DEPARTMENT OF HEALTH

NO. 620 **03 JUNE 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; Government Notice R.234 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 38586, 20 March 2015; and Government Notice R.254 (Medicines and Related Substances Act, 1965: Schedules) in Government *Gazette* 39815, 15 March 2016 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.

Hyaluronic acid and its salts,

a. when intended for topical application to the skin;
b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)
c. except when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent; (S2)
d. except when intended for parenteral use; (S4)
e. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

OPTOMETRIST		
ANALGESIC		
Substance	:	Paracetamol
Indication	:	Mild Pain
Route of Administration	:	Oral
ANALGESIC/ ANTI INFLAMMATORY		
Substance	:	Ibuprofen
Indication	:	Mild to Moderate Pain
Route of Administration	:	Oral

- 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.

Aspirin (acetyl salicylic acid), when intended for:

a. the treatment of children or adolescents; and
b. the prophylaxis of cardiovascular disease in adults (S0)

Codeine (methylmorphine),

a. 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, and limited to one pack per customer, when contained in products registered in terms of the Act, and not intended for export;

b. 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, when contained in products registered in terms of the Act, and not intended for export;

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, 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, when contained in products registered in terms of the Act, and not intended for export;

b. 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, when contained in products registered in terms of the Act, and not intended for export;

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)

Hyaluronic acid and its salts,

a. when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent;

b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)

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

d. except when intended for parenteral use; (S4)

e. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

ANNEXURE 2: DENTAL THERAPIST

DENTAL THERAPIST (Bachelors degree in Dental Therapy) registered with Health Professions Council of South Africa

DENTAL THERAPIST (Bachelors degree in Dental Therapy)		
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY		
Substance	:	Codeine **[in combination with one or more therapeutic active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit]**
Indication	:	Dental pain
Route of Administration	:	Oral

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

OPTOMETRIST		
ANTIBACTERIAL		
Substance	:	Mupirocin
Indication	:	Impetigo (Eyelids); External Hordeolum, Infected atopic dermatitis
Route of Administration	:	Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Antazoline
Indication	:	Allergic and Atopic Conjunctivitis
Route of Administration	:	Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Tetrazoline
Indication	:	Minor ocular irritation; Red eye
Route of Administration	:	Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Oxymetazoline
Indication	:	Minor ocular irritation; Red eye
Route of Administration	:	Topical application
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Cetirizine; Loratidine; Levocetirizine
Indication	:	Atopic dermatitis involving the eyelids
Route of Administration	:	Oral
ANTIHISTAMINE/ VASOCONSTRICTOR/ MAST CELL STABILISER		
Substance	:	Sodium Cromoglycate
Indication	:	Vernal Kerato conjunctivitis
Route of Administration	:	Topical application
STEROIDAL ANTI INFLAMMATORY		
Substance	:	Hydrocortisone
Indication	:	Dermatitis, Ectopic or Seborrhoeic Eczema
Route of Administration	:	Topical application

- 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.

Codeine (methylmorphine),

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, when contained in products registered in terms of the Act, and not intended for export;

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, when contained in products registered in terms of the Act, and not intended for export;

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 and limited to one pack per customer, when contained in products registered in terms of the Act, and not intended for export; (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 and limited to one pack per customer, when contained in products registered in terms of the Act, and not intended for export; (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, when contained in products registered in terms of the Act, and not intended for export;

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, when contained in products registered in terms of the Act, and not intended for export;

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)

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

OPTOMETRISTS		
CYCLOPLEGICS		
Substance	:	Atropine
Indication	:	Cyclopegic refraction; Treatment of Uveitis
Route of Administration	:	Topical Application (Drops)
MYDRIATICS/ CYCLOPLEGICS		
Substance	:	Tropicamide
Indication	:	Cyclopegic; Mydriatic
Route of Administration	:	Topical Application (Drops)
MYDRIATICS/ CYCLOPLEGICS		
Substance	:	Cyclopentolate
Indication	:	Cyclopegic; Mydriatic
Route of Administration	:	Topical Application (Drops)
MYDRIATICS/ CYCLOPLEGICS		
Substance	:	Homatropine
Indication	:	Cyclopegic; Mydriatic
Route of Administration	:	Topical Application (Drops)
ANTI GLAUCOMA		
Substance	:	Pilocarpine
Indication	:	Acute Glaucoma
Route of Administration	:	Topical Application (Drops)
ANTI GLAUCOMA		
Substance	:	Timolol
Indication	:	Acute Glaucoma
Route of Administration	:	Topical Application (Drops)

- 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.

Hyaluronic acid and its salts,

a. when intended for parenteral use;

b. except when intended for use with contact lens solutions or as an ophthalmic lubricant in concentrations of not more than 0,1 percent; (S0)

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

d. except when intended for ophthalmic use in preparations (except injectables) containing more than 0,1 percent;(S2)

e. except in preparations containing less than 2,5 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Rotigotine.

Sofosbuvir.

ANNEXURE 3: OPTOMETRIST

OPTOMETRIST (Bachelors degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and in possession of a Section 22A(15) permit as provided for by the Medicines and Related Substances Act, 1965 (Act 101 of 1965)

OPTOMETRISTS		
ANTIBACTERIAL		
Substance	:	Chloramphenicol
Indication	:	Bacterial conjunctivitis; Anterior blepharitis; Posterior blepharitis
Route of Administration	:	Topical Application
ANTIBACTERIAL		
Substance	:	Tetracycline
Indication	:	Chlamydial conjunctivitis; Blepharitis
Route of Administration	:	Topical Application
ANTIBACTERIAL		
Substance	:	Erythromycin
Indication	:	Chlamydial conjunctivitis; Blepharitis; Impetigo (Not to be used as 1st Line Treatment)
Route of Administration	:	Topical Application
ANTIBACTERIAL		
Substance	:	Aciclovir
Indication	:	Conjunctivitis; Herpes simplex blepharitis; Epithelial keratitis
Route of Administration	:	Topical Application
LOCAL ANAESTHETIC		
Substance	:	Tetracaine
Indication	:	Diagnostic Aide
Route of Administration	:	Topical Application (Drops)
LOCAL ANAESTHETIC		
Substance	:	Oxybuprocaine and other equivalent local anaesthetics
Indication	:	Diagnostic Aide
Route of Administration	:	Topical Application (Drops)

– 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.

(i) Annexure 1A: Emergency Care Provider (Paramedic);

(ii) Annexure 1B: Emergency Care Provider (Emergency Care Practitioner).

Codeine (methylmorphine),

a. single component codeine preparations;

b. **[except]** oral solid preparations, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export; (S2, S3)

c. **except** liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export. (S2, S3)

Dihydrocodeine,

a. single component dihydrocodeine preparations;

b. **[except]** oral solid preparations, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export; (S2, S3)

c. **[except]** liquid oral preparations and mixtures, in combination with one or more therapeutically active substances, in preparations not registered in terms of the Act, or when intended for export. (S2, S3)

Ibogaine.

– END SCHEDULE 6 –

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

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 26/4/2016