[Last checked: 1 August 2025.*]
*The last time this Act was reviewed for updates.

MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965

[S 40 Short title, formerly Medicines and Related Substances Control Act; prior to that Drugs Control Act, substituted by s 35 of Act 65 of 1974, s 28 of Act 90 of 1997.]

[Updated to 1 August 2025.**]
**Date of last changes incorporated into this Act.

(Afrikaans text signed by the President.)

(Assented to 19 June 1965.)

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Commencement: **1 April 1966**

Proc 94, G. 1413

Amended

Drugs Control Amendment Act 29 of 1968 (G. 2032, with effect from 3 April 1968),

Drugs Control Amendment Act 88 of 1970 (G. 2897, with effect from 21 October 1970),

Drugs Laws Amendment Act 95 of 1971 (G. 3211, with effect from 6 December 1971 [ProcR 267, G. 3321]),

Drugs Control Amendment Act 65 of 1974 (G. 4469, with effect from 21 February 1975 [ProcR 52, G. 4594]),

Medicines and Related Substances Control Amendment Act 19 of 1976 (G. 5035, with effect from 31 March 1976),

Health Laws Amendment Act 36 of 1977 (G. 5481, with effect from 30 March 1977),

Medicines and Related Substances Control Amendment Act 17 of 1979 (G. 6358, with effect from 21 March 1979),

Medicines and Related Substances Control Amendment Act 20 of 1981 (G. 7449, with effect from 4 March 1981),

Medicines and Related Substances Control Amendment Act 97 of 1986 (G. 10438, with effect from 3 October 1986 [Proc 185, G. 10475]),

Businesses Act 71 of 1991 (G. 13266, with effect from 24 May 1991),

Medicines and Related Substances Control Amendment Act 94 of 1991 (G. 13343, with effect from 12 July 1991),

General Law Amendment Act 49 of 1996 (G. 17477, with effect from 4 October 1996),

Abolition of Restrictions on the Jurisdiction of Courts Act 88 of 1996 (G. 17599, with effect from 22 November 1996),

Medicines and Related Substances Control Amendment Act 90 of 1997 (G. 18505, with effect from 2 May 2003 unless otherwise indicated [ProcR 23, G. 24627]),

Medicines and Related Substances Control Amendment Act 59 of 2002 (G. 24279, with effect from 2 May 2003 [ProcR 24, G. 24627]),

Medicines and Related Substances Amendment Act 72 of 2008 (G. 32148, with effect from 1 June 2017 [Proc 20, G. 40869]),
Medicines and Related Substances Amendment Act 14 of 2015 (G. 39585, with effect from 1 June 2017 [s 27 of Act 14 of 2015 & Proc 20, G. 40869 of 26 May 2017]),
Schedules amended (GN 6466, G. 53099 of 1 August 2025).

Uncommenced Amendment

National Health Insurance Act 20 of 2023 (G. 50664 of 16 May 2024, with effect from date to be proclaimed)

General substitutions:

1. Act 20 of 1981, s 8 substituted the expressions "Department of Health" and "Secretary", wherever they occur, of the expressions "Department of Health, Welfare and Pensions" and "Director-General" respectively.
2. Act 14 of 2015, s 24 substituted the words "product" and "products", wherever they occur except in sections 2, 22A, 22F(4)(c) and 22H(1)(a) and Schedules 0 up to and including 6, of the words "medicine" and "medicines", respectively.

ACT

To provide for the registration of medicines and related substances intended for human and for animal use; to provide for the establishment of a Medicines Control Council; to provide that such council shall be a juristic person; to make other provision for the constitution of the council; to provide that a member of the council or committee shall declare his or her commercial interest related to the pharmaceutical or health care industry; to provide that the appointment of members of the executive committee is subject to the approval of the Minister; to provide for the control of medicines and scheduled substances and medical devices; to make further provision for the prohibition on the sale of medicines which are subject to registration and are not registered; to provide for procedures that will expedite the registration of essential medicines, and for the re-evaluation of all medicines after five years; to provide, for measures for the supply of more affordable medicines in certain circumstances; to provide that labels be approved by the council; to prohibit sampling and bonusing of medicines; to provide for the licensing of certain persons to compound, dispense or manufacture medicines and medical devices and also to act as wholesalers or distributors; to provide for the generic substitution of medicines; to provide for the establishment of a pricing committee; to regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines; to make new provisions for appeals against decisions of the Director-General or the council; to provide that the council may acquire and appropriate funds; to regulate the Minister's power to make regulations; to provide for the rationalisation of certain laws relating to medicines and related substances that have remained in force in various territories on the national territory of the Republic by virtue of item 2 of Schedule 6 to the

Constitution of the Republic of South Africa, 1996; and to provide for matters connected therewith.

[Long title substituted by s 37 of Act 65 of 1974, s 15 of Act 17 of 1979, s 22 of Act 94 of 1991, s 29 of Act 90 of 1997, s 13 of Act 59 of 2002.]

BE IT ENACTED by the State President, the Senate and the House of Assembly of the Republic of South Africa, as follows:—

ARRANGEMENT OF SECTIONS

1. Definitions

(1) In this Act, unless the context otherwise indicates—

"advertisement", in relation to any medicine, Scheduled substance, medical device or IVD, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

(a) appearing in any newspaper, magazine, pamphlet, electronic media (including radio and television) or other publication;

(b) distributed to members of the public; or

(c) brought to the notice of members of the public in any manner whatsoever,

which is intended to promote the sale of that medicine, Scheduled substance, medical device or IVD; and **"advertise"** has a corresponding meaning;

["advertisement" amended by s 1(a) of Act 20 of 1981; substituted by s 1(a) of Act 72 of 2008, s 1(a) of Act 14 of 2015.]

"advisory committee" …

["advisory committee" inserted by s 1(a) of Act 72 of 2008; repealed by s 1(b) of Act 14 of 2015.]

"analyst" means an analyst to whom authority has been granted under section 27;

"appeal board" …

["appeal board" repealed by s 1(a) of Act 94 of 1991.]

"approved name", in relation to a medicine, means the international nonproprietary name (INN) of such medicine or, where no such name exists, such other name as the council may determine, not being a brand name or trade name registered in terms of the Trade Marks Act, 1993 (Act 194 of 1993);

["approved name" substituted by s 1(a) of Act 90 of 1997.]

"Authority" means the South African Health Products Regulatory Authority established by section 2;

["Authority" inserted by s 1(b) of Act 72 of 2008.]

"Board" means the Board referred to in section 2;

["Board" inserted by s 1(c) of Act 14 of 2015.]

"certificate of registration" means a certificate of registration issued under section 15(4), 15A(4) or 15B(4);

["certificate of registration" inserted by s 1(b) of Act 20 of 1981.]

"cosmetic" …

["cosmetic" inserted by s 1(c) of Act 72 of 2008; repealed by s 1(d) of Act 14 of 2015.]

"council" …

["council" repealed by s 1(d) of Act 72 of 2008.]

"dentist" means a person registered as such under the Health Professions Act, 1974;

["dentist" substituted by s 1(b) of Act 90 of 1997.]

"Director-General" means the Director-General: Health;

["Director-General" inserted by s 1(c) of Act 20 of 1981; substituted by s 1(b) of Act 94 of 1991, s 1(c) of Act 90 of 1997.]

"export" includes deliver or supply within the Republic for dispatch to any destination outside the Republic;

["export" inserted by s 1(a) of Act 17 of 1979.]

"foodstuff" …

["foodstuff" inserted by s 1(e) of Act 72 of 2008; repealed by s 1(e) of Act 14 of 2015.]

"hospital" means any institution established as a hospital or a nursing home or registered as such in terms of any law;

"immediate container", in relation to a medicine or Scheduled substance, means a container which is in direct contact with the medicine or substance;

["immediate container" inserted by s 1(b) of Act 17 of 1979.]

"inspector" means a person authorised as such under section 26;

"interchangeable multi-source medicine" means medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed;

["interchangeable multi-source medicine" inserted by s 1(d) of Act 90 of 1997.]

"IVD" (*in vitro* diagnostic) means a medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;

["IVD" inserted by s 1(f) of Act 72 of 2008; substituted by s 1(f) of Act 14 of 2015.]

"label", when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article;

"magistrate" means a magistrate as defined in section 1 of the Magistrates Act, 1993 (Act 90 of 1993), and includes an additional magistrate and an assistant magistrate;

["magistrate" inserted by s 1(a) of Act 59 of 2002.]

"Medical Act" …

["Medical Act" repealed by s 1(e) of Act 90 of 1997.]

"medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act 15 of 1973)—

(a) intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following—

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and

(b) which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;

["medical device" inserted by s 1(c) of Act 94 of 1991; substituted by s 1(g) of Act 72 of 2008, s 1(h) of Act 14 of 2015.]

"medical device or IVD establishment" means a facility used by a manufacturer, wholesaler, distributor, retailer, service provider or an importer of medical devices or IVDs for conducting business;

["medical device or IVD establishment" inserted by s 1(h) of Act 72 of 2008.]

"medical practitioner" means a person registered as such under the Health Professions Act, 1974, and includes an intern registered under that Act;

["medical practitioner" substituted by s 1(c) of Act 17 of 1979, s 1(d) of Act 94 of 1991, s 1(f) of Act 90 of 1997.]

"medicinal purpose" …

["medical purpose" repealed by s 1(e) of Act 94 of 1991.]

"medicine"—

(a) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

(i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function in humans; and

(b) includes any veterinary medicine;

["medicine" substituted by s 1(d) of Act 17 of 1979, s 1(i) of Act 72 of 2008, s 1(g) of Act 14 of 2015.]

"Minister" means the Minister of Health;

["Minister" substituted by s 1(d) of Act 20 of 1981, s 1(f) of Act 94 of 1991, s 1(g) of Act 90 of 1997.]

“nurse” means a person registered as such under the Nursing Act, 1978 (Act 50 of 1978);

[“nurse” inserted by s 1(g) of Act 94 of 1991.]

“package” means anything in or by which any medicine or Scheduled substance is enclosed, covered, contained or packed;

“pathologist” means a pathologist to whom authority has been granted under section 27;

“pharmacist” means a person registered as such under the Pharmacy Act, 1974;

[“pharmacist” substituted by s 1(e) of Act 17 of 1979, s 1(h) of Act 94 of 1991.]

“pharmacist intern” means a person registered as such under the Pharmacy Act, 1974;

[“pharmacist intern” inserted by s 1(h) of Act 90 of 1997.]

“pharmacist’s assistant” means a person registered as such under the Pharmacy Act, 1974;

[“pharmacist’s assistant” inserted by s 1(f) of Act 17 of 1979; repealed by s 1(i) of Act 94 of 1991; inserted by s 1(h) of Act 90 of 1997.]

“pharmacologist”, except for the purposes of section 24(1)(c), means a pharmacologist to whom authority has been granted under section 27;

[“pharmacologist” substituted by s 1(j) of Act 94 of 1991.]

“pharmacy Board” ...

[“pharmacy Board” repealed by s 1(k) of Act 94 of 1991.]

“practitioner” means a person registered as such under the Allied Health Professions Act, 1982 (Act 63 of 1982);

[“practitioner” inserted by s 1(l) of Act 94 of 1991; substituted by s 1(i) of Act 90 of 1997, s 1(b) of Act 59 of 2002.]

“prescribed” means prescribed by or under this Act;

“product” …

[“product” inserted by s 1(j) of Act 72 of 2008; repealed by s 1(i) of Act 14 of 2015.]

“public” includes a section of the public concerned with manufacturing, dispensing, selling or administering, or the issue of prescriptions for, medicines or a Scheduled substance;

[“public” inserted by s 1(e) of Act 20 of 1981.]

“register”, when used as a noun, means the register referred to in section 13, and when used as a verb, means to enter in such register;

“registered” means entered in the register;

“registrar” …

[“registrar” repealed by s 1(k) of Act 72 of 2008.]

“regulation” means a regulation made and in force under this Act;

“Scheduled substance” means any medicine or other substance prescribed by the Minister under section 22A;

[“Scheduled substance” substituted by s 1(m) of Act 94 of 1991.]

“Schedule 1 substance” …

[“Schedule 1 substance” repealed by s 1(n) of Act 94 of 1991.]

“Schedule 2 substance” …

[“Schedule 2 substance” repealed by s 1(n) of Act 94 of 1991.]

“Schedule 3 substance” …

[“Schedule 3 substance” repealed by s 1(n) of Act 94 of 1991.]

“Schedule 4 substance” …

[“Schedule 4 substance” repealed by s 1(n) of Act 94 of 1991.]

“Schedule 5 substance” …

[“Schedule 5 substance” repealed by s 1(n) of Act 94 of 1991.]

“Schedule 6 substance” …

[“Schedule 6 substance” repealed by s 1(n) of Act 94 of 1991.]

“Schedule 7 substance” …

[“Schedule 7 substance” repealed by s 1(n) of Act 94 of 1991.]

“Schedule 8 substance” …

[“Schedule 8 substance” repealed by s 1(n) of Act 94 of 1991.]

“Schedule 9 substance” …

[“Schedule 9 substance” repealed by s 1(n) of Act 94 of 1991.]

"Secretary" …

["Secretary" repealed by s 1(f) of Act 20 of 1981.]

"sell" means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and "sale" and "sold" have corresponding meanings;

"this Act" includes any regulation;

"the territory" ….

["the territory" repealed by s 1(o) of Act 94 of 1991, again repealed by s 1 of Act 49 of 1999.]

"trainee pharmacist" …

["trainee pharmacist" repealed by s 1(o) of Act 94 of 1991.]

"unqualified assistant" …

["unqualified assistant" repealed by s 1(g) of Act 17 of 1979.]

"veterinarian" means a person registered as such under the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982);

["veterinarian" substituted by s 1(p) of Act 94 of 1991.]

"veterinary medicine" means any substance or mixture of substances, other than a stock remedy or farm feed to be registered in terms of the Fertilisers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), used or purporting to be suitable for use or manufactured or sold for use in connection with vertebrates, for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, or for curing, correcting or modifying any somatic or organic function, or for correcting or modifying behaviour;

["veterinary medicine" inserted by s 1(h) of Act 17 of 1979.]

"vigilance", in relation to a medicine, medical device or IVD, means the continuous monitoring and evaluation of its safety, efficacy and performance profile and the management of any risk throughout its life-cycle.

["vigilance" inserted by s 1(j) of Act 14 of 2015.]

(2) Subject to section 15C, a medicine shall, notwithstanding the fact that its components are identical to those of any other medicine as to physical characteristics, quantity and quality, for the purposes of this Act not be regarded as being the same medicine as that other medicine if registration thereof is not applied for by the holder of the certificate of registration issued in respect of that other medicine.

[S 1(2) substituted by s 1(i) of Act 17 of 1979, s 1(g) of Act 20 of 1981, s 1(j) of Act 90 of 1997.]

(3) In determining whether or not the registration or availability of a medicine is in the public interest, regard shall be had only to the safety, quality and therapeutic efficacy thereof in relation to its effect on the health of man or any animal, as the case may be.

[S 1(3) substituted by s 1(j) of Act 17 of 1979.]

(4) International tendering for medicines shall be allowed in the prescribed manner and on the prescribed conditions.

[S 1 substituted by s 1 of Act 65 of 1974, s 1(4) inserted by s 1(k) of Act 90 of 1997.]

2. Establishment of South African Health Products Regulatory Authority

[S 2 heading substituted by s 2(a) of Act 14 of 2015.]

(1) The South African Health Products Regulatory Authority is hereby established as an organ of state within the public administration but outside the public service.

[S 2(1) substituted by s 2(b) of Act 14 of 2015.]

(2) The Authority is—

(a) a juristic person;

(b) subject to the Public Finance Management Act, 1999 (Act 1 of 1999); and

(c) accountable to and reports to the Minister.

(3) The Authority may exercise the powers and shall perform the functions conferred upon or assigned to it by this Act.

(4) In performing its functions, the Authority shall act without fear, favour or prejudice.

(5) The Authority acts through its Board.

[S 2(5) inserted by s 2(c) of Act 14 of 2015.]

[S 2 substituted by s 2 of Act 65 of 1974; amended by s 2 of Act 94 of 1991, s 2 of Act 90 of 1997; substituted by s 2 of Act 72 of 2008.]

2A. Objects of Authority

The objects of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest.

[S 2A inserted by s 3 of Act 14 of 2015.]

2B. Functions of Authority

(1) The Authority must, in order to achieve its objects—

(a) ensure the efficient, effective and ethical evaluation or assessment and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety, efficacy and performance, where applicable;

(b) ensure that the process of evaluating or assessing and registering medicines, medical devices and IVDs is transparent, fair, objective and concluded timeously;

(c) ensure the periodic re-evaluation or re-assessment and monitoring of medicines, medical devices and IVDs;

(d) ensure that evidence of existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance is being monitored, analysed and acted upon;

(e) ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation; and

(f) ensure that clinical trial protocols are being assessed according to prescribed ethical and professional criteria and defined standards.

(2) The Authority may—

(a) liaise with any other regulatory authority or institution and may, without limiting the generality of this power, require the necessary information from, exchange information with and receive information from any such authority or institution in respect of—

(i) matters of common interest; or

(ii) a specific investigation; and

(b) enter into agreements to co-operate with any regulatory authority in order to achieve the objects of this Act.

[S 2B inserted by s 3 of Act 14 of 2015.]

2C. Composition of Board

(1) The Board of the Authority consists of not less than 10 but not more than 15 members appointed by the Minister.

(2) Subject to section 2D, the Minister must appoint as members of the Board—

(a) not more than 10 persons who have expertise in the fields of medicine, medical devices, IVD, vigilance, clinical trials, good manufacturing practice, public health or epidemiology;

(b) one person on account of his or her knowledge of the law;

(c) one person on account of his or her knowledge of good governance;

(d) one person on account of his or her knowledge of financial matters and accounting;

(e) one person on account of his or her knowledge of information technology; and

(f) one person on account of his or her knowledge of human resource management.

(3) The Chief Executive Officer is by virtue of his or her office a member of the Board but with no voting rights.

[S 2C inserted by s 3 of Act 14 of 2015.]

2D. Appointment of members of Board

(1) The Minister must, before appointing the members contemplated in section 2C(2), by notice in the *Gazette* and in two or more nationally circulating newspapers in the Republic, invite all interested persons to nominate, within the period specified in the notice, persons who in the opinion of such interested persons are fit to be so appointed, stating the grounds upon which such opinion is based.

(2) If the Minister receives no nominations or an insufficient number of nominations within the period specified in the notice referred to in subsection (1), the Minister may either readvertise or, in any other transparent manner, appoint the required number of qualified persons in terms of this Act.

(3) Subject to section 2F, a member of the Board—

(a) holds office for a minimum period of three years, but not exceeding five years, determined by the Minister at the time of the appointment of the member; and

(b) is eligible for re-appointment for one additional term.

(4) A member of the Board, excluding a member who is in the full-time employment of the State, must be appointed on such conditions as the Minister may, with the concurrence of the Minister of Finance, determine.

[S 2D inserted by s 3 of Act 14 of 2015.]

2E. Appointment of chairperson and vice-chairperson of Board

(1) The Minister must appoint a chairperson and vice-chairperson of the Board from among the members contemplated in section 2C(2).

(2) Whenever the chairperson of the Board is absent or unable to perform his or her functions as chairperson, the vice-chairperson must act as chairperson and if the vice-chairperson is absent or unable to act as chairperson the Minister must designate another member of the Board to act as chairperson until the chairperson or vice-chairperson is available.

(3) Any person acting as chairperson of the Board in terms of subsection (2) has all the powers and duties of the chairperson.

[S 2E inserted by s 3 of Act 14 of 2015.]

2F. Disqualification from membership of Board and vacation of office

(1) A person may not be appointed as a member of the Board if that person—

(a) is not a South African citizen and ordinarily resident in the Republic;

(b) is an unrehabilitated insolvent;

(c) has at any time been convicted of an offence involving dishonesty, whether in the Republic or elsewhere, and sentenced to imprisonment without the option of a fine; or

(d) has been removed from an office of trust.

(2) A member of the Board must vacate office if—

(a) he or she becomes disqualified in terms of subsection (1), from being appointed as a member of the Board;

(b) he or she submits his or her resignation to the Minister in writing;

(c) he or she is declared by the High Court to be of unsound mind or mentally disordered or is detained under the Mental Health Care Act, 2002 (Act 17 of 2002);

(d) he or she has, without the leave of the Board, been absent from more than two consecutive meetings of the Board; or

(e) the Minister, after consultation with the Board, withdraws the appointment of that member because the member is incompetent or unfit to fulfil his or her duties.

(3) If a member of the Board dies or vacates office in terms of subsection (2), the Minister may, subject to section 2D, appoint a person to fill the vacancy for the unexpired portion of the period for which that member was appointed.

[S 2F inserted by s 3 of Act 14 of 2015.]

2G. Meetings of Board

(1) The meetings of the Board and the conduct of business at meetings must be determined by the rules of the Board.

(2) A quorum for a meeting of the Board is the majority of its voting members.

(3) A decision of the majority of the members of the Board present at any meeting constitutes a decision of the Board and, in the event of an equality of votes, the member presiding at the meeting has a casting vote in addition to his or her deliberative vote.

(4) A decision taken by the Board or an act performed under the authority of the Board is not invalid by reason only of a vacancy on the Board, or that a person who is not entitled to sit as a member of the Board sat as a member at the time when the decision was taken or the act was authorised, if the decision was taken or the act was authorised by the requisite majority of the members of the Board who were present at the time and entitled to sit as members.

(5) Minutes of the proceedings of every meeting of the Board must be prepared and stored by such means as may be determined by the Board.

(6) Minutes of the proceedings of each meeting must be submitted at the next meeting of the Board and, if passed as correct, must be confirmed by the signature of the chairperson or other member presiding thereat and may, when so confirmed, be evidence in a court of law of the proceedings of the first-mentioned meeting.

(7) In the absence of the chairperson or the person acting as the chairperson from a particular meeting of the Board, the members present at that meeting may elect one of their number to preside at that meeting.

[S 2G inserted by s 3 of Act 14 of 2015.]

