)
- g. except when registered as oral solid dosage forms containing not more than 2 mg; (S2)
- h. except when registered as inhalers containing not more than 10 mg per cartridge. (S2)

Silymarin[- see (Silymarin).], except when present in a complementary medicine with an accepted low risk claim or health claim, providing not more than 600 mg of Silymarin per day (calculated as silibinin/silybin). (S0)

- 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.

Brentuximab.

Chorionic gonadotrophin.

[Diprenorphine]

Dolutegravir.

Doxycycline, except



- a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older, for periods not exceeding 4 months of continuous use: (S2)
- b. [listed elsewhere in the Schedules and except]in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), excluding when intended for administration in animal feed.

[Human pappillomavirus vaccine]

[Isotretinoin]

*Mycoplasma gallisepticum* (Strain F) vaccine, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Peginterferon beta 1a.

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:

- (i) Chromium-51;
- (ii) <sup>14</sup>C – Urea;
- (iii) <sup>18</sup>F – Fludeoxyglucose (2 - deoxy – 2 - [<sup>18</sup>F] fluoro- D- glucose
- (iv) Gallium-67;
- (v) Indium-111;
- (vi) Iodine-123;
- (vii) Iodine-125;
- (viii) Iodine-131;
- (ix) Phosphorous-32;
- (x) Strontium-89;
- (xi) Technetium-99;
- (xii) Thallium-201;
- (xiii) Xenon-133;
- (xiv) Yttrium-90;

(xv) Gold – 198.

Ruxolitinib.

Serelaxin.

Tildipirosin, when intended for veterinary use.

– END SCHEDULE 4 –



**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.
- (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 \*\*

[Flunitrazepam\*\*.]

Isotretinoin.

Perampanel.

Thiopentone.

– 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).

Acetyldihydrocodeine];

- a. except oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit; and
- b. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S2)].

Codeine (methy/morphine),

- a. single component codeine preparations:
- b. except oral solid preparations, in combination with one or more therapeutically active substances[, and containing 20 milligrams or less of codeine (calculated as base) per dosage unit]; (S2, S3)
- c. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances[, and containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit]. (S2, S3)

Dihydrocodeine,

- a. single component dihydrocodeine preparations:
- b. except oral solid preparations, in combination with one or more therapeutically active substances[, and containing 20 milligrams or less of codeine (calculated as base) per dosage unit]; (S2, S3) and
- c. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances[, and containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit]. (S2, S3)

Norcodeine[,

- a. except oral solid preparations, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit; (S2) and
- b. except liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, and containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (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.

AH-7921.

AM-2201.

Amfetamine (Amphetamine) and its salts; preparations thereof. (S8)

Dexamfetamine (Dexamphetamine) and its salts; preparations thereof. (S8)

Lisdexamfetamine (lisdexamphetamine). (S8)

Mephedrone.



3,4-methylenedoxypyrovalerone (MDPV).

Methylone (beta-keto-MDMA).

25B-NBOMe (2C-B-NBOMe).

25C-NBOMe (2C-C-NBOMe).

25I-NBOMe (2C-I-NBOMe).

– 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.

Amfetamine (Amphetamine) and its salts; preparations thereof. (S7)

Dexamfetamine (Dexamphetamine) and its salts; preparations thereof. (S7)

Lisdexamfetamine (lisdexamphetamine). (S7)

- END SCHEDULE 8 -

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

\_\_\_\_\_  
DR A MOTSOLEDI, MP

MINISTER OF HEALTH

DATE:

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001  
Contact Centre Tel: 012-748 6200. eMail: [info.egazette@gpw.gov.za](mailto:info.egazette@gpw.gov.za)  
Publications: Tel: (012) 748 6053, 748 6061, 748 6065