2H. Committees of Board

The Board may appoint one or more committees from among its members to assist it with the performance of its functions.

[S 2H inserted by s 3 of Act 14 of 2015.]

2I. Dissolution of Board

(1) The Minister may dissolve the Board if the Minister, on good cause shown, loses confidence in the ability of the Board to perform its functions effectively and efficiently.

(2) The Minister may dissolve the Board only—

(a) after having given the Board a reasonable opportunity to be heard; and

(b) after having afforded the Board a hearing on any submissions received.

(3) If the Minister dissolves the Board, the Minister—

(a) may appoint an administrator to take over the functions of the Board and to do anything which the Board might otherwise be empowered or required to do by or under this Act, subject to such conditions as the Minister may determine; and

(b) must, as soon as it is feasible but not later than three months after the dissolution of the Board, replace the members of the Board in the same manner in which they were appointed.

(4) The costs associated with the appointment of an administrator shall be for the account of the Authority.

(5) The appointment of the administrator terminates when the Board members have been replaced in terms of section 2C(2).

[S 2I inserted by s 3 of Act 14 of 2015.]

3. Chief Executive Officer and other staff of Authority

(1) The Board, after consultation with the Minister, must appoint a suitably qualified person as the Chief Executive Officer of the Authority.

[S 3(1) substituted by s 4(a) of Act 14 of 2015.]

(2) A person may not be appointed as the Chief Executive Officer if such person—

(a) is an unrehabilitated insolvent;

(b) is mentally unfit; or

(c) has been convicted of an offence committed after the Constitution of the Republic of South Africa, 1993 (Act 200 of 1993) took effect and sentenced to imprisonment without the option of a fine.

(3) The Chief Executive Officer may be removed from office for—

(a) serious misconduct;

(b) permanent incapacity; or

(c) engaging in any activity that is reasonably capable of undermining the integrity of the Authority.

(4) The Chief Executive Officer—

(a) is appointed for a term of five years and may be reappointed for one additional term of five years;

(b) is appointed subject to the conclusion of a performance agreement with the Board;

[S 3(4)(b) substituted by s 4(b) of Act 14 of 2015.]

(c) is accountable to and reports to the Board;

[S 3(4)(c) substituted by s 4(b) of Act 14 of 2015.]

(d) is entitled to the benefits as may be determined by the Minister in consultation with the Minister for the Public Service and Administration;

(e) is responsible for the general administration of the Authority and for the carrying out of any functions assigned to the Authority by this Act and the Minister;

(f) must manage and direct the activities of the Authority;

(g) must appoint and supervise staff of the Authority; and

(h) must compile business and financial plans and reports in terms of the Public Finance Management Act, 1999 (Act 1 of 1999).

(5) The Chief Executive Officer shall appoint suitably qualified staff and may contract other suitably qualified persons to assist the Authority in carrying out its functions.

(6)

(a) The Minister shall, after consultation with the Minister for Public Service and Administration, determine the structure and the human resources policy for the Authority.

(b) The human resources policy shall include a code of conduct and provisions on conflict of interests applicable to the Chief Executive Officer and the staff of the Authority.

(7) The Authority may utilise persons seconded or transferred from the public service, and such transfer must be in accordance with the Labour Relations Act, 1995 (Act 66 of 1995).

(8) The Chief Executive Officer and the staff of the Authority become members of the Government Employees' Pension Fund contemplated in section 2 of the Government Employees Pension Law, 1996 (Proclamation No. 21 of 1996).

(9) The Chief Executive Officer shall, in consultation with the Board, appoint committees, as he or she may deem necessary, to investigate and report to the Authority on any matter within its purview in terms of this Act.

[S 3 amended by s 3 of Act 65 of 1974, s 1 of Act 36 of 1977, s 2 of Act 17 of 1979, s 46 of Act 97 of 1986, s 3 of Act 94 of 1991; substituted by s 3 of Act 90 of 1997, s 3 of Act 72 of 2008.]

4. …

[S 4 amended by s 4 of Act 65 of 1974, s 4 of Act 90 of 1997; substituted by s 4 of Act 72 of 2008; repealed by s 5 of Act 14 of 2015.]

5. …

[S 5 amended by s 46 of Act 97 of 1986; repealed by s 5 of Act 72 of 2008.]

6. …

[S 6 amended by s 5 of Act 65 of 1974, s 3 of Act 17 of 1979, s 46 of Act 97 of 1986, s 4 of Act 94 of 1991, s 1 of Act 49 of 1996; substituted by s 5 of Act 90 of 1997; amended by s 2 of Act 59 of 2002; repealed by s 5 of Act 72 of 2008.]

7. …

[S 7 amended by s 6 of Act 65 of 1974; repealed by s 5 of Act 72 of 2008.]

8. …

[S 8 repealed by s 5 of Act 72 of 2008.]

9. …

[S 9 amended by s 7 of Act 65 of 1974, s 6 of Act 90 of 1997; repealed by s 5 of Act 72 of 2008.]

10. …

[S 10 substituted by s 8 of Act 65 of 1974; amended by s 4 of Act 17 of 1979, s 46 of Act 97 of 1986; repealed by s 5 of Act 94 of 1991.]

11. …

[S 11 amended by s 9 of Act 65 of 1974, s 5 of Act 17 of 1979, s 46 of Act 97 of 1986; repealed by s 6 of Act 94 of 1991.]

12. …

[S 12 substituted by s 10 of Act 65 of 1974; amended by s 7 of Act 90 of 1997; substituted by s 3 of Act 59 of 2002; repealed by s 5 of Act 72 of 2008.]

13. Registers

(1) The Chief Executive Officer shall keep separate registers for medicines, medical devices or IVDs, in which he or she shall record—

(a) the registration of medicines, medical devices or IVDs by the Authority; and

(b) such particulars in regard to the medicines, medical devices or IVDs and the holder of certificate of registration in respect of such medicines, medical devices or IVDs as are required by this Act.

(2) The Chief Executive Officer shall publish on the Authority's website the registers referred to in subsection (1) and update those registers when registration is obtained.

[S 13 amended by s 11 of Act 65 of 1974; substituted by s 2 of Act 20 of 1981, s 6 of Act 72 of 2008, s 6 of Act 14 of 2015.]

14. Prohibition on the sale of medicines, medical devices or IVDs which are subject to registration and are not registered

(1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine, medical device or IVD which is subject to registration by virtue of a declaration published in terms of subsection (2) unless it is registered.

(2)

(a) The Authority may from time to time determine that a medicine, medical device or IVD, or class or category of medicine, medical device or IVD or part of any class or category of medicine, medical devices or IVDs mentioned in the declaration, shall be subject to registration in terms of this Act.

(b) Any such declaration may also relate only to medicines, medical devices or IVDs which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicine, medical devices or IVDs which were not then so available.

(c) Any such declaration shall be published in the *Gazette* by the Chief Executive Officer and shall come into operation on the date on which it is so published.

(3) In the case of a medicine, medical device or IVD which was available for sale in the Republic immediately prior to the date of publication in the *Gazette* of the declaration by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) shall come into operation—

(a) if no application for the registration of such medicine, medical device or IVD is made within the period of six months immediately succeeding that date, on the expiration of that period; or

(b) if an application for the registration of such medicine, medical device or IVD is made within the said period, on the date one month after the date on which a notice in respect of such medicine, medical device or IVD is published in the *Gazette* in terms of section 15(9) or section 17(a).

[S 14(3)(b) substituted by s 7 of Act 14 of 2015.]

(4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine—

(a) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a licence contemplated in section 22C(1)(a), for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or

(b) compounded by a pharmacist in a quantity not greater than that prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Health Professions Act, 1974, as referred to in section 22A, as the case may be,

if such medicine does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for registration has been rejected, and is not or has not been advertised: Provided that the active components of such medicine appear in another medicine which has been registered under this Act.

[S 14 substituted by s 1 of Act 29 of 1968, s 12 of Act 65 of 1974; amended by s 6 of Act 17 of 1979, s 7 of Act 94 of 1991, s 8 of Act 90 of 1997; substituted by s 7 of Act 72 of 2008.]

15. Registration of medicines, medical devices or IVDs

(1) Every application for the registration of a medicine medical device or IVD shall be submitted to the Chief Executive Officer in the prescribed form and shall be accompanied by—

(a) the prescribed particulars;

(b) samples of the relevant medicine;

(c) where practicable, samples of medical devices or IVDs; and

(d) the prescribed registration fee.

(2) As soon as possible after receipt by the Chief Executive Officer of an application contemplated in subsection (1), he or she shall inform the applicant in writing that the application is being considered.

(3)

(a) If after consideration of any such application and after any investigation or enquiry which it may consider necessary the Authority is satisfied that the medicine, medical device or IVD in question—

(i) is suitable for the purpose for which it is intended;

(ii) complies with the prescribed requirements; and

[S 15(3)(a)(ii) amended by s 8(a) of Act 14 of 2015.]

(iii) is safe, efficacious and of good quality and, in the case of a medical device and IVD, performs as intended,

[S 15(3)(a)(iii) substituted by s 8(a) of Act 14 of 2015.]

(iv) …

[S 15(3)(a)(iv) repealed by s 8(b) of Act 14 of 2015.]

the Authority shall issue the applicant with a certificate of registration to that effect.

(b) If the Authority is not satisfied as contemplated in paragraph (a), it shall cause the applicant to be notified in writing of the reasons why it is not so satisfied and cause the applicant to be informed that he or she may within a period of 30 days after the date of the notification furnish the Chief Executive Officer with his or her comments on the Authority's reasons for not being so satisfied.

(c) If no such comments are submitted by the applicant within the said period, or if after consideration of any comments so submitted the Authority is still not satisfied as aforesaid, it shall reject the application.

[S 15(3)(c) substituted by s 8(c) of Act 14 of 2015.]

(4) Every medicine, medical device or IVD shall be registered under such name as the Authority may approve.

(5) The Chief Executive Officer shall allocate to every medicine, medical device or IVD registered under this Act a registration number which shall be recorded in the register opposite the name of such medicine, medical device or IVD and which shall be stated in the certificate of registration issued in respect of such medicine, medical device or IVD.

(6) Any registration under this section—

(a) may be made subject to such conditions as may be determined by the Authority; and

(b) shall in the case of medicines, be valid for a period of five years.

(7) No condition shall be imposed under subsection (6) whereby the sale of the medicine in question by any person other than a pharmacist is prohibited or until after the applicant has in writing been notified by the Chief Executive Officer that the imposition of such condition is contemplated and invited to submit written representations to the Authority in regard to the matter.

(8) If no such representations are lodged by the applicant concerned within a period of 30 days after the receipt by him or her of any notification referred to in subsection (7), or if after consideration of any such representations the Authority is still of the opinion that the condition in question should be imposed, the Authority shall register the medicine, medical device or IVD concerned subject to the said condition.

(9) Notice of the rejection of an application for registration under this section in respect of a medicine, medical device or IVD referred to in subsection (3) of section 14 shall be given in the *Gazette* by the Chief Executive Officer.

(10) The Chief Executive Officer shall as soon as possible after the date of expiry of the appropriate period referred to in section 14(3) publish in the *Gazette* the prescribed particulars in respect of all applications for registration received by him or her prior to such date.

[S 15 amended by s 2 of Act 29 of 1968; substituted by s 13 of Act 65 of 1974; amended by s 8 of Act 94 of 1991, s 9 of Act 90 of 1997; substituted by s 8 of Act 72 of 2008.]

15A. Amendment of entries in register

(1) The entry made in the register in respect of any medicine, medical device or IVD may on application by the holder of a certificate of registration issued in respect of such medicine, medical device or IVD be amended by the Chief Executive Officer.

(2) An application for the amendment of an entry in the register shall be made to the Chief Executive Officer in the prescribed form and shall be accompanied by the prescribed application fee.

(3) The Chief Executive Officer may, if necessary, cancel the existing registration in respect of such medicine, medical device or IVD and issue a new certificate of registration.

[S 15A inserted by s 3 of Act 20 of 1981; substituted by s 9 of Act 72 of 2008.]

15B. Transfer of certificate of registration

(1) A certificate of registration may with the approval of the Chief Executive Officer be transferred by the holder thereof to any other person.

(2) An application for approval of the transfer of a certificate of registration shall be made to the Chief Executive Officer on the prescribed form and shall be accompanied by the certificate of registration in question and the prescribed application fee.

(3) If the Chief Executive Officer grants any application submitted to him or her in terms of subsection (2), the Chief Executive Officer shall make the necessary entries in the register relating to the person to whom the certificate of registration is transferred, cancel the existing certificate of registration and issue a new one in the prescribed form to such person.

[S 15B inserted by s 3 of Act 20 of 1981; substituted by s 10 of Act 72 of 2008.]

15C. Measures to ensure supply of more affordable medicines

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may—

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of

another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the Authority in the prescribed manner, may be imported;

[S 15C(b) substituted by s 11 of Act 72 of 2008.]

(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

[S 15C inserted by s 10 of Act 90 of 1997.]

16. Cancellation of registration

(1) If the Authority—

(a) is of the opinion that a holder of a certificate of registration has failed to comply with any condition subject to which any medicine, medical device or IVD was registered;

[S 16(1)(a) amended by s 9 of Act 14 of 2015.]

(b) is of the opinion that any medicine, medical device or IVD does not comply with any prescribed requirement; or

[S 16(1)(b) amended by s 9 of Act 14 of 2015.]

(c) is of the opinion that it is not in the public interest that any medicine, medical device or IVD shall be available to the public,

[S 16(1)(c) inserted by s 9 of Act 14 of 2015.]

the Authority shall cause notice in writing to be given accordingly by the Chief Executive Officer to the holder of the certificate of registration issued in respect of that medicine, medical device or IVD.

(2) Any such notice shall specify the grounds on which the Authority's opinion is based, and shall indicate that the person to whom it is directed may within one month after receipt thereof submit to the Chief Executive Officer any comments he or she may wish to put forward in connection with the matter.

(3) If no such comments are so submitted, or if after consideration of any comments so submitted the Authority is of the opinion that the registration of the medicine, medical device or IVD in question should be cancelled, the Authority may cancel the registration thereof.

(4) If the person who is the holder of the certificate of registration issued in respect of any medicine, medical device or IVD fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine, medical device or IVD before or on the prescribed date or such later date as the Chief Executive Officer may determine on application by that person, the Chief Executive Officer shall cancel the registration of that medicine, medical device or IVD.

[S 16 amended by s 3 of Act 29 of 1968, s 14 of Act 65 of 1974, s 4 of Act 20 of 1981; substituted by s 12 of Act 72 of 2008.]

17. Notification of registration or cancellation thereof

The Chief Executive Officer shall give notice in the *Gazette* of the registration or cancellation of registration of any medicine, medical device or IVD in terms of this Act, and shall in such notice specify—

(a) in the case of registration of any medicine, medical device or IVD, the name under which such medicine, medical device or IVD is registered, the active components of such medicine, if any, the name of the person who applied for registration of such medicine, medical device or IVD, the number allocated to it in terms of section 15 and the conditions (if any) subject to which it is registered;

(b) in the case of a cancellation of the registration, the name under which such medicine, medical device or IVD was registered, the name of the holder of the certificate of registration issued in respect of such medicine, medical device or IVD and the number which was allocated to it in terms of section 15.

[S 17 amended by s 4 of Act 29 of 1968; substituted by s 15 of Act 65 of 1974; amended by s 5 of Act 20 of 1981; substituted by s 13 of Act 72 of 2008.]

18. Labels and advertisements

(1) No person shall sell any—

(a) medicine or Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars; and

(b) medical device or IVD unless the medical device or IVD, or its packaging, bears a label, where practical, stating the prescribed particulars.

[S 18(1) substituted by s 10 of Act 14 of 2015.]

(2) No person shall advertise any medicine or Scheduled substance, medical device or IVD for sale unless such advertisement complies with the prescribed requirements.

[S 18(2) substituted by s 10 of Act 14 of 2015.]

(3) The label referred to in subsection (1) shall be approved by the Authority.

(4) The Authority may authorise a deviation from the prescribed format and contents of any label.

(5) The Minister may prescribe additional requirements for the labelling of medicines, medical devices or IVDs.

[S 18 substituted by s 16 of Act 65 of 1974, s 7 of Act 17 of 1979; amended by s 11 of Act 90 of 1997; substituted by s 14 of Act 72 of 2008.]

18A. Bonusing

(1) No person shall supply any medicine, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.

(2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1) in consultation with the Pricing Committee referred to in section 22G.

[S 18A inserted by s 12 of Act 90 of 1997 with effect from 2 May 2004; substituted by s 15 of Act 72 of 2008, s 11 of Act 14 of 2015.]

18B. Sampling of medicines

(1) No person shall sample any medicine, medical devices or IVD.

(2) Use of medicines, medical devices or IVDs for exhibition or appraisal purposes shall be as prescribed.

(3) For the purposes of this section “sample” means the free supply of medicines, medical devices or IVDs by a device or IVD establishment, manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974 (Act 56 of 1974), or any professional or person authorised to use the device.

[S 18B inserted by s 12 of Act 90 of 1997; substituted by s 16 of Act 72 of 2008.]

18C. Marketing of Medicines

The Minister shall, after consultation with the relevant industries and other stakeholders, make regulations relating to the marketing of medicines, medical devices or IVDs and such regulations shall also provide for Codes of Practice for relevant industries.

[S 18C inserted by s 12 of Act 90 of 1997; substituted by s 4 of Act 59 of 2002, s 17 of Act 72 of 2008.]

19. Prohibition on sale of medicines, medical devices or IVDs which do not comply with prescribed requirements and furnishing of information regarding medicines, medical devices or IVDs to the Authority

(1) No person shall sell any medicine, medical device or IVD unless it complies with the prescribed requirements.

(2) The Authority may by notice in writing require any person who manufactures or sells medicines, medical devices or IVDs or administers or prescribes any medicine, medical device or IVD or on whose direction any medicine or medical device is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his or her possession or which such person is in a position to obtain regarding such medicine, medical device or IVD.

[S 19(2) substituted by s 12 of Act 14 of 2015.]

(3) The Authority may, if so requested by any person to whom a notice under subsection (2) is addressed, extend the period stipulated in such notice.

[S 19 amended by s 17 of Act 65 of 1974; substituted by s 18 of Act 72 of 2008.]

20. Publication or distribution of false advertisements concerning medicines, medical devices or IVDs

(1) No person shall—

(a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any medicine, medical device or IVD; or

(b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine, medical device or IVD is other than that stated by the Authority in terms of section 22(1)(a)(ii) or state or suggest that any medicine, medical device or IVD should

be used for a purpose or under circumstances or manner other than that stated by the Authority in terms of section 22(1)(a)(ii).

[S 20(1)(b) substituted by s 13 of Act 14 of 2015.]

(2) It shall be a sufficient defence in any prosecution for an offence under paragraph (a) of subsection (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the medicine, medical device or IVD to which the false or misleading advertisement which is the subject of the prosecution relates, did not know, and could not reasonably be expected to have known, that the advertisement was in any respect false or misleading.

[S 20 amended by s 18 of Act 65 of 1974; substituted by s 19 of Act 72 of 2008.]

21. Authority may authorise sale of unregistered medicines, medical devices or IVDs for certain purposes

(1) The Authority may in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or IVD which is not registered.

(2) Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).

[S 21 amended by s 19 of Act 65 of 1974; substituted by s 20 of Act 72 of 2008.]

22. Authority to cause certain information to be furnished

(1) The Chief Executive Officer shall cause, in such manner as he or she considers most suitable—

(a) as soon as practicable after any medicine, medical device or IVD, other than a veterinary medicine, has been registered, medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine, medical device or IVD to be informed—

(i) of the name and number under which such medicine, medical device or IVD is registered and the conditions, if any, subject to which such medicine, medical device or IVD is registered;

(ii) of the therapeutic efficacy and effect of such medicine;

(iii) of the purpose for which, the circumstances under which and the manner in which such medicine, medical device or IVD should be used; and

(iv) regarding any other matter concerning such medicine, medical device or IVD which, in the opinion of the Chief Executive Officer, may be of value to them;

(b) as soon as practicable after the registration of any medicine, medical device or IVD, other than a veterinary medicine, has been cancelled in terms of section 16, medical practitioners, dentists, pharmacists, the public in general and the holder of the certificate of registration issued in respect of such medicine, medical device or IVD to be informed of the cancellation of such registration.

(2) The provisions of subsection (1) shall apply *mutatis mutandis* in respect of any veterinary medicine, and for the purposes of such application the reference in that subsection to medical practitioners and dentists shall be deemed to be a reference to veterinarians.

[S 22 substituted by s 20 of Act 65 of 1974, s 8 of Act 17 of 1979; amended by s 6 of Act 20 of 1981; substituted by s 21 of Act 72 of 2008.]

22A. Control of medicines, Scheduled substances, medical devices and IVDs

[S 22A heading substituted by s 14(a) of Act 14 of 2015.]

(1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine, Scheduled substance, medical device or IVDs, except in accordance with the prescribed conditions.

[S 22A(1) substituted by s 14(b) of Act 14 of 2015.]

(2) The Minister may, on the recommendation of the Authority, prescribe the Scheduled substances referred to in this section.

[S 22A(2) substituted by s 22(a) of Act 72 of 2008.]

(3) Any Schedule 0 substance may be sold in an open shop.

(4) Any Schedule I substance shall not be sold—

(a) by any person other than—

(i) a pharmacist, or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist;

(ii) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;

(iii) a medical practitioner or dentist, who may—

(aa) prescribe such substance;

(bb) compound and dispense such substance only if he or she is the holder of a licence as contemplated in section 22C(1)(a);

(iv) a veterinarian who may prescribe, compound or dispense such substance;

(v) a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may—

(aa) prescribe only the Scheduled substances identified in the Schedule for that purpose;

(bb) compound and dispense the Scheduled substances referred to in item (aa) only if he or she is the holder of a licence contemplated in section 22C(1)(a);

(b) to any person apparently under the age of 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C(1)(a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 12 years;

[S 22A(4)(b) substituted by s 22(b) of Act 72 of 2008.]

(c) unless the seller, other than a manufacturer or wholesale dealer in pharmaceutical products, enters in a prescription book required to be kept in the prescribed manner, the prescribed particulars of such sale.

(5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than—

(a) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;

(b) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;

(c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;

(d) a medical practitioner or dentist, who may—

(i) prescribe such substance;

(ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C(1)(a);

(e) a veterinarian who may prescribe, compound or dispense such substance;

(f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may—

(i) prescribe only the Scheduled substances identified in the Schedule for that purpose;

(ii) compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C(1)(a).

(6) Any sale under subsection (5) shall only take place on condition that—

(a) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner;

(b) the authorised prescriber who has given verbal instructions to a pharmacist to dispense a prescription shall within seven days after giving such instructions furnish such pharmacist with a prescription confirming such instructions;

(c) in the case of verbal instructions the treatment period shall not exceed seven days;

(d) if a prescription is not presented for dispensing within 30 days of issue it shall not be dispensed;

(e) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of 12 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C(1)(a), or on a written order disclosing the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of 12 years;

[S 22A(6)(e) substituted by s 22(c) of Act 72 of 2008.]

(f) in the case of a Schedule 2, Schedule 3 or Schedule 4 substance, such sale may be repeated if the person who issued the prescription has indicated thereon the number of times it may be dispensed, but not for longer than six months;

(g) in the case of a Schedule 5 substance, such sale shall not be repeated for longer than six months, and then only if the authorised prescriber has indicated on the prescription the number of times and the intervals at which it may be dispensed;

(h) where a Schedule 5 substance is used for—

(i) its anxiolytic, antidepressant or tranquillising properties it shall not be prescribed for longer than six months unless the authorised prescriber has consulted a registered psychiatrist, or, in the case of a psychiatrist, another psychiatrist before issuing a new prescription;

(ii) its analgesic properties it shall not be prescribed for longer than six months unless the authorised prescriber has consulted another medical practitioner, before issuing a new prescription;

(i) in the case of a Schedule 6 substance, it shall not be repeated without a new prescription being issued;

(j) in an emergency in which the health or life of a patient is at stake, a pharmacist engaged in wholesale practice may, on receipt of a telephonic or telefaxed or other electronic request, supply a Schedule 6 substance to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, without a written order: Provided that—

(i) it shall be the responsibility of such pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person to ensure that such pharmacist receives a written order within seven days;

(ii) the Schedule 6 substance shall be supplied in the smallest unit sales pack available;

(iii) a permanent record is made and kept of such supply.

(k) in an emergency a pharmacist may sell any Schedule 5 or Schedule 6 substance in a quantity not greater than that required for continuous use for a period of 48 hours, on the verbal instructions of a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, who is known to such pharmacist, but the prescriber who has given such verbal instructions shall within 72 hours after giving such instructions furnish to such pharmacist a written prescription confirming the instructions;

(l) in an emergency a pharmacist may sell a Schedule 2, Schedule 3 or Schedule 4 substance on a non-recurring basis for a period not exceeding 30 days in accordance with the original prescription in order to ensure that therapy is not disrupted if he or she is satisfied that an authorised prescriber initiated the therapy, with the intention that the therapy be continued, and that the particulars of such sale are recorded in a prescription book or other prescribed permanent record;

(m) a pharmacist may sell a greater or a lesser quantity of a Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance than the quantity prescribed or ordered, according to the therapeutic pack in the original container of such substance as supplied to him or her, but the quantity so sold shall not exceed or be less than, 25 per cent of the quantity specified in the prescription or order in question;

(n) any seller referred to in this subsection shall retain the prescription or order concerned for a period of not less than five years as from the date of such sale;

(o) a Schedule 6 substance may only be sold if the course of treatment does not exceed 30 consecutive days;

(p) the sale of as specified Schedule 5 or Schedule 6 substance by a manufacturer of or wholesale dealer in pharmaceutical products shall be recorded in a register which shall be kept in the prescribed manner, and shall be balanced so as to show clearly the quantity of every specified Schedule 5 or Schedule 6 substance remaining in stock as on the last day

of March, June, September and December of each year, and such balancing shall be completed within the 14 days following each of the said dates;

[S 22A(6)(p) substituted by s 5(a) of Act 59 of 2002.]

(q) a pharmacist shall endorse on the prescription the date of sale and the quantity of the substance sold, and when it is repeated, the date of sale and the quantity of the said substance sold, and the last seller shall retain the prescription for a period of not less than five years as from the date of the last sale;

(r) any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal may be supplied by any person practising a para-veterinary profession within the meaning of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982), upon a written prescription issued by a veterinarian or on the verbal instructions of a veterinarian.

(7)

(a) No person, other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, shall sell or export a Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit, issued in accordance with the prescribed conditions has, subject to paragraph (b), been obtained from the Director-General for such purpose.

(b) The Director-General may revoke any permit referred to in paragraph (a) if the conditions on which such permit was issued, are not complied with or if it is not in the public interest that the particular action be continued.

(8) Subject to subsection (9), a Schedule 8 substance shall not be acquired by any person other than the Director-General for the purpose of providing a medical practitioner therewith, on the prescribed conditions. for the treatment of a particular patient of that medical practitioner upon such conditions as the Director-General, on the recommendation of the council, may determine.

[S 22A(8) substituted by s 5(b) of Act 59 of 2002.]

(9)

(a) No person shall—

(i) acquire, use, possess, manufacture or supply any Schedule 7 or Schedule 8 substance, or manufacture any specified Schedule 5 or Schedule 6 substance unless he or she has been issued with a permit by the Director-General for such acquisition, use, possession, manufacture or supply: Provided that the

Director-General may subject to such conditions as he or she may determine, acquire or authorise the use of any Schedule 7 or Schedule 8 substance in order to provide a medical practitioner, analyst, researcher or veterinarian therewith on the prescribe conditions for the treatment or prevention of a medical condition in a particular patient, or for the purposes of education, analysis or research;

[S 22A(9)(a)(i) substituted by s 5(c) of Act 59 of 2002.]

(ii) manufacture, use or supply any Schedule 5 or Schedule 6 substance for other than medicinal purposes, unless he or she has been issued by the Director-General with a permit for such manufacture, use or supply upon the prescribed conditions.

(b) Notwithstanding paragraph (a), the Director-General may at any time revoke any permit issued in terms of that paragraph if any condition on which the permit was issued is not being complied with.

(c) A permit issued in terms of this subsection shall be valid for a period of 12 calendar months after the date of issue thereof.

(10) Notwithstanding anything to the contrary contained in this section, no person shall sell or administer any Scheduled substance or medicine for other than medicinal purposes: Provided that the Minister may, subject to the conditions or requirements stated in such authority, authorise the administration outside any hospital of any Scheduled substance or medicine for the satisfaction or relief of a habit or craving to the person referred to in such authority.

(11)

(a) No person shall import or export any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance or other substance or medicine prescribed for that purpose unless a permit has been issued to him or her by the Director-General in the prescribed manner and subject to such conditions as may be determine by the Director-General;

[S 22A(11)(a) substituted by s 5(d) of Act 59 of 2002.]

(b) A pen-nit referred to in paragraph (a) may be issued for any purpose other than the satisfaction or relief of a habit or craving in respect of such substance or medicine.

(c) The issue of a permit referred to in paragraph (a) may be refused if—

(i) the Director-General is not convinced that the applicant is capable of keeping or storing the substance or medicine in a satisfactory manner in order to prevent the loss thereof;

(ii) the use of such substance or medicine has not been authorised in terms of this Act;

(iii) the Director-General is of the opinion that the annual importation quota for such substance has been exceeded or will be exceeded;

(iv) the Director-General is of the opinion that such substance or medicine, of an acceptable quality, is already available in the Republic; or

(v) the applicant did not comply with the conditions under which a previous permit was issued to him or her.

(d) If an application is refused, the applicant shall be furnished with the reasons for such refusal.

(e) A permit issued in terms of this subsection shall be valid for a period of six months from the date of issue thereof.

(12)

(a) The control on the importation of Scheduled substances shall relate to—

(i) any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance;
[S 22A(12)(a)(i) substituted by s 5(e) of Act 59 of 2002.]

(ii) such substances irrespective of the scheduling status allocated thereto, as the Minister may prescribe;

(iii) any other substance which becomes subject to international control in terms of the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances entered into by the Republic.

(b) The obtaining of import or export permits as required ill terms of subsection (11) shall not apply to any preparation which contains a substance as prescribed which is specifically exempted from all control measures for the obtaining of such import or export permits by the 1961 Single Convention on Narcotic Drugs referred to in paragraph (a).
[S 22A(12)(b) substituted by s 5(f) of Act 59 of 2002.]

(c) Notwithstanding paragraph (b), no such importation or exportation shall take place unless authorised by the Director-General.
[S 22A(12)(c) substituted by s 5(g) of Act 59 of 2002.]

(13) Any permit issued under subsection (11) shall be subject—

(a) to the applicant's furnishing the Chief Executive Officer annually with the prescribed information;

[S 22A(13)(a) substituted by s 22(d) of Act 72 of 2008.]

(b) to the requirement that there shall be no deviation from the particulars reflected on the permit: Provided that if the quantity of such substance or medicine to be imported is less than that provided for in the permit, the Director-General shall be informed in writing thereof within 10 days after the importation of such substance or medicine; and

(c) to the conditions, as detailed on the permit, having been complied with, the triplicate copy of the pen-nit having been certified by a customs officer or an employee of the S.A. Post Office Limited.

(14) Notwithstanding anything to the contrary contained in this section—

(a) a pharmacist's assistant shall not handle any specified Schedule 5 or Schedule 6 substance except as contemplated in subsection (5)(a) and (b); and

[S 22A(14)(a) substituted by s 5(h) of Act 59 of 2002.]

(b) no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional council concerned.

(15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the South African Pharmacy Council as referred to in section 2 of the Pharmacy Act, 1974 (Act 53 of 1974), issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine.

[S 22A(15) substituted by s 22(e) of Act 72 of 2008.]

(16) Notwithstanding anything to the contrary contained in this section—

(a) any person may possess a Schedule 0, Schedule 1 or Schedule 2 substance for medicinal purposes;

(b) any person may possess a Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance if he or she is in possession of a prescription issued by an authorised prescribed;

[S 22A(16)(b) substituted by s 5(i) of Act 59 of 2002.]

(c) any medicine or scheduled substance may be possessed by a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, or under the Veterinary and Para-Veterinary Professions Act, 1982, for the purposes of administering it in accordance with his or her scope of practice;

(d) any medicine or scheduled substance may be possessed for sale by a pharmacist, a person licenced to own a pharmacy in terms of the Pharmacy Act, 1974, or a person who is the holder of a licence as contemplated in section 22C.

(17) For the purposes of this section—

(a) **"authorised prescriber"** means a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974; and

(b) **"medicinal purpose"** means for the purposes of the treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or craving for the substance used or for any other such substance, except where the substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a provincial government or approved for such purpose by the Minister.

[S 22A inserted by s 21 of Act 65 of 1974; amended by s 9 of Act 17 of 1979, s 7 of Act 71 of 1991; substituted by s 13 of Act 90 of 1997.]

22B. Publication of information relating to medicines, Scheduled substances, medical devices or IVDs

[S 22B heading substituted by s 15(a) of Act 14 of 2015.]

(1) Notwithstanding the provisions of section 34 the Authority may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, Scheduled substance, medical device or IVD.

[S 22B(1) substituted by s 15(b) of Act 14 of 2015.]

(2) The Director-General may publish the information referred to in section (1) or release it to the public in a manner which he or she thinks fit.

[S 22B inserted by s 10 of Act 94 of 1991; substituted by s 23 of Act 72 of 2008.]

22C. Licensing

(1) Subject to the provisions of this section—

(a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, veterinarian, nurse or other person registered under the Health Professions Act, 1974(Act 56 of 1974), a licence to compound and dispense medicines, on the prescribed conditions;

[S 22C(1)(a) substituted by s 16(a) of Act 14 of 2015.]

(b) the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a medical device or IVD establishment, manufacturer, wholesaler or distributor of a medicine, Scheduled substance, medical device or IVD a licence to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such medicine, Scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

[S 22C(1) amended by s 6(a) of Act 59 of 2002; substituted by s 24(a) of Act 72 of 2008, s 22C(1)(b) substituted by s 16(a) of Act 14 of 2015.]

(2) A licence referred to in subsection (1)(a) shall not be issued unless the applicant has successfully completed a supplementary course determined by the South African Pharmacy Council after consultation with the Health Professions Council of South Africa and the South African Nursing Council.

[S 22C(2) substituted by s 6(b) of Act 59 of 2002, s 24(b) of Act 72 of 2008.]

(3) The Director-General or the Authority, as the case may be, may require an applicant contemplated in subsection (1) to furnish such information, in addition to any information furnished by the applicant in terms of the said subsection, as the Director-General or the Authority may deem necessary.

[S 22C(3) substituted by s 24(c) of Act 72 of 2008.]

(4) When the Director-General or the Authority, as the case may be, grants or refuses an application for a licence—

[S 22C(4), words preceding (a), substituted by s 24(d) of Act 72 of 2008.]

(a) written notice shall be given of that fact to the applicant; and

(b) in the event of the refusal of an application, the applicant shall be furnished with the reasons for such refusal.

(5) No person shall compound or dispense a medicine unless he or she is authorised thereto in terms of the Pharmacy Act, 1974, is a veterinarian or is the holder of a licence as contemplated in subsection (1)(a).

[S 22C(5) substituted by s 6(c) of Act 59 of 2002.]

(6) No medical device or IVD establishment, manufacturer, wholesaler or distributor referred to in subsection (1)(b) shall manufacture, act as a wholesaler of or distribute, as the case may be, any medicine, Scheduled substance, medical device or IVD unless he or she is the holder of a licence contemplated in the said subsection.

[S 22C(6) substituted by s 6(d) of Act 59 of 2002, s 24(e) of Act 72 of 2008, s 16(b) of Act 14 of 2015.]

(7) Subsections (5) and (6) shall come into operation twelve months from the date of commencement of this section.

[S 22C(7) substituted by s 6(e) of Act 59 of 2002.]

[S 22C inserted by s 14 of Act 90 of 1997.]

22D. Period of validity and renewal of licence

A licence issued under section 22C shall be valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Director-General or the Authority, as the case may be, may allow and on payment of the prescribed fee.

[S 22D inserted by s 14 of Act 90 of 1997; substituted by s 25 of Act 72 of 2008.]

22E. Suspension and cancellation of licence

(1) If the holder of a licence under section 22C—

(a) has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the Authority, as the case may be, with any information which to the knowledge of such holder is untrue or misleading in any material respect;

[S 22E(1)(a) substituted by s 26(a) of Act 72 of 2008.]

(b) has contravened or failed to comply with a condition upon which the licence was issued;

(c) has contravened or failed to comply with a provision of this Act;

(d) has, in the case of a licence issued in terms of section 22C(1)(a), at any time been convicted of an offence which is of such a nature that, in the opinion of the Director-General, it renders him or her unsuitable to compound or dispense medicines,

the Director-General or the Authority, as the case may be, may by way of a notice in writing call upon him or her to show cause within the period specified in the notice, which period shall not be less than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked.

[S 22E(1), words following (d), substituted by s 26(b) of Act 72 of 2008.]

(2) The Director-General or the Authority, as the case may be, may after considering the reasons furnished in terms of subsection (1)—

(a) suspend the licence in question for such period the Director-General or the Authority may determine; or

(b) revoke the licence in question.

[S 22E(2) substituted by s 26(c) of Act 72 of 2008.]

(3) No person shall be entitled to the repayment of any prescribed fee in respect of any application for the granting or renewal of a licence if such application has been refused or if the licence has been suspended or revoked.

[S 22E inserted by s 14 of Act 90 of 1997.]

22F. Generic substitution

(1) Subject to subsections (2), (3) and (4), a pharmacist or a person licensed in terms of section 22C(1)(a) shall—

[S 22F(1), words preceding (a), substituted by s 7(a) of Act 59 of 2002.]

(a) inform all members of the public who visit the pharmacy or any other place where dispensing takes place, as the case may be, with a prescription for dispensing, of the benefits of the substitution for a branded medicine by an interchangeable multi-source medicine, and shall, in the case of a substitution, take reasonable steps to inform the person who prescribed the medicine of such substitution;

[S 22F(1)(a) substituted by s 7(b) of Act 59 of 2002.]

(b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.

(2) If a pharmacist is forbidden as contemplated in subsection (1)(b), that fact shall be noted by the pharmacist on the prescription.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A pharmacist shall not sell an interchangeable multi-source medicine—

(a) if the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed;

(b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or

(c) where the product has been declared not substitutable by the Authority.

[S 22F(4)(c) substituted by s 27 of Act 72 of 2008.]

[S 22F inserted by s 14 of Act 90 of 1997.]

22G. Pricing committee

(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.

[S 22G(1) substituted by s 8(a) of Act 59 of 2002.]

Uncommenced amendment

(1) The Minister shall after consultation with the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2023, appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.

[S 22G(1) substituted by s 58 of Act 20 of 2023 with effect from date to be proclaimed.]

(2) The Minister may, on the recommendation of the pricing committee, make regulations—

(a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;

(b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a).

(c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule O medicines.

[S 22G(2)(c) inserted by s 8(b) of Act 59 of 2002.]

(3)

(a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.

(b) No pharmacist or person licensed in terms of section 22C(1)(a) or wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).

[S 22G(3)(b) substituted by s 8(c) of Act 59 of 2002.]

(c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2)(b).

(4) To the members of the pricing committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

[S 22G inserted by s 14 of Act 90 of 1997.]

22H. Purchase and sale of medicines, medical devices, IVDs and Scheduled substances by wholesalers

[S 22H heading substituted by s 17(a) of Act 14 of 2015.]

(1)

(a) No wholesaler shall purchase medicines, Scheduled substances, medical devices or IVDs from any source other than from the original manufacturer or from the primary importer of the finished product.

(b) A wholesaler shall—

(i) sell medicines, medical devices or IVDs only into the retail sector; and

(ii) sell Scheduled substances to any person who may lawfully possess such substance.

[S 22H(1) substituted by s 28 of Act 72 of 2008, s 17(b) of Act 14 of 2015.]

(2) Subsection (1) shall not be construed as preventing the return of medicines, medical devices or IVDs for credit purposes only, to the manufacturer or wholesaler from which those medicines, medical devices or IVDs were initially obtained.

[S 22H(2) substituted by s 28 of Act 72 of 2008, s 17(b) of Act 14 of 2015.]

(3) Any wholesaler may in the prescribed manner and on the prescribed conditions be exempted by the Director-General from the provisions of subsection (1).

[S 22H inserted by s 14 of Act 90 of 1997.]

23. Disposal of undesirable medicines, medical devices or IVDs

(1) If the Authority is of the opinion that it is not in the public interest that any medicine, medical device or IVD shall be made available to the public, it may—

(a) by notice in writing transmitted by registered post to any person direct that person; or

(b) by notice in the *Gazette* direct any person,

to return any quantity of such medicine, medical device or IVD which he or she has in his or her possession to the manufacturer thereof or (in the case of any imported medicine, medical device or IVD) to the importer concerned or to deliver or send it to any other person designated by the Authority.

(2) The Authority may by notice in writing direct any medical device or IVD establishment, manufacturer or importer of any such medicine, medical device or IVD who has in his or her possession any quantity thereof (including any quantity returned, delivered or sent to him or her in pursuance of a direction under subsection (1)), or any other person to whom any quantity of such medicine, medical device or IVD has been so returned, delivered or sent, to deal with or dispose of that quantity in such manner as the Authority may determine.

(3) No person shall sell any medicine, medical device or IVD which is the subject of a notice under subsection (1) which has not been set aside on appeal.

[S 23 amended by s 22 of Act 65 of 1974; substituted by s 29 of Act 72 of 2008.]

24. Appeal against decision of the or Director-General

(1) Any person aggrieved by the decision of the Director-General may within the prescribed period and in the prescribed manner make written representations with regard to such decision to the Minister.

(2) The Minister shall, after considering representations made in terms of subsection (1), confirm, set aside or vary the decision of the Director-General.

[S 24 amended by s 23 of Act 65 of 1974; substituted by s 11 of Act 94 of 1991, s 15 of Act 90 of 1997; amended by s 9 of Act 59 of 2002; substituted by s 30 of Act 72 of 2008.]

24A. Appeal against decision of Authority

(1) Any person aggrieved by the decision of the Authority may appeal against such decision by notifying the Chief Executive Officer within 30 days of becoming aware of such decision of his or her intention to appeal and setting out the full grounds of appeal.

(2) Upon being notified the Chief Executive Officer shall meet with the appellant within 30 days of being so notified in the absence of legal representatives to try to resolve the matter, especially if the appeal involves administrative matters.

(3) Should the Chief Executive Officer and the appellant fail to resolve the matter as contemplated in subsection (2), the appellant shall within 30 days of being notified by the Chief Executive Officer of the failure to resolve the matter and upon payment of a prescribed fee, request the Minister in writing to convene an appeal committee.

(4) The appeal committee contemplated in subsection (3) shall—

(a) comprise the chairperson who shall have knowledge of the law and four other persons who shall have knowledge of the subject matter of appeal but with no financial or business interests in the affairs of the parties to the appeal, two of them nominated by the appellant and the other two by the Chief Executive Officer; and

(b) conduct the appeal hearing and make a decision within 30 days from the day when it first meets to hear the appeal.

(5) A party aggrieved by the decision of the appeal committee may approach the High Court for a judicial review.

[S 24A inserted by s 31 of Act 72 of 2008.]

25. Privileges of Authority and committees

The Authority, persons contracted by the Authority to perform work Act for the Authority, committees appointed in terms of this Act or their members are not liable in respect of anything done in good faith under this Act.

[S 25 substituted by s 32 of Act 88 of 1996, s 10 of Act 59 of 2002, s 32 of Act 72 of 2008.]

26. Inspectors

(1) The Chief Executive Officer may authorise such persons as inspectors as he or she may consider necessary for the proper enforcement of this Act.

(2) Every inspector shall be furnished with a certificate signed by the Chief Executive Officer and stating that he or she has been authorised as an inspector under this Act.

(3) An inspector shall, before he or she exercises or performs any power or function under this Act, produce and exhibit to any person affected by such exercise or performance, the certificate referred to in subsection (2).

[S 26 substituted by s 24 of Act 65 of 1974; amended by s 1 of Act 19 of 1976, s 10 of Act 17 of 1979; substituted by s 33 of Act 72 of 2008.]

27. Analysts, pharmacologists, engineers, technicians and pathologists

Chief Executive Officer may grant such authority to such analysts, pharmacologists, engineers, technicians and pathologists or any other appropriately qualified person as he or she may consider necessary for the proper enforcement of this Act.

[S 27 substituted by s 25 of Act 65 of 1974, s 11 of Act 17 of 1979, s 34 of Act 72 of 2008.]

28. Powers of inspectors

(1) An inspector may, at all reasonable times—

(a) enter upon—

(i) any place or premises from which a person, authorised under this Act to compound or dispense medicines or Scheduled substances, dispenses or handles medicines, Scheduled substances, medical devices or IVDs or from which the holder of a licence as contemplated in section 22C(1)(b) conducts a business; or

[S 28(1)(a)(i) substituted by s 35(a) of Act 72 of 2008, s 18(a) of Act 14 of 2015.]

(ii) any place, premises, vessel or aircraft if he or she suspects on reasonable grounds that an offence in terms of this Act has been or is being committed thereon or therein or that an attempt has been made or is being made to commit such an offence thereon or therein; or

(iii) any private dwelling, with the consent of the occupier or under the authority of a warrant issued in terms of subsection (5) or without a warrant in terms of subsection (6);

(b) inspect any medicine, Scheduled substance, medical device or IVD, or any book, record or document found in or upon the premises, place, vehicle, vessel or aircraft contemplated in subparagraph (ii) of subsection (1)(a);

[S 28(1)(b) substituted by s 35(b) of Act 72 of 2008, s 18(b) of Act 14 of 2015.]

(c) seize any such medicine, Scheduled substance, medical device or IVD, any books, records or documents found in or upon such premises, place, vehicle, vessel or aircraft and appearing to afford evidence of a contravention of any provision of this Act.

[S 28(1)(c) substituted by s 35(b) of Act 72 of 2008, s 18(b) of Act 14 of 2015.]

(d) take so many samples of any such medicine or Scheduled substance, medical device or IVD as he or she may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act.

[S 28(1)(d) inserted by s 35(c) of Act 72 of 2008; substituted by s 18(b) of Act 14 of 2015.]

[S 28(1) amended by s 26(a) of Act 65 of 1974, s 16 of Act 90 of 1997; substituted by s 11(a) of Act 59 of 2002.]

(2)

(a) Any sample taken in terms of paragraph (d) of subsection (1) shall—

(i) be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such medicine, Scheduled substance, medical device or IVD, or if there is no such person or if he or she is absent for any reason, in the presence of any other witness;

[S 28(2)(a)(i) substituted by s 18(c) of Act 14 of 2015.]

(ii) forthwith be packed and sealed and suitably labelled or marked in such manner as its nature may permit; and

(iii) then be transmitted to an analyst, pharmacologist, technician, engineer, scientist, pathologist or expert designated by the Authority together with a certificate in the prescribed form signed by such inspector.

[S 28(2)(a)(iii) substituted by s 18(d) of Act 14 of 2015.]

(b) A copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such medicine, Scheduled substance, medical device or IVD or his or her agent.

[S 28(2)(b) substituted by s 18(e) of Act 14 of 2015.]

[S 28(2) amended by s 26(a) of Act 65 of 1974; substituted by s 12(a) of Act 17 of 1979, s 35(d) of Act 72 of 2008.]

(3) The analyst, pharmacologist, engineer, scientist, pathologist or expert designated by the Authority to whom a sample has been transmitted in terms of the provisions of subsection (2) shall with all convenient speed test, examine or analyse the sample delivered to him or her, and the result of the test, examination or analysis shall be stated in a certificate in the prescribed form.

[S 28(3) substituted by s 12(b) of Act 17 of 1979, s 18(f) of Act 14 of 2015.]

(4) The owner of the medicine, Scheduled substance, medical device or IVD from which the sample was taken may claim from the Authority an amount equal to the market value thereof.

[S 28(4) substituted by s 26(b) of Act 65 of 1974, s 35(e) of Act 72 of 2008, s 18(f) of Act 14 of 2015.]

(5) Where on application to a magistrate in appears to such magistrate from information on oath that there are reasonable grounds to believe that—

(a) the conditions for entry described in subsection (1)(a) exist in relation to a private dwelling;

(b) entry to that private dwelling is necessary for any purpose relating to the administration or enforcement of this Act; and

(c) entry to the private dwelling has been refused or that entry thereto will be refused,

a magistrate may issue a warrant authorising the inspector named therein to enter that private dwelling subject to such conditions as may be specified in the warrant.

[S 28(5) inserted by s 11(b) of Act 59 of 2002.]

(6) If an inspector believes on reasonable grounds that—

(a) a warrant would be issued to him or her under subsection (5) if he or she applies for such a warrant; and

(b) a delay in obtaining such warrant would defeat the object of the entry, search and seizure,

he or she may without a warrant enter and search any premises for any medicines, scheduled substance, book, record or document relevant to the administration or enforcement of this Act and seize or take samples as contemplated in subsection (1)(c).

[S 28(6) added by section 11(b) of Act 59 of 2002.]

29. Offences

Any person who—

(a) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties under this Act; or

[S 29(a) substituted by s 17(a) of Act 90 of 1997.]

(b) contravenes or fails to comply with the provisions of section 14(1), 18, 18A or 18B; or

[S 29(b) substituted by s 17(a) of Act 90 of 1997.]

(c) contravenes the provisions of section 19(1) or fails to comply with a notice issued under section 19(2); or

[S 29(c) substituted by s 17(a) of Act 90 of 1997.]

(d) contravenes the provisions of section 20(1); or

[S 29(d) substituted by s 17(a) of Act 90 of 1997.]

(e) contravenes or fails to comply with any condition imposed under section 15(6); or

[S 29(e) substituted by s 17(a) of Act 90 of 1997, s 36(a) of Act 72 of 2008.]

(f) fails to comply with any direction given under section 23 or contravenes the provisions of section 23(3); or

[S 29(f) substituted by s 17(a) of Act 90 of 1997.]

(g) with fraudulent intent tampers with any sample taken in terms of this Act; or

(h) makes any false or misleading statement in connection with any medicine, Scheduled substance, medical device or IVD—

[S 29(h), words preceding (i), substituted by s 36(b) of Act 72 of 2008, s 19(a) of Act 14 of 2015.]

(i) in an application for the registration thereof; or

(ii) in the course of the sale thereof; or

[S 29(h) substituted by s 27(a) of Act 65 of 1974.]

(i) sells any medicine, Scheduled substance, medical device or IVD upon the container of which a false or misleading statement in connection with the contents is written; or

[S 29(i) substituted by s 27(b) of Act 65 of 1974, s 36(c) of Act 72 of 2008, s 19(b) of Act 14 of 2015.]

(j) for purposes of business or trade makes use of any report or certificate made or issued by an inspector, analyst, pharmacologist or pathologist under this Act, or

[S 29(j) amended by s 27(c) of Act 65 of 1974.]

(k) contravenes any provision of section 22A, 22C(5) and (6), 22F, 22G or 22H or contravenes or fails to comply with any condition imposed thereunder;

[S 29(k) inserted by s 27(d) of Act 65 of 1974; substituted by s 17(b) of Act 90 of 1997.]

(l) contravenes or fails to comply with the provisions of section 34;

[S 29(l) inserted by s 12 of Act 94 of 1991.]

(m) manufactures, sells or uses a veterinary medicine in contravention of a prohibition referred to in section 36A, or contravenes, or fails to comply with, a condition impose in terms of the said section,

[S 29(m) inserted by s 12 of Act 94 of 1991.]

shall be guilty of an offence.

30. Penalties

(1) Any person who is convicted of an offence referred to in section 29 shall be liable to a fine, or to imprisonment for a period not exceeding 10 years.

[S 30(1) substituted by s 13 of Act 94 of 1991, s 18(a) of Act 90 of 1997.]

(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any medicine, Scheduled substance, medical device or IVD in respect of which the offence has been committed to be forfeited to the State.

[S 30(2) amended by s 28(a) of Act 65 of 1974; substituted by s 37(a) of Act 72 of 2008, s 20(a) of Act 14 of 2015.]

(3) Any medicine, Scheduled substance, medical device or IVD forfeited under this Act shall be destroyed or otherwise dealt with as the Chief Executive Officer may direct.

[S 30(3) substituted by s 28(b) of Act 65 of 1974, s 37(b) of Act 72 of 2008, s 20(b) of Act 14 of 2015.]

(4) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty provided for in this section.

[S 30(4) inserted by s 18(b) of Act 90 of 1997.]

31. Procedure and evidence

(1) In any criminal proceedings under this Act—

(a) any quantity of a medicine, Scheduled substance, medical device or IVD in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample;

[S 31(1)(a) amended by s 29 of Act 65 of 1974; substituted by s 38(a) of Act 72 of 2008, s 21(a) of Act 14 of 2015.]

(b) …

[S 31(1)(b) repealed by s 19(a) of Act 90 of 1997.]

(c) a certificate stating the result of a test, examination or analysis carried out in terms of the provisions of section 28 and purporting to be signed by the analyst, pharmacologist or pathologist who carried out such test, examination or analysis, shall be accepted as *prima facie* proof of the facts stated therein;

(d) any statement or entry contained in any book, record or document kept by any owner of a medicine, Scheduled substance, medical device or IVD or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him or her as an admission of the facts set forth in that statement or entry, unless evidence to the contrary which raises a reasonable doubt shows that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner in the course of his or her work as manager, or in the course of his or her agency or employment.

[S 31(1)(d) amended by s 29 of Act 65 of 1974; substituted by s 38(b) of Act 72 of 2008, s 21(b) of Act 14 of 2015.]

(2) …

[S 31(2) substituted by s 13 of Act 17 of 1979; repealed by s 19(b) of Act 90 of 1997.]

(3) The court in which any such certificate is adduced in evidence may in its discretion cause the person who signed such certificate to be summoned to give oral evidence in the proceedings in question or may cause written interrogatories to be submitted to him for reply, and such interrogatories and any reply thereto, purporting to be a reply from such person, shall be admissible in evidence in such proceedings.

32. …

[S 32 amended by s 30 of Act 65 of 1974; repealed by s 20 of Act 90 of 1997.]

33. Act or omission by manager, agent or employee

(1) Whenever any manager, agent or employee of any person (hereinafter called the employer) does or omits to do any act which it would be an offence under this Act for the employer to do or omit to do, then unless it is proved that—

(a) in doing or omitting to do that act the manager, agent or employee was acting without the connivance or the permission of the employer; and

(b) all reasonable steps were taken by the employer to prevent any act or omission of the kind in question; and

(c) it was not under any condition or in any circumstances within the scope of the authority or in the course of the employment of the manager, agent or employee to do or to omit to do acts, whether lawful or unlawful, of the character of the act or omission charged,

the employer shall be presumed himself to have done or omitted to do that act and shall be liable to be convicted and sentenced in respect thereof; and the fact that he issued instructions forbidding any act or omission of the kind in question shall not, of itself, be accepted as sufficient proof that he took all reasonable steps to prevent the act or omission.

(2) Whenever any manager, agent or employee of any such employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, he shall be liable to be convicted and sentenced in respect thereof as if he were the employer.

(3) Any such manager, agent or employee may be so convicted and sentenced in addition to the employer.

33A. Funds of Authority

(1) The funds of the Authority shall consist of—

(a) State funds received through the Department of Health;

(b) fees raised and interest on overdue fees;

(c) money accruing to the Authority from any other source.

(2)

(a) The Authority may accept money or other goods donated or bequeathed to the Authority, provided no condition is attached to such donation or bequest;

(b) Details of any such donation or bequest shall be specified in the relevant annual report of the Authority.

(3) The Authority shall utilise its funds for the defrayal of expenses incurred by the Authority in the performance of its functions under this Act.

(4) The Authority shall open an account with a bank as defined in section 1(1) of the Banks Act, 1990 (Act 94 of 1990), and shall deposit in that account all money referred to in subsections (1) and (2).

(5) The Authority shall keep full and proper records of all money received or expended, of its assets and liabilities and of its financial transactions.

(6) The records and annual financial statements referred to in subsection (5), shall be audited by the Auditor-General.

(7) The Authority may invest money which is deposited in terms of subsection (4) and which is not required for immediate use in any manner as it may deem fit.

(8) Any money which at the close of the Authority's financial year stands to the credit of the Authority in the account referred to in subsection (4) and money which has been invested in terms of subsection (7), shall be carried forward to the next financial year as a credit in the account of the Authority.

[S 33A inserted by s 21 of Act 90 of 1997; substituted by s 39 of Act 72 of 2008.]

34. Preservation of secrecy

No person shall, except for the purpose of the exercise of his powers or the performance of his functions under this Act, or for the purpose of legal proceedings under this Act, or when required to do so by any competent court or under any law, or with the written authority of the Director-General, disclose to any other person any information acquired by him in the exercise of his powers or the performance of his functions under this Act and relating to the business or affairs of any person, or use such information for self-gain of for the benefit of his employer.

[S 34 substituted by s 14 of Act 94 of 1991.]

34A. Delegation of powers

(1) The Minister may in writing authorise the Director-General or any officer of the Department of Health to exercise any of the powers conferred upon the Minister by this Act other than the powers referred to in section 3, 24(1) and 35, or to exercise or perform any of the duties or functions conferred or imposed on the Minister in terms of this Act.

[S 34A(1) substituted by s 22(a) of Act 90 of 1997.]

(2) The Director-General may in writing authorise any officer of the Department of Health to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function, excluding any power, duty or function referred to in subsection (1), conferred or imposed on the Director-General by or in terms of this Act.

[S 34A(2) amended by s 22(b) of Act 90 of 1997.]

(3) The Chief Executive Officer may, in writing, authorise any staff member of the Authority to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function conferred or imposed on the Chief Executive Officer in terms of this Act.

[S 34A(3) inserted by s 40 of Act 72 of 2008.]

[S 34A inserted by s 2 of Act 19 of 1976; substituted by s 15 of Act 94 of 1991.]

35. Regulations

(1) The Minister may, in consultation with the Authority, make regulations—

[S 35(1), words preceding (i), substituted by s 41(a) of Act 72 of 2008.]

(i) prescribing the categories of persons by whom application may be made for the registration of any medicine, medical device or IVD or to whom a certificate of registration may be transferred;

[S 35(1)(i) substituted by s 22(a) of Act 14 of 2015.]

(ii) prescribing the forms which shall be used for any application for the registration of any medicine, medical device or IVD and the particulars which shall be furnished with any such application (including particulars regarding the method by which the medicine, medical device or IVD in question or any component of such medicine, medical device or IVD is manufactured and the premises at which such medicine, medical device or IVD or any such component is manufactured);

[S 35(1)(ii) substituted by s 22(a) of Act 14 of 2015.]

(iii) providing for the classification of medicines, medical device or IVDs into classes or categories for the purposes of this Act;

[S 35(1)(iii) substituted by s 22(a) of Act 14 of 2015.]

(iv) prescribing the samples of any medicine, medical device or IVD and the quantity thereof which shall accompany any application for the registration of a medicine, medical device or IVD;

[S 35(1)(iv) substituted by s 22(a) of Act 14 of 2015.]

(v) prescribing the form in which the medicines, medical devices or IVDs register shall be kept and the particulars which shall be entered therein in respect of any registered medicine, medical device or IVD, as the case may be;

[S 35(1)(v) substituted by s 22(a) of Act 14 of 2015.]

(vi) prescribing the form of any certificate of registration of any medicine, medical device, or IVD;

[S 35(1)(vi) substituted by s 22(a) of Act 14 of 2015.]

(vii) prescribing the circumstances in which, the conditions on which and the persons or categories of persons to whom any medicine, Scheduled substance, medical device or IVD may be sold;

[S 35(1)(vii) substituted by s 22(a) of Act 14 of 2015.]

(viii) prescribing the manner in which any package containing any medicine, Scheduled substance, medical device or IVD shall be labelled, packed or sealed;

[S 35(1)(viii) substituted by s 22(a) of Act 14 of 2015.]

(ix) prescribing the particulars in regard to the use thereof which shall be furnished with any medicine, Scheduled substance, medical device or IVD sold, and the manner in which such particulars shall be furnished;

[S 35(1)(ix) substituted by s 22(a) of Act 14 of 2015.]

(x) prescribing the particulars which shall appear in any advertisement relating to any medicine, Scheduled substance, medical device or IVD, or prohibiting the inclusion of any specified particulars in such advertisement, or the distribution of any such advertisement to a specified person or a specified category of persons or to a specified organisation or a specified category of organisations;

[S 35(1)(x) substituted by s 22(a) of Act 14 of 2015.]

(xi) prescribing the requirements with which any medicine, or any component thereof, medical device or IVD shall comply in regard to composition, therapeutic suitability and effect, purity or any other property;

[S 35(1)(xi) substituted by s 22(a) of Act 14 of 2015.]

(xii) prescribing the particulars which shall be published in the *Gazette* in respect of any application for registration referred to in section 15(10);

[S 35(1)(xii) substituted by s 41(b) of Act 72 of 2008.]

(xiii) relating to the responsibilities of both medical device and IVD establishments and users of medical devices and IVDs, in relation to the use, training, maintenance, calibration, post-marketing surveillance, sterilisation, disinfection, recall, decomposition, decommissioning or decontamination of medical devices and IVDs;

[S 35(1)(xiii) substituted by s 41(c) of Act 72 of 2008.]

(xiv) prescribing the particulars which shall appear on a prescription or an order for a medicine or a Scheduled substance, the number of issues of a medicine or a Scheduled substance that may be made on any such specified prescription or order, the manner in which any such prescription or order shall be issued and the period for which any such prescription or order shall be retained;

(xv) prescribing the forms of licences, registers, prescription books, records and other documents which shall be kept or used in respect of medicines, Scheduled substances, medical devices or IVDs, the manner in which they shall be kept, the particulars which shall be entered therein and the place where and the period for which they shall be retained;

[S 35(1)(xv) substituted by s 22(b) of Act 14 of 2015.]

(xvi) requiring the furnishing of returns, reports and information in respect of Scheduled substances and plants from which any such substance can be extracted, derived, produced or manufactured, and in respect of any medicine or other substance of which any such Scheduled substance is a component;

(xvii) as to the transhipment or the exportation from or importation into the Republic of any medicine, Scheduled substance, medical device or IVD, specifying the ports or places at which such medicine, Scheduled substance, medical device or IVD may be brought into the Republic;

[S 35(1)(xvii) substituted by s 22(c) of Act 14 of 2015.]

(xviii) authorising and regulating or restricting the transmission through the Republic of medicines, Scheduled substances, medical devices or IVDs;

[S 35(1)(xviii) substituted by s 22(c) of Act 14 of 2015.]

(xix) prescribing the manner in which packages containing medicines, Scheduled substances, medical devices or IVDs shall be labelled when imported into or manufactured in the Republic and the persons by whom and the manner in which they shall be kept;

[S 35(1)(xix) substituted by s 22(c) of Act 14 of 2015.]

(xx) authorising and regulating the purchase, acquisition, keeping or use of preparations of cocaine by managers or persons in charge of factories or workshops in connection with the treatment of eye injuries or for other essential purposes;

(xxi) authorising and regulating the purchase, acquisition, keeping or use of Scheduled substances by particular persons or categories of persons;

(xxii) authorising and regulating the possession by persons entering or departing from the Republic of specified quantities of medicines, Scheduled substances, medical devices or IVDs for personal medicinal use;

[S 35(1)(xxii) substituted by s 22(d) of Act 14 of 2015.]

(xxiii) as to the disposal or destruction of a medicine, Scheduled substance, medical device or IVD, and the records which shall be kept in respect thereof;

[S 35(1)(xxiii) substituted by s 22(d) of Act 14 of 2015.]

(xxiv) as to the importation, exportation, conveyance, keeping, storage, processing and packing of medicines, Scheduled substances, medical devices or IVDs, and the manner in which medicines, Scheduled substances, medical devices or IVDs shall be kept and controlled in different categories of hospitals;

[S 35(1)(xxiv) substituted by s 12(a) of Act 59 of 2002, s 22(d) of Act 14 of 2015.]

(xxv) prescribing the methods in accordance with which samples may be taken under this Act and the form of the certificates to be issued by inspectors in respect of such samples;

(xxvi) prescribing the methods to be employed and the form of the certificates to be issued in connection with the testing, examination or analysis of samples taken under this Act;

(xxvii) authorising, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device, IVD or class of medical devices, IVDs or medicines in respect of its safety, quality and efficacy;

[S 35(1)(xxvii) substituted by s 12(b) of Act 59 of 2002, s 22(e) of Act 14 of 2015.]

(xxviii) with regard to any matter to ensure the safety, quality and efficacy of medicines, medical devices or IVDs;

[S 35(1)(xxviii) substituted by s 22(e) of Act 14 of 2015.]

(xxix) as to the summary seizure and disposal of any medicine, Scheduled substance, medical device or IVD found in the possession or custody of any person not entitled under this Act to keep or use it;

[S 35(1)(xxix) substituted by s 22(e) of Act 14 of 2015.]

(xxx) as to the disposal or destruction of a medicine, Scheduled substance, medical device or IVD which has become unfit for use, and the report to be furnished in respect thereof;

[S 35(1)(xxx) substituted by s 22(e) of Act 14 of 2015.]

(xxxi) prescribing the fee to be paid to the Authority in respect of an application for the registration, and in respect of the registration of a medicine, medical device or IVD, the fee to be paid annually to the Authority in respect of the retention of the certification or the registration of a medicine, medical device or IVD and the date on which such annual fee shall be paid;

[S 35(1)(xxxi) substituted by s 41(d) of Act 72 of 2008, s 22(e) of Act 14 of 2015.]

(xxxii) prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, medical devices or IVDs, the issuing of permits and certificates under this Act, the issuing or renewal of any licence under this Act, the performance of inspections to assess the safety, quality and efficacy of medicines, Scheduled substances, medical devices or IVDs for the purpose of registration, the evaluation of technical amendments

and changes to the particulars contained in registers and the testing for batch release of biological medicines;

[S 35(1)(xxxii) substituted by s 22(e) of Act 14 of 2015.]

(xxxiii) relating to appeals against decisions of the Director-General or the Authority;

[S 35(1)(xxxiii) substituted by s 41(e) of Act 72 of 2008.]

(xxxiv) relating to the conditions under which medicines, Scheduled substances, medical devices or IVDs may be sold;

[S 35(1)(xxxiv) substituted by s 22(f) of Act 14 of 2015.]

(xxxv) relating to the repackaging of medicines in patient-ready packs;

(xxxvi) relating to the safety, quality and efficacy of any interchangeable multi-source medicine;

(xxxvii) relating to the scientific, pharmaceutical, clinical, technical and other skills required by members of staff of the Authority to evaluate the quality, efficacy and safety of medicines, medical devices and IVDs;

[S 35(1)(xxxvii) substituted by s 41(f) of Act 72 of 2008.]

(xxxviii) relating to the safety, quality and efficacy of imported medicines, Scheduled substances, medical devices and IVDs;

[S 35(1)(xxxviii) substituted by s 22(g) of Act 14 of 2015.]

(xxxix) relating to the control and conduct of clinical trials;

(xl) relating to medicines, Scheduled substances, medical devices or IVDs in respect of matters contemplated in paragraphs (i) up to and including paragraph (xi) and paragraphs (xxiii), (xxiv), (xxxii), (xxxiv) and (xxxviii);

[S 35(1)(xl) inserted by s 41(g) of Act 72 of 2008; substituted by s 22(h) of Act 14 of 2015.]

(xli) relating to the control of medicines, Scheduled substances, medical devices and IVDs in general;

[S 35(1)(xli) inserted by s 41(g) of Act 72 of 2008; substituted by s 22(h) of Act 14 of 2015.]

(xlii) relating to the licensing for possessing or using certain medicines, Scheduled substances, medical devices or IVDs;

[S 35(1)(xlii) inserted by s 41(g) of Act 72 of 2008; substituted by s 22(h) of Act 14 of 2015.]

(xliii) relating to time frames for the consideration of applications by the Authority;

[S 35(1)(xliii) inserted by s 41(g) of Act 72 of 2008.]

(xliv) with regard to any matter which in terms of this Act shall or may be prescribed; and

[S 35(1)(xl) renumbered as s 35(1)(xliv) by s 41(g) of Act 72 of 2008.]

(xlv) generally for the efficient carrying out of the objects and purposes of this Act, and the generality of this provision shall not be limited by the preceding paragraphs of this subsection.

[S 35(1)(xli) renumbered as s 35(1)(xlv) by s 41(g) of Act 72 of 2008.]

(2) The Minister shall, not less than three months before any regulation is made under subsection (1), cause the text of such regulation to be published in the Gazette, together with a notice declaring his or her intention to make that regulation and inviting interested persons to furnish him or her with any comments thereon or any representations they may wish to make in regard thereto.

(3) The provisions of subsection (2) shall not apply in respect of—

(a) any regulation which, after the provisions of that subsection have been complied with, has been amended by the Minister in consequence of comments or representations received by him or her in pursuance of the notice issued thereunder; or

(b) any regulation in respect of which the Minister is, after consultation with the Authority, of the opinion that the public interest requires it to be made without delay.

[S 35(3)(b) substituted by s 41(h) of Act 72 of 2008.]

(4) A regulation under subsection (1)(xxxi) and (xxxii) shall be made only in consultation with the Minister of Finance.

(5) Regulations made under subsection (1)(xi) may prescribe that any medicines, Scheduled substances, medical device or IVD or any component thereof shall comply with the requirements set out in any publication which in the opinion of the Authority is generally recognised as authoritative.

[S 35(5) substituted by s 41(i) of Act 72 of 2008, s 22(i) of Act 14 of 2015.]

(6) Regulations may be made under this section in respect of particular medicines, Scheduled substances, medical devices or IVDs or classes or categories of medicines, Scheduled substances or medical devices or IVDs or in respect of medicines, Scheduled substances,

medical devices or IVDs other than particular classes or categories thereof, and different regulations may be so made in respect of different medicines, Scheduled substances, medical devices or IVDs or different classes or categories thereof.

[S 35(6) substituted by s 41(j) of Act 72 of 2008, s 22(i) of Act 14 of 2015.]

(7)

(a) Regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith of a fine, or imprisonment for a period not exceeding 10 years.

(b) Notwithstanding anything to the contrary in any law contained a magistrate's court shall be competent to impose any penalty provided for in paragraph (a).

(8) Notwithstanding the provisions of subsection (1), the Minister may, if he or she deems it to be in the public interest, after consultation with the Authority, make regulations relating to any matter referred to in subsection (1) or amend or repeal any regulation made in terms of that subsection.

[S 35 amended by s 5 of Act 29 of 1968, s 1 of Act 88 of 1970, s 7 of Act 95 of 1971; substituted by s 31 of Act 65 of 1974; amended by s 3 of Act 19 of 1976, s 14 of Act 17 of 1979, s 7 of Act 20 of 1981, s 7 of Act 71 of 1991, s 16 of Act 94 of 1991; substituted by s 23 of Act 90 of 1997; s 35(8) substituted by s 41(k) of Act 72 of 2008.]

36. Exclusion of any medicine, Scheduled substance, medical device or IVD from operation of Act

(1) The Minister may, on the recommendation of the Authority, by notice in the *Gazette* exclude, subject to such conditions as he or she may determine, any medicine, Schedule substance, medical device or IVD from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice.

(2) Notwithstanding subsection (1), the exclusion of any medicine or Scheduled substance from the operation of sections 18A and 22G shall be effected by the Minister on the recommendation of the Pricing Committee.

[S 36 amended by s 32 of Act 65 of 1974; substituted by s 42 of Act 72 of 2008, s 23 of Act 14 of 2015.]

36A. Minister may prohibit the manufacture, sale or use of certain veterinary medicines

Notwithstanding anything to the contrary in this Act or in any other law contained, the Minister may by notice in the *Gazette* for any reason other than the safety, quality or therapeutic efficacy of a veterinary medicine—

(a) prohibit the manufacture, sale or use of any veterinary medicine containing a substance mentioned in the notice; or

(b) prohibit such manufacture, sale or use, except in accordance with such conditions as may be specified in the notice,

and may in like manner repeal or amend such notice.

[S 36A inserted by s 17 of Act 94 of 1991.]

37. …

[S 37 substituted by s 33 of Act 65 of 1974, s 18 of Act 94 of 1991; repealed by s 24 of Act 90 of 1997.]

37A. Amendment of Schedules

Notwithstanding the provisions of section 35(2), the Minister may, on the recommendation of the Authority, from time to time by notice in the *Gazette* amend any Schedule prescribed under section 22A(2) by the inclusion therein or the deletion therefrom of any medicine or other substance, or in any other manner.

[S 37A inserted by s 34 of Act 65 of 1974; substituted by s 25 of Act 90 of 1997, s 43 of Act 72 of 2008.]

38. Operation of Act in relation to other laws

The provisions of this Act shall be in addition to and not in substitution for any other law which is not in conflict with or inconsistent with this Act.

39. State bound

This Act binds the State.

[S 39 repealed by s 20 of Act 94 of 1991; inserted by s 26 of Act 90 of 1997 With effect from 1 July 2005.]

40. Short title

This Act shall be called the Medicines and Related Substances Act, 1965.

[S 40, formerly Medicines and Related Substances Control Act; prior to that Drugs Control Act, substituted by s 35 of Act 65 of 1974, s 28 of Act 90 of 1997.]

SCHEDULE 0

[Schedule 0 inserted by GNR 509 in G. 24727 of 10 April 2003; substituted by GN 935 in G. 31387 of 5 September 2008; amended by GNR 1230 in G. 32838 of 31 December 2009.]

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.

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

[Schedule 1 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, R 2082 of 5 November 1976; amended by GNR 278 of 25 February 1977, GNR 437 of 1 April 1977, GNR 1194 of 1 July 1977, GNR 1674 of 18 August 1978 (as amended GNR 2410 of 8 December 1978), GNR 1926 of 31 August 1979, GNR 2416 of 12 November 1982, GNR 1289 of 14 June 1985 (as amended GN 155 of 31 January 1986); substituted by GN 225 of 17 February 1989; amended by GNR 2841 of 7 December 1990, GNR 2169 of 6 September 1991, GNR 348 of 5 March 1993, GNR 775 of 7 May 1993; repeal, inserted, amended by s 21 of Act 94 of 1991, amended by GNR 1556 of 16 September 1994, GNR 673 of 12 May 1995, GNR 42 of 19 January 1996, GNR 1496 of 13 September 1996, GNR 1098 of 15 August 1997, GNR 1099 of 15 August 1997, GNR 1203 of 15 October 1999, GNR 1077 of 3 November 2000, repealed by s 27 of Act 90 of 1997, inserted by GNR 509 in G. 24727 of 10 April 2003; amended by GNR 491 in G. 31010 of 25 April 2008; substituted by GN 935 in G. 31387 of 5 September 2008, GNR 1230 in G. 32838 of 31 December 2009; amended by GNR 227 in G. 35149 of 15 March 2012, GNR 674 in G. 36827 of 13 September 2013, GNR 690 in G. 36850 of 20 September 2013, GNR 104 in G. 37318

of 11 February 2014, GNR 352 in G. 37622 of 8 May 2014, GNR 234 in G. 38586 of 20 March 2015, GN 254 in G. 39815 of 15 March 2016, GN 620 in G. 40041 of 3 June 2016, GN 748 in G. 41009 of 28 July 2017, GN 1261 in G. 41256 of 17 November 2017, GNR 1098 in G. 41971 of 12 October 2018, GNR 1262 in G. 42052 of 23 November 2018, GNR 755 in G. 42477 of 23 May 2019, GNR 219 & GNR 220 in G. 43051 of 28 February 2020, GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021, GN 2685 in G. 47373 of 28 October 2022, GNR 3261 in G. 48358 of 24 March 2023, GN 6466 in G. 53099 of 1 August 2025.]

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 Authority, 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)
   Annexure 1B: Emergency Care Provider (Emergency Care Practitioner)
   Annexure 1C: Basic Ambulance Assistant
   Annexure 1D: Ambulance Emergency Assistant
   Annexure 1E: Emergency Care Technician
   Annexure 1F: Emergency Care Assistant
   (ii) Annexure 2: Dental Therapist
   (iii) Annexure 3: Optometrist
   (iv) Annexure 4: Podiatrist
   (v) Annexure 5: Oral hygienists

Acetanilide and alkyl acetanilides.

Acetarsol, when intended for human vaginal use.

Acetylcysteine,

a. when used as a mucolytic in acute respiratory conditions for a maximum treatment period of 14 days;
b. except when intended for injection or for the management of paracetamol overdosage. (S3)

Acyclovir, when intended for application to the lips in the early treatment of recurrent herpes simplex virus infections (S4)

Ambroxol.

Amethocaine—see Tetracaine.

Amorolfine.

Anethole trithione.

Anticoagulants, when intended for application to the skin. (S4)

Antimony potassium tartrate and antimony sodium tartrate; in concentrations of 1 percent or more. (S0)

Any compound structurally derived from either beta-aminopropylbenzene or beta-aminoisopropylbenzene by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure) and presented as:

a. preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine-containing nose and eye preparations; and
b. appliances for inhalation in which the

Substance is adsorbed onto solid material but excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine. (S2, S6, S7)

Arsenic;

a. in oral dosage forms in concentrations equivalent to 0,01 percent or less of arsenic trioxide. (S2)
b. except when intended for injection. (S4)

Ascorbic Acid—see Vitamin C.

Azelaic acid.

Bacitracin, when intended for topical application to the epidermis, nares and external ear. (S4)

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

Belladonna alkaloids, when specifically intended for topical application. (S2)

Benzethonium chloride, when intended for human vaginal use.

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)

Benzydamine,

a. preparations and mixtures intended for use as a mouth rinse or for topical application in the mouth and throat; provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day. (S3)
b. preparations containing more than 3 percent of benzydamine, but not exceeding 5 percent, when intended for application to the skin; (S3)
c. except preparations and mixtures containing 3 percent or less of benzydamine, when intended for application to the skin (S0); or
d. except preparations and mixtures containing 3 milligrams or less of benzydamine per throat lozenge: Provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day and the pack size does not exceed 16 lozenges (S0)
e. except when indicated for human vaginal use. (S2)

Bifidobacterium adolescentis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Bifidobacterium animalis subsp. Animalis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Bifidobacterium animalis subsp. Lactis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Bifidobacterium bifidum,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Bifidobacterium breve,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Bifidobacterium lactis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Bifidobacterium longum subsp. Infantis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Bifidobacterium longum subsp. Longum,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Bifonazole, when intended for application to the skin. (S4)

Bioallethrin.

Bitolterol.

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

Boron, in oral preparations or mixtures containing more than 3 mg of Boron per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Bufexamac, when intended for application to the skin. (S3)

Bunamidine.

Butoconazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) or
b. when intended for application to the skin. (S4)

Calcium,

a. in oral preparations or mixtures containing more than 1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection; (S3)
c. except when indicated for the treatment of hyperphosphataemia; (S4)
d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Carbamoyl benzamide phenyl isoxazoline, except when intended and registered as a stock remedy in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Cetirizine

Chlorhexidine, when intended for human vaginal use. (S0)

Chloroform, preparations and mixtures containing more than 0.5 percent and less than 20 percent of chloroform, except for industrial purposes including the manufacturing and compounding of products not intended for medicinal use. (S0, S5)

Chromium, in oral preparations or mixtures containing more than 200 µg of Chromium per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

Ciclopirox.

Clotrimazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) and
b. when intended for application to the skin. (S4)

Deanol and its derivatives, unless listed in another Schedule, when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as 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) and for analytical laboratory purposes (S5)

Collagenase clotridiopeptidase, when intended for application to the skin.

Copper,

a. in oral preparations or mixtures containing more than 4 mg of Copper per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection. (S3)

Cyanocobalamin—see Vitamin B12.

Dequalinium,

a. when intended for oral topical use, as oral solutions or lozenges;
b. except when intended for human vaginal use. (S2)

Diclofenac,

a. when intended for application to the skin and containing more than 1% m/m of diclofenac; (S3)

b. except when intended for application to the skin and containing 1% m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)
c. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)
d. except when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 day; (S2)
e. except when intended for veterinary use (S3).

Diosmine.

Dithiazanine.

Econazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) or
b. when intended for application to the skin. (S4)

Enilconazole, when intended for application to the skin. (S4)

Ephedra alkaloids (natural or synthetic),

a. when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids, and not intended for export; (S6)
b. except oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer. (S2)

Ephedrine,

a. 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; (S6)
b. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer. (S2)

Escin (aescin); medicinal preparations and mixtures thereof intended for application to the skin and containing 1 percent or less of escin. (S3)

Ether (diethyl ether); in concentrations of less than 20 percent. (S5)

Ethyl chloride.

Ethylphenylephrine.

Etofenamate, when intended for application to the skin. (S3)

Felbinac, when intended for application to the skin. (S3)

Fenbendazole, except when registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Fenticonazole, when intended for application to the skin. (S3)

Fexofenadine

Flubendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Flufenamic acid, when intended for application to the skin. (S3)

Flurbiprofen,

a. when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
    (i) a maximum of 8,75 milligrams per lozenge;
    (ii) a maximum treatment period of 3 days, and
    (iii) a maximum pack size of 15 lozenges (S3)
b. except when intended for application to the skin and indicated for the symptomatic refief of localised pain and inflammation provided that in the case of application by transdermal patch:
    (i) use is restricted to adults and children 12 years and older; and
    (ii) the treatment period is limited to a maximum of 4 weeks (S0);
c. except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)
d. except when intended for ophthalmic use. (S4)

Fluorescein, when intended for ophthalmic use by the topical route only. (S3)

Fluorides,

a. in oral medicinal preparations or mixtures intended for ingestion containing not more than 0,25 milligrams of fluorine per dosage unit;
b. except in toothpaste containing not more than 0,15 percent fluoride; (S0) and
c. except in mouth rinses containing not more than 0,15 percent fluoride; (S0)
d. except in oral medicinal preparations or mixtures intended for ingestion containing more than 0,25 milligrams of fluorine per dosage unit. (S4)

Folic Acid, in oral preparations or mixtures containing more than 500 µg of Folic Acid per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester) when intended for application to the skin. (S4)

Gramicidin, when intended for topical application to the epidermis, nares and external ear. (S4)

O-(ß-hydroxyethyl) rutosides.

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 2,6 percent when intended for topical use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Hyoscine butylbromide; substances, preparations and mixtures thereof—

a. when intended for oral administration in pack sizes not exceeding 20 tablets of 10 mg strength or less, or 100 ml of oral liquid dosage of 0.1% mass/volume or less; (S2)
b. except transdermal preparations when intended for the prevention of the symptoms of motion sickness; (S2)
c. except when intended for parenteral administration. (S3)

Ibuprofen

a. when contained in preparations intended for application to the skin, containing 5% m/m or less of ibuprofen, and presented in a pack size exceeding 50 grams; (S0)
b. when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older;
c. when contained in oral medicinal preparations, intended for human use only, supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S2, S3)
d. except when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)
e. except when intended for veterinary use. (S3)

Icodextrin.

Idoxuridine, when intended for application to the skin. (S4)

Indanazoline.

Indometacin,

a. when intended for application to the skin; (S3)
b. except when intended for the emergency treatment of acute gout attacks; (S2)
c. except when intended for veterinary use. (S3)

Iodine,

a. in oral preparations or mixtures containing more than 150 µg of Iodine per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

Iron,

a. in oral preparations or mixtures containing more than 24 mg of elemental iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection; (S3)
c. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Irrigation fluids, being sterile fluids intended for irrigation of wounds or hollow visci.

Isoconazole, when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis (S4); and

application to the skin. (S4)

Ketoconazole,

a. when intended for application to the skin,
b. except preparations and mixtures containing not more than 1,0 percent of ketoconazole, when intended for the prevention and treatment of dandruff. (S0, S4)

Ketoprofen,

a. when intended for application to the skin; (S3)
b. except when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)
c. except when intended for the emergency treatment of acute gout attacks; (S2)
d. except when intended for the treatment of post-traumatic conditions, subject to a maximum dose of 100 milligrams of ketoprofen per day, for a maximum treatment period of 5 days; (S2)
e. except in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to—
    (i) a maximum of 12,5 milligrams per lozenge;
    (ii) a maximum of 5 lozenges in any 24 hour period;
    (iii) a maximum treatment period of 3 days; and
    (iv) a maximum pack size of 15 lozenges (S2)

Lactobacillus acidophilus and Lactobacillus bifidus, when intended for therapeutic purposes, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Lactobacillus acidophilus,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus brevis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus caucasicus,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus casei,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus fermentum,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus gasseri,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus helveticus,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus johnsonii,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactococcus lactis,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus paracasei,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus plantarum,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus reuteri,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus rhamnosus,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);

b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Lactobacillus salivarius,

a. in pharmaceutical preparations and mixtures with medicinal claim(s);
b. except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 109 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)

Levocetirizine,

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.

Local anaesthetics, except

a. when intended for ophthalmic or parental use; (S4)
b. oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of "arc eyes"; (S2) and
c. ophthalmic preparations registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Loratidine,

Lufenuron, except when intended and registered as a systemic preparation against fleas in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Luxabendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Lysozyme, when intended for application to the skin. (S4)

Magnesium, in oral preparations or mixtures containing more than 250 mg of Magnesium per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

Malathion, except when intended and registered as an ectoparasiticide in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Manganese,

a. in oral preparations or mixtures containing more than 4 mg of Manganese per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. in preparations thereof for injection when intended for veterinary use

Manganese salts, preparations thereof for injection, when intended for veterinary use.

Mebendazole, except when registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Methenamine (hexamine), when intended for application to the skin, (S4)

Methionine,

a. in oral preparations containing more than the maximum daily dose of 210 mg of methionine alone or in combination with other active pharmaceutical ingredients (S0)

Miconazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) and
b. when intended for application to the skin. (S4)
c. except for topical treatment of fungal infections of the mouth. (S2)

Microfibrillar collagen hydrochloride.

Molybdenum and derivatives thereof in oral preparations or mixtures containing more than 230 µg of Molybdenum per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

Morantel except when registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

N-acetyl-aspartyl-glutamic acid.

Naphazoline, when intended for nasal use. (S2)

Naproxen

a. when contained in preparations intended for application to the skin; (S2, S3)
b. when contained in oral medicinal preparations, intended for humans only 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; (S2, S3)
c. except when intended for veterinary use. (S3)

Niacin (Nicotinic Acid, Vitamin B3) and derivatives thereof,

a. in oral preparations or mixtures containing more than 35 mg of Niacin per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except when intended for hyperchoiesterolaemia and for the management of dyslipidaemias (S4)

Nicotinamide and derivatives thereof, in oral preparations or mixtures containing more than 500 mg of Nicotinamide per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

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. when registered as metered sprays containing not more than 1 mg per dose or less;
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)

Nitrofurantoin, when intended for application to the skin. (S4)

Nitrofurazone, when intended for application to the skin. (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)

Nystatin,

a. when intended for application to the skin; and
b. when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis; and
c. except when presented as oral drops containing not more than 100 000 I.U. per ml; (S2)
d. except when intended for systemic use or the initial treatment of vaginal candidiasis (S4)
e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Ornidazole, when intended for application to the skin. (S4)

Orthodichlorobenzene, when intended for topical human medicinal use.

Oxetacaine (Oxethazaine),

a. in oral preparations containing an antacid;
b. except when intended for ophthalmic or parenteral use. (S4)

Oxibendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Oxymetazoline, when intended for nasal use. (S2)

Pancreatin.

Pantothenic Acid—see Vitamin B5.

Paracetamol, except—

a. immediate release tablets or capsules each containing 500 milligrams or less of paracetamol, or in individually wrapped powders or in sachets containing 1 000 milligrams or less of paracetamol, subject to—
   (i) a maximum of 12,5 grams of paracetamol per primary pack, and
   (ii) in the case of tablets or capsules, presented in blister strip packaging or in containers with child-resistant closures; and
   (iii) labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):
   "CONTAINS PARACETAMOL – READ THE PACKAGE INSERT"; (S0)
b. in liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres or in paediatric drops containing 120 milligrams or less of paracetamol per 1,2 millilitres, subject to—
   (i) a maximum of 100 millilitres per primary pack in the case of the liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres;
   (ii) a maximum of 20 millilitres per primary pack in the case of the paediatric drops;
   (iii) labelled with the following boxed warning, placed prominently on at least the main panel of the immediate container label and outer label (carton):
   "CONTAINS PARACETAMOL – READ THE PACKAGE INSERT"; (S0)
c. when contained in rectal suppositories; (S2)
d. when contained in modified release formulations; (S2)
e. when intended for injection. (S3)

Paradichlorobenzene, when intended for topical human medicinal use.

Penciclovir, when intended for application to the lips in the early treatment of recurrent herpes simplex virus infections (S4)

Pentosan polysulfate sodium, except when intended for the treatment of interstitial cystitis (S3)

Phenylephrine,

a. when intended for oral dosage forms, nasal dosage forms, or ophthalmic dosage forms containing more than 0,2 percent; (S1)
b. except ophthalmic preparations containing 0,2 percent or less (S0)
c. when intended for injection. (S4)

Phospholipids, when applied for therapeutic purposes.

Phosphorus, in oral preparations or mixtures containing more than 250 mg of Phosphorus per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

Polymixin B, when intended for topical application to the epidermis, nares or external ear. (S4)

Pramoxine.

Prilocaine,

a. in topical preparations containing 10 % or less of prilocaine;
b. except when intended for ophthalmic or parenteral use. (S4)

Procaine, when intended for oral administration.

Propentofylline, when intended for veterinary use. (S4)

Propylhexedrine, when used as a vasoconstrictor and decongestant in nose preparations and inhalants (S4)

Proteolytic (fibrinolytic) enzymes,

a. for oral use, and
b. when intended for application to the skin, and
c. except when intended for soft contact lens cleaners; (S0) and
d. except when intended for injection. (S4)

Pyrantel pamoate, including veterinary use, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Pyridoxilate.

Pyridoxine—see Vitamin B6.

Racecadotril.

Riboflavin—see Vitamin B2.

Selenium,

a. in oral preparations or mixtures containing more than 200 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection when intended for veterinary use. (S4)

Sertaconazole, when intended for application to the skin. (S4)

p-Synephrine,

a. oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days; (S6)
b. except preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0,2 percent or less for application to the eyes; (S0)
c. except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams (S2)

Terbinafine, when intended for application to the skin. (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)

Tetrahydrozoline, when intended for nasal use. (S2)

Thiabendazole, when intended for application to the skin. (S4)

Thiamine—see Vitamin B1.

Thiomersal.

Thiram, except when intended and registered as a fungicide in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Ticlatone, when intended for application to the skin.

Tioconazole,

a. when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; and
b. when intended for application to the skin. (S4)

Tolmetin, when intended for application to the skin. (S3)

Tyrothricin when intended for topical application to the epidermis, nares and external ear. (S4)

5-Hydroxy Tryptophan,

a. in oral preparations with a maximum daily dose not exceeding 220 mg of 5-Hydroxy tryptophan, alone or in combination with other active pharmaceutical ingredients; (S5)
b. except in oral preparation with a maximum daily dose not exceeding 220 mg of 5-Hydroxy alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0)

L-tryptophan,

a. in oral preparations with a maximum daily dose not exceeding 220 mg of L- tryptophan, alone or in combination with other active pharmaceutical ingredients; (S5)
b. except in oral preparation with a maximum daily dose not exceeding 220 mg of L-tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0)

Vanadium,

a. in oral preparations or mixtures containing more than 182 µg of Vanadium per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

Vitamin B1 (Thiamine) and derivatives thereof,

a. in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection. (S3)

Vitamin B2 (Riboflavin) and derivatives thereof,

a. in oral preparations or mixtures containing more than 100 mg of Vitamin B2 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection. (S3)

Vitamin B5 (Pantothenic Acid) and derivatives thereof,

a. in oral preparations or mixtures containing more than 200 mg of Vitamin B5 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection. (S3)

Vitamin B6 (Pyridoxine) and derivatives thereof,

a. in oral preparations or mixtures containing more than 100 mg of Vitamin B6 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection. (S3)

Vitamin B12 (Cyanocobalamin) and derivatives thereof,

a. in oral preparations or mixtures containing more than 100 µg of Vitamin B12 per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection. (S3)

Vitamin C (Ascorbic Acid),

a. in oral preparations or mixtures containing more than 1000 mg of Vitamin C per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in preparations thereof for injection. (S3)

Vitamin H (Biotin) and derivatives thereof, in oral preparations or mixtures containing more than 500 µg of Vitamin H per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S0)

Vitamin K and derivatives thereof,

a. in oral preparations or mixtures containing more than 120 µg of Vitamin K per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
b. except in injection preparations; (S3)

c. except when used in infant milk feeds or formulae in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Water for Injection in a dosage form not exceeding 20 millilitres in volume. (S3)

Xylometazoline, when intended for nasal use. (S2)

Zinc and derivatives thereof,

a. in injection preparations when intended for veterinary use;
b. except in oral preparations or mixtures containing not more than 25 mg of Zinc per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)
c. except when intended for topical use; (S0)
d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Zinc salts,

a. except when intended for oral ingestion, where the daily dose is less than 50 milligrams of elemental zinc; (S0),
b. except when intended for topical use by humans; (S0),
c. when intended for veterinary use as an injection;
d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Schedule 1 Annexure 1A added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020.]

PARAMEDIC (National Diploma in Emergency Medical Care graduates only) registered with Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates only)

LOCAL ANAESTHETIC

Substance	: Lignocaine Hydrochloride
Indication	: Local Anaesthetic
Schedule	: 1
Route of Administration	: Topical application

WATER

Substance : Water for injection

Indication : Diluent

Route of Administration : Parenteral

WATER

Substance : Water for irrigation

Indication : Wound and dressing irrigation

Route of Administration : Solution

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Schedule 1 Annexure 1B added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020.]

EMERGENCY CARE PRACTITIONER (Bachelor of Technology Degree in Emergency Medical Care) registered with Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)

LOCAL ANAESTHETIC

Substance : Lignocaine Hydrochloride

Indication : Local Anaesthetic

Schedule : 1

Route of Administration : Topical application

WATER

Substance : Water for injection

Indication : Diluent

Route of Administration : Parenteral

WATER

Substance : Water for irrigation

Indication : Wound and dressing irrigation

Route of Administration : Solution

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

[Schedule 1 Annexure 1C added by GNR 1375 in G. 44019 of 18 December 2020.]

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa

WATER
Substance : Water for injection
Indication : Diluent
Route of Administration : Parenteral

WATER
Substance : Water for irrigation
Indication : Wound and dressing irrigation
Route of Administration : Solution

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

[Schedule 1 Annexure 1D added by GNR 1375 in G. 44019 of 18 December 2020.]

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

WATER
Substance : Water for injection
Indication : Diluent
Route of Administration : Parenteral

WATER
Substance : Water for irrigation
Indication : Wound and dressing irrigation
Route of Administration : Solution

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

[Schedule 1 Annexure 1E added by GNR 1375 in G. 44019 of 18 December 2020.]

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

WATER
Substance : Water for injection
Indication : Diluent
Route of Administration : Parenteral

WATER
Substance : Water for irrigation
Indication : Wound and dressing irrigation
Route of Administration : Solution

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

[Schedule 1 Annexure 1F added by GNR 1375 in G. 44019 of 18 December 2020.]

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa

WATER
Substance : Water for injection
Indication : Diluent
Route of Administration : Parenteral

WATER
Substance : Water for irrigation
Indication : Wound and dressing irrigation
Route of Administration : Solution

ANNEXURE 2: DENTAL THERAPIST

[Schedule 1 Annexure 2 added by GNR 674 in G. 36827 of 13 September 2013, amended by GN 6466 in G. 53099 of 1 August 2025.]

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

DENTAL THERAPIST (Bachelor's degree in Dental Therapy)

ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY
Substance : Paracetamol
Indication : Dental pain
Route of Administration : Oral

SURFACE ANAESTHETIC
Substance : Lidocaine / Lignocaine hydrochloride
Indication : Dental surface anaesthesia
Route of Administration : Topical / Jelly / Pump Spray

ANTI-VIRAL
Substance : Acyclovir
Indication : Viral infection of lips
Route of Administration : Topical

ANTI-FUNGAL
Substance : Ketoconazole
Indication : Treatment of fungal infections
Route of Administration : Cream / Gel

VITAMINS AND MINERALS
Substance : —
Indication : Applicable to Dentistry
Route of Administration : Oral

MOUTH AND THROAT PREPARATIONS
Substance : —
Indication : Applicable to Dentistry
Route of Administration : Oral

ANNEXURE 3: OPTOMETRIST

[Schedule 1 Annexure 3 added by GNR 674 in G. 36827 of 13 September 2013; substituted by GN 620 in G. 40041 of 3 June 2016; amended by GN 748 in G. 41009 of 28 July 2017, GNR 219 & GNR 220 in G. 43051 of 28 February 2020; substituted by GNR 3261 in G. 48358 of 24 March 2023.]

OPTOMETRIST (Bachelor's degree in Optometry – B OPTOM) registered with the Health Professions Council of South Africa.

OPTOMETRIST

OPHTHALMIC PREPARATIONS: OTHER

Substance : Fluorescein

Indication : For diagnostic purpose only i.e.

In detecting corneal abrasions and foreign bodies in the eye, in applanation tonometry, in assessing the patency of the nasolacrimal duct and in contact lens fitting procedures

Route of Administration : Intra-ocular

OPTOMETRIST (Bachelor's degree in Optometry – B OPTOM) with additional qualifications registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974) and recognised by the Health Professions Council of South Africa as an authorised prescriber

ANALGESIC

Substance : Paracetamol

Indication : Mild Pain

Route of Administration : Oral

ANALGESIC/ANTI INFLAMMATORY

Substance : Ibuprofen

Indication : Mild to Moderate Pain

Route of Administration : Oral

ANTIHISTAMINE/VASOCONSTRICTOR/ MAST CELL STABILISER

Substance : Loratadine

Indication : Atopic dermatitis involving the eyelids

Route of Administration : Oral

SYMPATHOMIMETIC

Substance : Phenylephrine

Indication : Minor ocular irritation
Route of Administration : Topical (Drops)

ANNEXURE 4: PODIATRIST

[Schedule 1 Annexure 4 added by GNR 220 in G. 43051 of 28 February 2020; amended by GNR 1375 in G. 44019 of 18 December 2020.]

PODIATRIST registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974).

PODIATRIST

LOCAL ANAESTHETIC
Substance : Amethocaine/Tetracaine
Indication : Local Anaesthesia
Route of Administration : Topical (Cream)

LOCAL ANAESTHETIC
Substance : Chloroethane (Ethyl Chloride)
Indication : Local Anaesthesia
Route of Administration : Topical (Spray)

LOCAL ANAESTHETIC
Substance : Lignocaine/Lidocaine
Indication : Local Anaesthesia
Route of Administration : Topical (Pump, Spray, Cream, Patch)

ANNEXURE 5: ORAL HYGIENISTS

[Schedule 1 Annexure 5 added by GN 2685 in G. 47373 of 28 October 2022; substituted by GNR 3261 in G. 48358 of 24 March 2023.]

ORAL HYGIENISTS registered with the Health Professions Council of South Africa (HPCSA) in terms of the Health Professions Act,

ORAL HYGIENISTS

LOCAL ANAESTHETIC
Substance : Lignocaine/Lidocaine hydrochloride with or without Adrenaline or Noradrefaline
Indication : Dental surface anaesthesia (local anaesthetic)
Route of Administration : Local injection

LOCAL ANAESTHETIC

Substance : Mepivacaine with or without Adrenaline

Indication : Dental surface anaesthesia (local anaesthetic)

Route of Administration : Local injection

LOCAL ANAESTHETIC

Substance : Articaine with Adrenaline

Indication : Dental surface anaesthesia (local anaesthetic)

Route of Administration : Local injection

LOCAL ANAESTHETIC

Substance : Prilocaine with or without Adrenaline

Indication : Dental surface anaesthesia (local anaesthetic)

Route of Administration : Local injection

TOPICAL ANAESTHETIC

Substance : Ethyl chloride

Indication : Dental surface anaesthesia

Route of Administration : Topical

SCHEDULE 2

[Schedule 2 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, GNR 2082 of 5 November 1976; amended by GNR 278 of 25 February 1977, GNR 437 of 1 April 1977, GNR 1988 of 30 September 1977, GNR 1674 of 18 August 1978 (as amended GNR 2410 of 8 December 1978), GNR 1926 of 31 August 1979, GNR 2507 of 9 November 1979, GNR 2416 of 12 November 1982, GNR 1289 of 14 June 1985 (as amended GN 155 of 31 January 1986), GN 154 of 31 January 1986; substituted by GN 225 of 17 February 1989; amended by GNR 1132 of 2 June 1989, GNR 1862 of 10 August 1990, GNR 2841 of 7 December 1990, GNR 2169 of 6 September 1991, GNR 141 of 5 February 1993, GNR 775 of 7 May 1993, repealed, inserted by s 21 of Act 94 of 1991; amended by GNR 1556 & GNR 1557 of 16 September 1994, GNR 673 of 12 May 1995, GNR 1496 of 13 September 1996, GNR 1203 of 15 October 1999, GNR 1077 of 3 November 2000; repealed by s 27 of Act 90 of 1997; inserted by GNR 509 in G. 24727 of 20 April 2003; amended by GNR 491 in G. 31010 of 25 April 2008; substituted by GN 935 in G. 31387 of 5 September 2008, R 1230 in G. 32838 of 31 December 2009; amended by GNR 227 in G. 35149 of 15 March 2012, GNR 674 in G. 36827 of 13 September 2013, GNR 690 in G. 36850 of 20 September 2013, GNR 104 in G. 37318 of 11 February 2014, GNR 352 in G. 37622 of 8 May 2014, GNR 234 in G. 38586 of 20 March 2015, GN 254 in G. 39815 of 15 March 2016, GN 620 in G. 40041 of 3 June 2016, GN 748 in G. 41009 of 28 July 2017, GN 1261 in G. 41256 of 17 November 2017, GNR 1098 in G. 41971 of 12 October 2018, GNR 1262 in G. 42052 of 23 November

2018, GNR 755 in G. 42477 of 23 May 2019, GNR 219 in G. 43051 of 28 February 2020, GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021, GNR 2412 in G. 46789 of 26 August 2022, GN 2685 in G. 47373 of 28 October 2022, GNR 3261 in G. 48358 of 24 March 2023, GN 6466 in G. 53099 of 1 August 2025.]

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 Authority, 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)
	Annexure 1B:	Emergency Care Provider (Emergency Care Practitioner)
	Annexure 1C:	Basic Ambulance Assistant
	Annexure 1D:	Ambulance Emergency Assistant
	Annexure 1E:	Emergency Care Technician
	Annexure 1F:	Emergency Care Assistant
(ii)	Annexure 2:	Dental Therapist
(iii)	Annexure 3:	Optometrist
(iv)	Annexure 4:	Podiatrist

Aconite alkaloids, preparations containing 0,02 percent or more. (S0)

Acrivastine.

Adrenaline (epinephrine), except—
   a. ophthalmic preparations when intended for glaucoma, and
   b. preparations for injection. (S3, S4)

Albendazole,

a. when intended for the treatment of intestinal parasites, as a single oral dose; (S4)
b. except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Alcaftadine.

Alkaloids and glycosides, all poisonous alkaloids and glycosides, and the salts of such poisonous alkaloids and glycosides, when not specifically named in any other Schedule.

Alverin.

Amethocaine,—see Tetracaine.

Aminopentamide.

Amyl nitrite.

Antihistamines, except—

a. astemizole and terfenadine; (S4)
b. when listed separately in these Schedules (S5)

Antimicrobial substances, namely

a. griseofulvin, mupirocin, natamycin when intended for application to the skin, nares and external ear; (S4)
b. nystatin preparations intended for application to the oral cavity, nares and external ear. (S1, S4)

Antazoline.

Apomorphine; except when indicated for the treatment of erectile dysfunction. (S4)

Aptocaine.

Arecoline.

Arsenic;

a. except in oral dosage forms containing the equivalent of 0,01 percent or less of arsenic trioxide; (S1)

b. except when intended for injection. (S4)

Aspirin (acetyl salicylic acid), when intended for:

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

Atovaquone,

a. when co-formulated with proguanil and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S4)

Atropine, except

a. when intended for use in ophthalmic preparations; (S3)
b. when intended for use in injections (S4)

Azatadine.

Azelastine.

Bambuterol.

Bamipine.

BCG vaccine—see Mycobacterium bovis.

Beclomethasone dipropionate, when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—

a. a maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms per nostril and
b. a maximum pack size of 200 doses (S3, S4)

Belladonna alkaloids, except when intended for topical application. (S1)

Benproperine.

Benzydamine,

a. when intended for use human vaginal use; (S3)
b. except preparations and mixtures containing 3 percent or less of benzydamine, when intended for application to the skin; (S0)

c. except preparations containing more than 3 percent of benzydamine, but not exceeding 5 percent, when intended for application to the skin; (S1)
d. except preparations and mixtures intended for use as a mouth rinse or for topical application in the mouth and throat; provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day; (S1)
e. except preparations and mixtures containing 3 milligrams or less of benzydamine per throat lozenge: Provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day and the pack size does not exceed 16 lozenges (S0)

Bevonium methylsulphate.

Bilastine.

Bismuth, when intended for oral use.

Bromhexine.

Bromides, preparations containing less than 80 milligrams of bromine per recommended daily dose. (S5)

Brompheniramine.

Buclizine.

Budesonide,
a. when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older; (S3)
b. except when intended for inhalation and nasal administration, unless listed in another Schedule. (S4)
c. Schedule. (S4)

Butinoline.

Calabar bean alkaloids.

Camphorated Opium Tincture.

Camylofin.

Cantharidin.

Canthaxanthin

Carbinoxamine.

Carbocisteine.

Carbuterol, except

a. when contained in respirator solutions; (S3) and
b. when intended for injection. (S4)

Carisoprodol.

Chlormezanone; preparations containing not more than 100 milligrams per recommended dose. (S5)

Chlorodyne (as described by Chloroform and Morphine Tincture BP 1980); preparations containing 5,0 percent or less of chlorodyne in combination with other active medicinal ingredients (S6)

Chlorpheniramine.

Chlorprenaline.

Cholestyramine.

Chlorzoxazone.

Clonidine when intended for the prevention of migraine. (S3)

Cimetidine, when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to a maximum unit dose of 200 milligrams, a maximum daily dose of 800 milligrams and a maximum treatment period of 2 weeks (S3)

Cinnarizine.

Clemastine.

Clemizole.

Clidinium bromide.

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)

Colchicine, when intended for the emergency treatment of acute gout, subject to a maximum total treatment course of 6 milligrams (S3)

Cyclandelate.

Cyclizine.

Cyclopentolate, except when intended for ophthalmic administration. (S3)

Cyproheptadine, when indicated for allergic rhinitis or antipruritic use. (S5)

Dequalinium,

a. when intended for human vaginal use;
b. except when intended for oral topical use, as oral solutions or lozenges (S1)

Desloratidine.

Dexchlorpheniramine.

Dextromethorphan.

Diclofenac,

a. when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S3)
b. when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, or for the treatment of post-traumatic conditions, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days;
c. except when intended for application to the skin and containing 1 % m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)
d. except when intended for application to the skin and containing more than 1% m/m of diclofenac; (S1)
e. except when intended for veterinary use. (S3)

Dicyclomine.

Diphenoxin (or diphenoxylic acid), mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5 percent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S6)

Diphenoxylate preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not less than 25 micrograms of atropine sulphate per dosage unit. (S6)

Diphtheria toxoid vaccine.

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)

Dimethindene.

Dimethothiazine.

Dimetindene.

Diphenhydramine.

Diphenylpyraline.

(D-norpseudoephedrine—see cathine (S6))

Doxycycline, when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older. (S4)

Doxylamine.

Ebastine.

Emedastine.

Emepronium.

Emetine, substances, preparations and mixtures containing less than 0,2 percent of alkaloids, calculated as emetine. (S4)

Ephedra alkaloids (natural or synthetic), contained in products registered in terms of the Act, and not intended for export, unless listed separately in the Schedules,

a. oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer; (S6)
b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids (S1)

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

a. oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 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)

Epinastine.

Ergot alkaloids (natural or synthetic), when intended for the treatment of migraine. (S4)

Ergotamine.

Esomeprazole when indicated for the temporary, short-term relief of heartburn and hyperacidity subject to—

a. a maximum daily dose of 20 milligrams;
b. a maximum treatment period of 14 days (S4)

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)

Estriol,

a. when intended for human vaginal use;
b. except when intended for oral contraception; (S3)
c. except when intended for hormone replacement therapy. (S4)
d. except when intended for veterinary use. (S4)

Ethylmorphine:

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

Etilefrine.

Etodroxizine, preparations and mixtures when used solely as an antihistamine. (S5)

Exalamide.

Famotidine, when intended for the short-term symptomatic relief of heartburn caused by excess acid, subject to—

a. a maximum dose of 10 milligrams;
b. a maximum daily dose (per 24 hours) of 20 milligrams;
c. a maximum treatment period of 2 weeks (S4)

Fedrilate.

Fenoprofen,

a. when intended for the emergency treatment of acute gout attacks, and
b. when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days (S3)

Fenoterol, except—

a. when contained in respirator solutions; (S3) and
b. when intended for injection or for the prevention or delay of labour. (S4)

Flavoxate.

Fluconazole, as a single dose of 150 mg when indicated for the following fungal infections in adults:

a. Vaginal candidiasis, recurrent
b. Candidial balanitis associated with viginal candidiasis

Flunarizine.

Flunisolide, when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, in a strength not exceeding 0,025 percent (m/v), and indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—

a. a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms per nostril in the case of adults and children over 16 years of age;
b. a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms per nostril in children 12 to 16 years of age;
c. a maximum pack size of 240 doses (S3, S4)

Flurbiprofen,

a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S3)
b. except when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
    (i) a maximum of 8,75 milligrams per lozenge;
    (ii) a maximum treatment period of 3 days; and
    (iii) a maximum pack size of 15 lozenges (S1)
c. except when intended for application to the skin and indicated for the symptomatic relief of localised pain and inflammation, provided that in the case of application by transdermal patch:
    (i) use is restricted to adults and children 12 years and older; and
    (ii) the treatment period is limited to a maximum of 4 weeks (S0)
d. except when intended for ophthalmic use; (S4)

Fluticasone furoate,

a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—
    (i) a maximum daily dose of 55 micrograms per nostril; and
    (ii) a maximum pack size of 120 doses (S3)
b. except when intended for administration other than by inhalation or nasal administration. (S4)

Fluticasone propionate,

a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—
    (i) a maximum daily dose of 100 micrograms per nostril;
    (ii) and a maximum pack size of 120 doses (S3)
b. except when intended for administration other than by inhalation or nasal administration. (S4)

Fusafungine.

Fusidic acid, when intended for topical application. (S4)

Gadopentetic acid.

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

Gelsemium alkaloids.

Griseofulvin, when intended for application to the skin, nares and external ear. (S4)

Halogenated hydroxyquinolines, when intended for application to the skin. (S4)

Haemophilus influenzae vaccine (Hib).

Hepatitis B vaccine

Hexametazine.

Hexoprenaline—

a. except when contained in respirator solutions; (S3) and
b. except when intended for injection or for the prevention or delay of labour. (S4)

Homatropine; preparations and mixtures thereof, except ophthalmic preparations (S3)

Hormones (natural or synthetic, including recombinant forms), with either hormonal, prohormonal or anti-hormonal action unless listed elsewhere in the Schedules,

a. when intended for human vaginal use, and
b. when specifically intended for emergency postcoital contraception. (S3, S4, S5)

Human papillomavirus vaccine.

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).

Hydrocortisone and hydrocortisone acetate,

a. when used in maximum concentration of 1 percent in preparations intended for application to the skin, and
b. in a maximum concentration of 1 percent used in combination with miconazole for topical application in the treatment of athlete's foot. (S4)

Hydroquinone; preparations and mixtures containing 2 percent or less thereof, when intended for application to the skin. (S3)

Hyoscine butylbromide; substances, preparations and mixtures thereof—

a. when intended for oral administration in pack sizes exceeding 20 tablets or 100 ml, or strengths exceeding 10 mg per oral solid dosage form or 0.1% mass/volume; (S1)
b. transdermal preparations when intended for the prevention of the symptoms of motion sickness; (S3)
c. except when intended for parenteral administration. (S3)

Ibuprofen,

a. when contained in oral medicinal preparations, intended for human use only in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S3)
b. when contained in oral medicinal preparations, intended for human use only as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S1, S3)
c. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S3)
d. except when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)
e. except when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older; (S1)

f. except when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)
g. except when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age; (S4)
h. except when intended for veterinary use. (S3)

Indometacin,

Indometacin,

a. when intended for the emergency treatment of acute gout attacks; (S3)
b. except when intended for application to the skin; (S1)
c. except when intended for veterinary use. (S3)

Influenza vaccine.

Influenza virus vaccine.

Ipratropium, except when contained in respirator solutions (S3)

Isoaminile.

Isoprenaline (isoproterenol), except

a. when contained in respirator solutions; (S3) and
b. when intended for injection. (S4)

Isopropamide.

Isothipendyl.

Ketoprofen,

a. when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours;

b. when intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions, subject to a maximum dose of 100 milligrams of ketoprofen per day, for a maximum treatment period of 5 days;
c. in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to—
    (i) a maximum of 12,5 milligrams per lozenge;
    (ii) a maximum of 5 lozenges in any 24 hour period;
    (iii) a maximum treatment period of 3 days; and
    (iv) a maximum pack size of 15 lozenges (S3)
d. except when intended for application to the skin. (S1)

Ketotifen.

Lansoprazole, when intended for the temporary short-term relief of heartburn and hyperacidity, subject to—
a. maximum daily dose of 15 milligrams;
b. maximum treatment period of 14 days (S4)

Levocabastine.

Levodropropizine.

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)

Lithium salts, when intended for application to the skin. (S5)

Local anaesthetics, except when intended for ophthalmic and parental use; (S4)

oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of “arc eyes”.

Lobelia alkaloids.

Lodoxamide.

Loperamide.

Measles vaccine.

Mebeverine.

Mebhydrolin.

Meclozine.

Mefenamic acid,

a. when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days; and
b. preparations containing mefenamic acid as the only therapeutically active substance, when intended for human use only in the treatment of primary dysmenorrhoea, subject to a maximum daily dose of 500 millligrams 3 times a day and a maximum treatment period of 3 days; (S3)
c. except when intended for veterinary use. (S3)

Melatonin, when used for the amelioration of desyncronosis (jet-lag) in doses not exceeding 6mg daily. (S4).

Mepenzolate bromide.

Mephenesin.

Mepyramine.

Mequitazine.

Mercuric ammonium chloride.

Mercuric chloride.

Mercuric iodide.

Mercuric oxides, substances, preparations and mixtures thereof, containing less than 3 percent of mercury. (S4)

Mercury organic compounds

a. substances, preparations and mixtures in the form of aerosols, intended for application to the skin and mucous membranes and substances,

b. preparations and mixtures containing the equivalent of 0,6 percent or more of elemental mercury, intended for application to the skin and mucous membranes,
c. except phenylmercuric nitrate when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Mesna, except preparations intended for injection. (S4)

Metaproterenol (orciprenaline), except
a. when contained in respirator solutions; (S3) and
b. when intended for injection; (S4)
c. when intended for the prevention or delay of labour. (S4)

Methixene.

Methocarbamol.

Metholilazine.

Methoxyphenamine.

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)

Miconazole, when intended for human use in preparations containing 2 percent or less of miconazole, for the topical treatment of fungal infections of the mouth (oral candidiasis). (S1, S4)

Minoxidil, when intended for application to the scalp in preparations containing not more than 2 percent (m/v) and which are registered in terms of the Act. (S4)

Mizolastine.

Mometasone furoate, when intended for nasal administration as an aqueous spray, other than by pressurized aerosol, and indicated for the treatment of the symptoms of seasonal or perennial allergic rhinitis (hay fever) in adults and children between the age of 2 and 11 years of age, subject to—
a. a maximum dose of 200 micrograms per nostril in adults and 50 micrograms per nostril in children; and
b. a maximum pack size of 200 doses (S3, S4)

Monoethanolamine.

Morphine; mixtures containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (S6)

Mumps vaccine.

Mupirocin, when intended for application to the skin, nares and external ear. (S4)

Mycobacterium bovis vaccine (BCG).

Nabumetone, when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days (S3)

Naphazoline, except when intended for nasal use. (S1)

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, intended for human use only 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)
d. except when intended for veterinary use. (S3)

Natamycin, when intended for application to the skin, nares and external ear. (S4)

Nedocromil.

Nicergoline.

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. …
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 an 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)

Nizatidine, when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to—
a. a maximum dose of 150 milligrams;
b. a maximum daily dose of 300 milligrams;
c. a maximum treatment period of two weeks (S4)

((+)-norpseudoephedrine—see cathine. (S6))

Noscapine.

Nux vomica; substances, preparations and mixtures thereof, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Nystatin,
a. when presented as oral drops containing not more than 100 000 I.U. per ml, and
b. except when intended for application to the skin, (S1) and
c. except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, (S1) and
d. except when intended for systemic use or the initial treatment of vaginal candidiasis (S4)
e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Octatropine.

Oleoresin of aspidium (Filix Mas).

Olopatadine.

Olopatidine.

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

a. a maximum daily dose of 20 mg;
b. a maximum treatment period of 14 days (S4)

Opium; mixtures containing not more than 0,2 percent of morphine, calculated as anhydrous morphine. (S6)

Orlistat, when used in a dose not exceeding 60mg per main meal and not exceeding a maximum dose of 180mg per 24-hour period. (S3)

Orphenadrine, when contained in preparations intended for use as a muscle relaxant. (S4).

Otilonium bromide.

Oxatomide.

Oxybuprocaine, when contained in eye drops intended for emergency treatment of arc eyes (S4)

Oxymetazoline, except when intended for nasal use. (S1)

Oxyphencyclimine.

Oxyphenonium.

Papaverine; substances, preparations and mixtures thereof.

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)

Paracetamol,

a. when contained in rectal suppositories, or

b. when contained in modified release formulations (S0, S1, S3)

Pentoxyfylline.

Perfluorooctane, except when intended for intraocular use. (S4)

Pertussis toxoid vaccine.

Phenazone (antipyrone).

Phenazopyridine.

Phenindamine.

Pheniramine.

Phenylpropanolamine (norephedrine), contained in products registered in terms of the Act, and not intended for export, unless listed separately in the Schedules, oral preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer. (S6)

Phenyltoloxamine.

Pholedrine.

Pimethixene, preparations and mixtures thereof when used solely as an antihistaminic. (S5)

Pinaverium.

Pipenzolate.

Pipoxolan.

Pirbuterol, except when contained in respirator solutions (S3)

Piroxicam,

a. when intended for the emergency treatment of acute gout attacks, for a maximum treatment period of 5 days; (S3)
b. when intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days; (S3)
c. except when intended for veterinary use. (S3)

Pizotifen; preparations and mixtures, when intended for prophylaxis of migraine. (S5)

Pneumococcal vaccine, conjugated.

Podophyllum resin; preparations and mixtures containing 20 percent or less thereof. (S4)

Poldine methylsulphate.

Polio vaccine.

Potassium,

a. in oral preparations or mixture containing more than 20 millimoles (1500 mg) of potassium per 24 hours;
b. except when intended for intravenous infusion or for injection; (S3)
c. except when contained in oral rehydration preparations (S0)

Povidone iodine when intended for application to the vagina. (S0)

Prifinium bromide.

Procaterol, except when contained in respirator solutions (S3)

Procyclidine.

Proglumide.

Proguanil,

a. when co-formulated with atovaquone and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S4)

Promethazine,

a. when intended for use as an antihistamine, and
b. when intended for application to the skin, and
c. when intended specifically for the treatment of travel sickness (S5)

Propantheline bromide.

Propyphenazone.

Proxymetacaine, when contained in eye drops intended for the emergency treatment of arc eyes (S4)

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

a. Immediate-release oral preparations and mixtures containing not more than 60 milligrams of pseudoephedrine per dose or controlled-release oral preparations and mixtures containing not more than 120 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, 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)

p-Synephrine,

a. oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams; (S6)
b. except preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0,2 percent or less for application to the eyes; (S0)
c. except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days (S1)

Pyrobutamine.

Quinine, preparations and mixtures containing not more than 1 percent thereof. (S4)

Ranitidine, when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to—

a. a maximum dose of 75 milligrams;

b. a maximum daily dose of 300 milligrams;
c. a maximum treatment period of two weeks (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)

Reproterol, except when contained in respirator solutions (S3)

Rimiterol, except
a. when contained in respirator solutions (S3) and
b. when intended for injection. (S4)

Rizatriptan, when in oral solid dosage forms providing 5mg or less and presented as packs of no more than 2 oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with rizatriptan. (S4)

Rotavirus, live attenuated.

Rubella vaccine.

Rupatidine.

Sabadilla alkaloids; substances, preparations and mixtures containing 1 percent or more thereof.

Salbutamol, except
a. when contained in respirator solutions; (S3) and
b. when intended for injection. (S4)

Salmefamol, except
a. when contained in respirator solutions; (S3) and
b. when intended for injection. (S4)

Siccanin, when intended for application to the skin.

Sodium cromoglycate, except when intended for veterinary use. (S4)

Strychnine, preparations and mixtures containing 0,2 percent or less thereof. (S4)

Sulfadiazine silver when intended for application to the skin in the short-term treatment of minor burns, provided that the pack size is limited to a maximum of 50 grams (S4)

Sulphonamides when intended for application to the eyes, nares and vagina. (S4)

Sumatriptan, when in oral solid dosage forms providing 50 mg or less and presented as packs of no more than two oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with sumatriptan. (S4)

Terbutaline, except when contained in respirator solutions (S3)

Tetanus vaccine.

Tetanus toxoid.

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)

Tetrahydrozoline, except when intended for nasal use. (S1)

Thenalidine.

Theophylline and its derivatives, unless listed in another Schedule, and except in preparations for injection. (S4)

Thiethylperazine.

Tiaprofenic acid, when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days (S3)

Timepidium.

Triamcinolone, when intended for application to oral lesions (S4)

Trimebutine.

Trimeprazine (Alimemazine).

Tripelennamine.

Triprolidine.

Trospium.

Tulobuterol, except when contained in respirator solutions (S3)

Typhoid vaccine.

Ulipristal.

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)

Xylometazoline, except when intended for nasal use. (S1)

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Schedule 2 Annexure 1A added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020.]

PARAMEDIC (National Diploma in Emergency Medical Care graduates only) registered with Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical (*Care graduates only*)

ANTI-CHOLINERGIC
Substance : Ipratropium Bromide
Indication : Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Schedule : 2
Route of Administration : Respirator Solution

SELECTIVE β2 AGONISTS
Substance : Salbutamol
Indication : Bronchodilator
Route of Administration : Aerosol

NON-STEROIDAL ANTI-INFLAMMATORY
Substance : Ibuprofen
Indication : Analgesic/Anti-inflammatory
Route of Administration : Oral

ANALGESIC
Substance : Paracetamol
Indication : Analgesic/Anti-pyrexia
Route of Administration : Oral

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Schedule 2 Annexure 1B added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020.]

EMERGENCY CARE PRACTITIONER
(Bachelor of Technology Degree in Emergency Medical Care) registered with Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)

ANTI-CHOLINERGIC
Substance : Ipratropium Bromide
Indication : Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Schedule : 2
Route of Administration : Respirator Solution

SELECTIVE β2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Aerosol

ANTI-SPASMODIC

Substance : Hyoscine butylbromide

Indication : Anti-spasmodic

Route of Administration : Oral

ANTI-PROPULSIVE

Substance : Loperamide

Indication : Symptomatic management of diarrhoea in adults

Route of Administration : Oral

NON-STEROIDAL ANTI-INFLAMMATORY

Substance : Ibuprofen

Indication : Analgesic/Anti-inflammatory

Route of Administration : Oral

ANALGESIC

Substance : Paracetamol

Indication : Analgesic/Anti-pyrexia

Route of Administration : Oral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

[Schedule 2 Annexure 1C added by GNR 1375 in G. 44019 of 18 December 2020.]

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa

*ANTI-CHOLINERGIC

Substance : Ipratropium bromide

Indication : Inhalant Bronchodilator (atropine derivative anti-cholinergic)

Route of Administration : Respirator Solution

*SELECTIVE β2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Aerosol

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

[Schedule 2 Annexure 1D added by GNR 1375 in G. 44019 of 18 December 2020.]

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

ANTI-CHOLINERGIC

Substance : Ipratropium bromide

Indication : Inhalant Bronchodilator (atropine derivative anti-cholinergic)

Route of Administration : Respirator Solution

SELECTIVE β2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Aerosol

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

[Schedule 2 Annexure 1E added by GNR 1375 in G. 44019 of 18 December 2020.]

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

ANTI-CHOLINERGIC

Substance : Ipratropium bromide

Indication : Inhalant Bronchodilator (atropine derivative anti-cholinergic)

Route of Administration : Respirator Solution

SELECTIVE β2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Aerosol

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

[Schedule 2 Annexure 1F added by GNR 1375 in G. 44019 of 18 December 2020.]

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa

ANTI-CHOLINERGIC
Substance : Ipratropium bromide
Indication : Inhalant Bronchodilator (atropine derivative anti-cholinergic)
Route of Administration : Respirator Solution

SELECTIVE β2 AGONISTS
Substance : Salbutamol
Indication : Bronchodilator
Route of Administration : Aerosol

ANNEXURE 2: DENTAL THERAPIST

[Schedule 2 Annexure 2 added by GNR 674 in G. 36827 of 13 September 2013; amended by GN 620 in G. 40041 of 3 June 2016, GN 6466 in G. 53099 of 1 August 2025.]

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

DENTAL THERAPIST (Bachelor's degree in Dental Therapy)

ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY
Substance : Ibuprofen
Indication : Dental pain
Route of Administration : Oral

Substance : Diclofenac
Indication : Dental pain
Route of Administration : Oral

Substance : Indometacin
Indication : Dental pain
Route of Administration : Oral

ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY

Substance : Codeine

Indication : Dental pain

Route of Administration : Oral

ANTI-FUNGALS

Substance : Nystatin

Indication : Candidal infections of the oral cavity

Route of Administration : Oral

Substance : Miconazole

Indication : Treatment of fungal infections

Route of Administration : Oral

ANNEXURE 3: OPTOMETRIST

[Schedule 2 Annexure 3 added by GN 620 in G. 40041 of 3 June 2016; amended by GN 748 in G. 41009 of 28 July 2017, GNR 219 in G. 43051 of 28 February 2020.]

OPTOMETRIST (Bachelor's 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 recognised by the Health Professions Council of South Africa as an authorised prescriber.

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 ANT INFLAMMATORY
Substance : Hydrocortisone
Indication : Dermatitis, Ectopic or Seborrhoeic Eczema
Route of Administration : Topical application

ANNEXURE 4: PODIATRIST

[Schedule 2 Annexure 4 added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 2685 in G. 47373 of 28 October 2022.]

PODIATRIST registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974).

PODIATRIST

ANTI-INFLAMMATORIES
Substance : Diclofenac sodium and Ibuprofen
Indication : Pain management
Route of Administration : Oral

SCHEDULE 3

[Schedule 3 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, GNR 2082 of 5 November 1976; amended by GNR 278 of 25 February 1977, GNR 437 of 1 April 1977, GNR 1674 of 18 August 1978 (as amended GNR 2410 of 8 December 1978), GNR 1926 of 31 August 1979, GNR 2507 of 9 November 1979, GNR 658 of 27 March 1981, GNR 1289 of 14 June 1985, GN 154 of 31 January 1986; substituted by GN 225 of 17 February 1989; amended by GNR 2841 of 7 December 1990, GNR 2169 of 6 September 1991, GNR 775 of 7 May 1993; repealed, amended, inserted s 21 of Act 94 of 1991; amended by GNR 1556 of 16 September 1994, GNR 673 of 12 May 1995, GNR 42 of 19 January 1996, GNR 1496 of 13

September 1996, GNR 1203 of 15 October 1999, GNR 1077 of 3 November 2000; repealed by s 27 of Act 90 of 1997; inserted by GNR 509 in G. 24727 of 10 April 2003; substituted by GN 935 in G. 31387 of 5 September 2008; amended by GNR 1230 in G. 32838 of 31 December 2009, GNR 227 in G. 35149 of 15 March 2012, GNR 674 in G. 36827 of 13 September 2013, GNR 690 in G. 36850 of 20 September 2013, GNR 104 in G. 37318 of 11 February 2014, GNR 352 in G. 37622 of 8 May 2014, GNR 234 G. 38586 of 20 March 2015, GN 254 in G. 39815 of 15 March 2016, GN 620 in G. 40041 of 3 June 2016, GN 748 in G. 41009 of 28 July 2017, GN 1261 in G. 41256 of 17 November 2017, GNR 1098 in G. 41971 of 12 October 2018, GNR 1262 in G. 42052 of 23 November 2018, GNR 755 in G. 42477 of 23 May 2019, GNR 219 & GNR 220 in G. 43051 of 28 February 2020, GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021, GN 2685 in G. 47373 of 28 October 2022, GN 6466 in G. 53099 of 1 August 2025.]

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 Authority, 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.
   (iii) Annexure 4: Podiatrist

Acamprosate.

Acebutolol.

Aceclofenac.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use.

Acetylcysteine,

a. when intended for injection or for the management of paracetamol overdosage;
b. except when used as a mucolytic in acute respiratory conditions for a maximum treatment period of 14 days (S2)

Acipimox.

Aclidinium.

Adapalene.

Adrenaline (epinephrine); ophthalmic preparations thereof, when intended for glaucoma. (S2, S4)

Alclofenac.

Alendronic acid.

Aliskiren.

Allopurinol.

Alogliptin.

Alprenolol.

Amiloride.

Amlodipine.

Ancrod.

Anthiolimine, when intended for injection.

Arsanilic acid.

Ascorbic Acid—see Vitamin C.

Atenolol.

Atropine,

a. when intended for use in ophthalmic preparations; (S2)
b. except when intended for use in injections (S4)

Atropine; ophthalmic preparations (S2, S4)

Azapropazone.

Balsalazide.

Barnidipine.

Beclamide.

Beclomethasone dipropionate, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—

a. a maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms per nostril; and
b. a maximum pack size of 200 doses (S2, S4)

Benazepril.

Bendazac.

Benfluorex.

Benoxaprofen.

Benzbromarone.

Benzydamine, except preparations and mixtures—

a. containing 3 percent or less of benzydamine, when intended for application to the skin; (S0)
b. containing more than 3 percent of benzydamine, but not exceeding 5 percent, when intended for application to the skin; (S1)
c. intended for use as a mouth rinse or for topical application in the mouth and throat; provided that the total dose swallowed does not exceeds 36 milligrams of benzydamine per day; (S1)
d. containing 3 milligrams or less of benzydamine per throat lozenge: Provided that the total dose swallowed does not exceed 36 milligrams of benzydamine per day and the pack size does not exceed 16 lozenges (S0)
e. intended for human vaginal use. (S2)

Bepridil.

Beta-benzalbutyramide.

Beta-galactosidase, when intended for therapeutic purposes.

Betahistine.

Betaxolol.

Bethanidine.

Bevantolol.

Bezafibrate.

Bisoprolol.

Bopindolol.

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)

Brimonidine.

Brinzolamide.

Budesonide,

a. when intended inhalation or nasal administration, unless listed in another Schedule. (S4)
b. except when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older. (S2)

Bufexamac, except when intended for application to the skin. (S1)

Buflomedil.

Buformin.

Bumetanide.

Butecosone, when intended for inhalation or nasal administration.

Cadralazine.

Caffeine, when intended for injection.

Calcipotriol.

Calcium,

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
c. except when indicated for the treatment of hyperphosphataemia; (S4)
d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Calcium carbimide.

Calcium salts, preparations thereof, when intended for injection, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Calcium disodium edetate, when intended for injection.

Calcium dobesilate.

Candesartan.

Captopril.

Carazolol.

Carbachol, ophthalmic preparations thereof when intended for glaucoma. (S4)

Carbamazepine.

Carbenoxolone, except when intended for application to the oral mucosa. (S0)

Carbuterol, when contained in respirator solutions (S2, S4)

Carprofen.

Carteolol.

Carvedilol.

Celecoxib.

Celiprolol.

Chenodeoxycholic acid.

Chlorazanil.

Chlorexolone.

Chlorothiazide and other derivatives of benzo-1,2,4-thiadiazine-7-sulphonamide-1,1-dioxide, whether hydrogenated or not, including hydrochlorothiazide, bendrofluazide, benzthiazide, cyclopenthiazide, hydroflumethiazide, metchlorothiazide and polythiazide.

Chlorpropamide.

Chlorthalidone.

Cholecalciferol,—see Vitamin D.

Chromonar

Ciclesonide.

Cilazapril.

Cilomilast.

Cimetidine, except when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to a maximum unit dose of 200 milligrams, a maximum daily dose (per 24 hours) of 800 milligrams and a maximum treatment period of 2 weeks (S2)

Clofibrate.

Clonidine except when intended for the prevention of migraine. (S2)

Clopidogrel.

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)

Colchicine, except when intended for the emergency treatment of acute gout, subject to a maximum total treatment course of 6 milligrams (S2)

Colecalciferol see—Vitamin D.

Colestipol.

Copper,

a. in preparations thereof for injection; (S0)
b. in oral preparations or mixtures containing more than 4 mg of Copper per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Copper salts, when intended for injection.

Corticosteroids (natural or synthetic), except when listed separately in the Schedules, when contained in preparations intended for inhalation or nasal administration (S4)

Cyanocobalamin—see Vitamin B12.

Cyclandalate.

Cyclopentolate; ophthalmic preparations thereof. (S2)

Cyphenothrin (Pyrethroid), except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Darifenacin.

Debrisoquine.

Delapril.

Dexketoprofen trometamol.

Dialysate preparations.

Dichlorphenamide.

Diclofenac,

a. except when intended for application to the skin and containing 1% m/m or less of diclofenac subject to a maximum pack size of 50 grams; (S0)
b. except when intended for application to the skin and containing more than 1% m/m of diclofenac; (S1)
c. except when intended for the emergency treatment of acute gout attacks, subject to a maximum daily dose of 150 mg for a maximum treatment period of 3 days; (S2)
d. except when intended for human use only in the treatment of fever or mild to moderate pain of inflammatory origin, subject to a maximum daily dose of 75 mg for a maximum treatment period of 5 days (S2)

Dienogest.

Diflunisal.

Diftalone.

Digitalis, its glycosides and other active principles thereof, unless diluted below one unit (BP) in each 2,0 grams (S0)

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)

Dihydroergocristine.

Dilevalol.

Diltiazem.

Dimercaprol, when intended for injection.

Dipivefrin.

Dipyridamole.

Dipyrocetyl.

Disulfiram.

Dithranol.

Dornase alfa (rh DNase).

Dorzolamide.

Doxazosin.

Drospirenone,

a. when intended for oral contraception;
b. except when intended for hormone replacement therapy. (S4)

Eltenac.

Enalapril.

Endralazine.

(-)-6 epigallocatechin gallate.

Eprosartan.

Ergocalciferol—see Vitamin D.

Escin (aescin), except preparations and mixtures thereof intended for application to the skin and containing 1 percent or less of escin. (S1)

Esculin, when intended for oral use.

Esmolol.

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)

Estriol,

a. when intended for oral contraception;
b. except when intended for human vaginal use; (S2)
c. except when intended for hormone replacement therapy. (S4)
d. except when intended for veterinary use. (S4)

Ethacrynic acid.

Ethosuximide.

Etisazol.

Etodolac.

Etodolic acid.

Etofenamate, except when intended for application to the skin. (S1)

Etofenprox (Pyrethroid), except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Etoricoxib.

Exenatide.

Felbamate.

Felbinac, except when intended for application to the skin. (S1)

Felodipine.

Fenbufen.

Fenclofenac.

Fendiline.

Fenofibrate.

Fenoprofen,

a. except when intended for the emergency treatment of acute gout attacks, (S2) and
b. when intended for the treatment of post traumatic conditions, for a maximum treatment period of 5 days (S2)

Fenoterol, when contained in respirator solutions (S2, S4)

Fentiazac.

Fenticonazole, except when intended for application to the skin. (S1)

Firocoxib.

Floctafenine.

Flufenamic acid, except preparations and mixtures intended for application to the skin. (S1)

Fluorescein, except when intended for ophthalmic use by the topical route only. (S1)

Flunisolide, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurised aerosol, in a strength not exceeding 0,025 percent (m/v), and indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—

a. a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms of per nostril in the case of adults and children over 16 years of age;
b. a maximum dose of 25 micrograms per nostril and a maximum dose of 75 micrograms in children 12 to 16 years of age;
c. a maximum pack size of 2400 doses (S2, S4)

Flunixin.

Flurbiprofen, except

a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S3)
b. when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
    (i) a maximum of 8,75 milligrams per lozenge;
    (ii) a maximum treatment period of 3 days; and
    (iii) a maximum pack size of 15 lozenges (S1)
c. except when intended for application to the skin and indicated for the symptomatic relief of localised pain and inflammation, provided that in the case of application by transdermal patch:
    (i) use is restricted to adults and children 12 years and older; and
    (ii) the treatment period is limited to a maximum of 4 weeks (S0)
d. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)
e. when intended for ophthalmic use; (S4)

Fluticasone furoate,

a. when intended for inhalation or nasal administration;
b. except when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—
    (i) a maximum daily dose of 55 micrograms per nostril; and
    (ii) a maximum pack size limit of 120 doses (S2)
c. except when intended for administration other than by inhalation or nasal administration. (S4)

Fluticasone propionate,

a. when intended for inhalation or nasal administration;
b. except when intended for nasal administration as an aqueous spray, in the short-term (less than 6 months prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—
    (i) a maximum daily dose of 100 micrograms per nostril; and
    (ii) a maximum pack size of 120 doses (S2)
c. except when intended for administration other than by inhalation or nasal administration. (S4)

Folinic acid (leucovorin).

Fosinopril.

Frusemide.

Gabapentin.

Gadoxetic acid.

Gelatine succinylated.

Gemfibrozil.

Gestodene.

Glafenine.

Glibenclamide.

Glibornuride.

Gliclazide.

Glimepiride.

Glimidine.

Glipizide.

Gliquidone.

Glucosamine, substances, preparations and mixtures when intended for the treatment of primary and secondary osteoarthritis, osteochondrosis and spondylosis, except when registered as a feed supplement in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Glutathione, when intended for intravenous infusion or for injection. (S0)

Glycopyrronium.

Guanabenz.

Guanethidine.

Guanfacine.

Guanoxan.

Hexoprenaline, when contained in respirator solutions (S2, S4)

Homatropine; ophthalmic preparations thereof. (S2)

Hormones (natural or synthetic, including recombinant forms), with either hormonal, prohormonal or anti-hormonal action, unless listed elsewhere in the Schedules;

a. when intended for oral contraception;
b. except when intended for human vaginal use (S2), and
c. except hormones when specifically intended for emergency postcoital contraception. (S2, S4, S5)

Hydralazine.

Hydrochlorothiazide.

Hydroquinone; preparations and mixtures thereof containing more than 2,0 percent hydroquinone. (S2)

Hydroxypropyl methylcellulose when intended for opthalmic use (S0)

Hyoscine butylbromide; substances, preparations and mixtures thereof—

a. except when intended for oral administration; (S1, S2) and
b. except transdermal preparations when intended for the prevention of the symptoms of motion sickness.(S2)

Ibuprofen, except

a. when contained in preparations intended for application to the skin, containing 5 % m/m or less of ibuprofen; (S0, S1)
b. when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not
c. exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults

does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)

d. when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

e. when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days; or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

f. for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

g. when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S4)

h. Imepitoin, when intended for veterinary use.

Imidapril.

Indacaterol.

Indapamide.

Indometacin, except

a. for application to the skin (S1), and

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

Indoprofen.

Indoramin.

Injections, unless listed in another Schedule.

Insulin.

Insulin aspart.

Insulin degludec.

Insulin Glargine.

Ipratropium, when contained in respirator solutions (S2)

Irbesartan.

Iron,

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than 24 mg of elemental iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
c. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Iron salts, when intended for injection, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Isoprenaline (isoproterenol), when contained in respirator solutions (S2, S4)

Isosorbide.

Isoxicam.

Isradipine.

Ivabradine.

Ivermectin, except when intended and registered as an anthelmintic and/or ectoparasiticide in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Ketanserin.

Ketoprofen,

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

b. except when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, subject to a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)

c. except when intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions, subject to a maximum dose of 75milligrams of ketoprofen per day and a maximum treatment period of 5 days; (S2)

d. except in the form of lozenges indicated and intended for the relief of pain associated with sore throats in patients 18 years and older subject to—

(v) a maximum of 12,5 milligrams per lozenge;

(vi) a maximum of 5 lozenges in any 24 hour period;

(vii) a maximum treatment period of 3 days; and

(viii) a maximum pack size of 15 lozenges (S2)

[Numbering as published in original Gazette.]

Ketorolac when intended for ophthalmic use. (S4)

Labetalol.

Lacidipine.

Lacosamide.

Lumiracoxib.

Lamotrigine.

Lercanidipine.

Levalbuterol.

Levothyroxine.

Levetiracetam.

Levobunolol.

Levonorgestrel,

a. when intended for oral contraception

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

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

Levosemindan.

Lidoflazine.

Linagliptin.

Liothyronine sodium.

Lisinopril.

Lonazolac.

Lornoxicam.

Losartan.

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

Meclofenamic acid.

Mefenamic acid, except—

a. when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; and
b. preparations containing mefenamic acid as the only therapeutic active substance, when intended for human use only in the treatment of primary dysmenorrhoea subject to a maximum daily dose of 500 milligrams mefenamic acid 3 times a day and a maximum treatment period of 3 days (S2)

Meloxicam. (S4)

Mepindolol.

Mesalazine (5-aminosalicylic acid).

Mesulphene.

Metaproterenol (orciprenaline), when contained in respirator solutions (S2, S4)

Metformin.

Methazolamide.

Methimazole.

Methsuximide.

Methyldopa.

Metipranolol.

Metolazone.

Metoprolol.

Mibefradil.

Mirabegron.

Moexipril.

Mometasone furoate, when intended for inhalation or nasal administration, except when intended for nasal administration as an aqueous spray, other than by pressurized aerosol, and indicated for the treatment of the symptoms of seasonal or perennial allergic rhinitis (hay fever) in adults and children between the age of 2 and 11 years of age, subject to—

a. a maximum dose of 200 micrograms per nostril in adults and 50 micrograms per nostril in children; and

b. a maximum pack size of 200 doses (S2, S4)

Montelukast.

Moxonidine.

Nabumetone, except when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days (S2)

Nadolol.

Naftidrofuryl.

Naproxen, except

a. when contained in preparations intended for application to the skin; (S1, S2)
b. when contained in oral medicinal preparations, intended for human use only 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, 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)

Nateglinide.

Nebivolol.

Nepafenac.

Nicardipine.

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 and 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 21 mg/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; (S1)
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)

Nifedipine.

Niflumic acid.

Nimodipine.

Nisoldipine.

Nitrendipine.

Nitroglycerine, when intended for medicinal use.

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)

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)

Olsalazine.

Omesartan.

Orlistat, except when used in a dose not exceeding 60mg per main meal and not exceeding a maximum dose of 180mg per 24-hour period. (S2)

Oxaprozin.

Oxcarbazepine.

Oxitracetam.

Oxovinca.

Oxyprenolol.

Oxybutynin.

Pantothenic Acid—see Vitamin B5.

Parecoxib.

Para-aminosalicylic acid and its esters.

Paracetamol, when intended for injection. (S0, S1, S2)

Parenteral Nutrition formulations.

Penbutolol.

Penicillinase, when intended for injection.

Pentaerythritol tetranitrate.

Pentolinium.

Pentosan polysulfate sodium, when intended for the treatment of interstitial cystitis (S1)

Perindopril.

Phenformin.

Phenobarbital, preparations and mixtures containing not more than 90 milligrams of phenobarbital per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S5)

Phenoxymethylpenicillin, when intended for the prophylaxis of rheumatic fever. (S4)

Phentolamine.

Phenytoin.

Physostigmine; ophthalmic preparations thereof, when intended for glaucoma. (S4)

Pilocarpine; ophthalmic preparations thereof intended for glaucoma. (S4)

Pindolol.

Pioglitazone.

Piracetam.

Pirbuterol, when contained in respirator solutions (S2)

Piretanide.

Piroxicam, except:

a. when intended for the emergency treatment of acute gout attacks, for a maximum treatment period of 5 days; and
b. when intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days (S2)

Pirprofen.

Potassium canrenoate.

Potassium,

a. when intended for intravenous infusion or for injection;
b. except when contained in oral rehydration preparations; (S0)
c. except in oral preparations or mixtures containing more than 20 millimoles (1500mg) of potassium per 24 hours (S2)

Practolol.

Prazosin.

Primidone.

Probenecid.

Probucol.

Procaterol, when contained in respirator solutions (S2)

Proctofene.

Propacetamol.

Propiverine.

Propranolol.

Proquazone.

Proscillaridine.

Protamine.

Prothionamide, when intended for oral use.

Pygeum africanum (lipido-sterolic complex extract thereof).

Pyrazinamide, when intended for oral use.

Pyridoxine—see Vitamin B6.

Pyrimethamine.

Pyrithioxin.

Quinapril.

Racecadotril.

Raloxifene.

Ramipril.

Ranitidine, except where administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to a maximum dose of 75 milligrams, a maximum daily dose of 300 milligrams and a maximum treatment period of two weeks (S2)

Raubasine.

Rauwolfia alkaloids.

Repaglinide.

Reproterol, when contained in respirator solutions (S2)

Reserpine (natural or synthetic).

Riboflavin -see Vitamin B2.

Rimiterol, when contained in respirator solutions (S2, S4)

Risedronate.

Rofecoxib.

Rosiglitazone.

Roxarzone (3-nitro-4-hydroxyphenylarsonic acid), when intended for veterinary use.

Sacubitril.

Salbutamol, when contained in respirator solutions (S2, S4)

Salmefamol, when contained in respirator solutions (S2, S4)

Saxagliptin.

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)

Solcoseryl; ophthalmic preparations thereof. (S0, S4)

Solifenacin.

Sotalol.

Spirapril.

Spironolactone.

Strontium, except when contained in toothpaste. (S0)

Strophanthus; its glycosides and their hydrolysis products, and their derivatives, unless listed in another Schedule.

Sulindac.

Suloctidil.

Sulphinpyrazone.

Sulthiame.

Suprofen.

Sylimarin—see (Silimarin).

Tasosartan.

Tazarotene.

Telmisartan.

Tenidap.

Tenoxicam.

Tepoxalin.

Terazosin.

Terbutaline, when contained in respirator solutions (S2)

Terizidone.

Terodiline.

Theodrenaline—see Noradrenaline theophylline.

Thiacetazone.

Thiamine—see Vitamin B1.

Thiocolchicoside.

Thyroid gland and its active principles and derivatives, unless listed in another Schedule.

Tiagabine.

Tiaprofenic acid, except when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days (S2)

Ticagrelor.

Ticlopidine.

Timolol.

Tiotropium.

Tolamolol.

Tolazamide.

Tolbutamide.

Tolfenamic acid.

Tolmetin, except when intended for application to the skin. (S1)

Tolterodine.

Topiramate.

Torasemide.

Trandolapril.

Tretinoin, when intended for application to the skin. (S5)

Triamterene.

Tricaine.

Trifarotene.

Trimethadione.

Tropicamide.

Tulobuterol, when contained in respirator solutions (S2)

Umeclidinium.

Ursodeoxycholic acid.

V. cholera.

Valdecoxib.

Valproic acid and its derivatives, unless listed in another Schedule.

Valsartan.

Vedaprofen.

Verapamil (iproveratril).

Veratrum alkaloids.

Vigabatrin.

Vildagliptin.

Vincamine.

Vinpocetine.

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 B1 (Thiamine) and derivatives thereof,

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Vitamin B2 (Riboflavin) and derivatives thereof,

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Vitamin B3—See Niacin.

Vitamin B5 (Pantothenic Acid) and derivatives thereof,

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Vitamin B6 (Pyridoxine) and derivatives thereof,

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Vitamin B12 (Cyanocobalamin) and derivatives thereof,

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Vitamin C (Ascorbic Acid),

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than 100 mg of Vitamin B1 per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Vitamin D (cholecalciferol), preparations thereof for injection and oral preparations and mixtures thereof containing more than 1 000 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).(S0)

Vitamin K and derivatives thereof,

a. in injection preparations; (S0)
b. except in oral preparations or mixtures containing more than 120 µg of Vitamin K per recommended daily dose alone or in combination with other active pharmaceutical ingredients, (S1)
c. except when used in infant milk feeds or formulae in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

Water for injection except in a dosage form not exceeding 20 millilitres in volume. (S1)

Xamoterol.

Xipamide.

Zafirlukast.

Zinc salts,

a. for oral ingestion, where the daily dose is more than 50 milligrams of elemental zinc; (S0),

b. except preparations thereof for injection, when intended for veterinary use; (S1) and

c. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Zomepirac.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Schedule 3 Annexure 1A added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021.]

PARAMEDIC (National Diploma in Emergency Medical Care graduates only) registered with Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates only)

PLATELET AGGREGATION INHIBITOR
Substance : Clopidogrel
Indication : Platelet aggregation inhibitor
Schedule : 3
Route of Administration : Oral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Dextran
Indication : Plasma expanders
Schedule : 3
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Hydroxyethyl Starch
Indication : Plasma expanders
Schedule : 3
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Sodium Chloride
Indication : Plasma expanders
Schedule : 3
Route of Administration : Parenteral

PARAMEDIC (National Diploma in Emergency Medical Care graduates only)

SELECTIVE β2 AGONISTS

Substance : Salbutamol
Indication : Bronchodilator
Schedule : 3
Route of Administration : Inhalant

SELECTIVE β2 AGONISTS

Substance : Fenoterol
Indication : Bronchodilator Treatment
Schedule : 3
Route of Administration : Inhalant

MINERAL SUPPLEMENT/ELECTROLYTE

Substance : Calcium Chloride
Indication : Positive inotrope- peri-cardiac and cardiac arrest / Electrolyte / Mineral Supplement
Schedule : 3
Route of Administration : Parenteral

OTHER MINERAL SUPPLEMENT

Substance : Magnesium sulphate
Indication : Mineral supplement; prevention and control of seizures and hypertension in toxaemia of pregnancy
Schedule : 3
Route of Administration : Parenteral

CARBOHYDRATES

Substance : Dextrose
Indication : Nutrition / Acute Symptomatic Hypoglycaemic
Schedule : 3
Route of Administration : Parenteral

HIGH CEILING LOOP DIURETIC

Substance : Furosemide
Indication : Diuretic
Schedule : 3
Route of Administration : Parenteral

ORGANIC NITRATES

Substance : Glyceryl Trinitrate
Indication : Vasodilator
Schedule : 3
Route of Administration : Oral

PARAMEDIC (National Diploma in Emergency Medical Care graduates only)

ANTI-EMETIC

Substance : Cyclizine
Indication : Antihistamine, anti-emetic
Schedule : 3
Route of Administration : Parenteral

CO-ENZYME

Substance : Thiamine (Vitamin B1)
Indication : Nutritional supplement/Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Schedule : 3
Route of Administration : Parenteral

ANALGESIC

Substance : Paracetamol
Indication : Analgesic/Anti-pyrexia
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Ringers Lactate
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Polygeline
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Sodium Bicarbonate 8,5 %
Indication : Metabolic acidosis

Route of Administration : Parenteral

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Schedule 3 Annexure 1B added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE PRACTITIONER

(Bachelor of Technology Degree in Emergency Medical Care) registered with Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)

PLATELET AGGREGATION INHIBITOR
Substance : Clopidogrel
Indication : Platelet aggregation inhibitor
Schedule : 3
Route of Administration : Oral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Dextran
Indication : Plasma expanders
Schedule : 3
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Hydroxyethyl Starch
Indication : Plasma expanders
Schedule : 3
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Sodium Chloride
Indication : Plasma expanders
Schedule : 3
Route of Administration : Parenteral

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)

SELECTIVE β2 AGONISTS
Substance : Salbutamol

Indication : Bronchodilator Treatment
Schedule : 3
Route of Administration : Inhalant

SELECTIVE β2 AGONISTS
Substance : Fenoterol
Indication : Bronchodilator
Schedule : 3
Route of Administration : Inhalant

MINERAL SUPPLEMENT/ELECTROLYTE
Substance : Calcium Chloride
Indication : Positive inotrope- peri cardiac and cardiac arrest / Electrolyte / Mineral Supplement
Schedule : 3
Route of Administration : Parenteral

OTHER MINERAL SUPPLEMENTS
Substance : Magnesium sulphate
Indication : Mineral supplement; prevention and control of seizures and hypertension in toxaemia of pregnancy
Schedule : 3
Route of Administration : Parenteral

CARBOHYDRATES
Substance : Dextrose
Indication : Nutrition / Acute Symptomatic Hypoglycaemic
Schedule : 3
Route of Administration : Parenteral

HIGH CEILING LOOP DIURETIC
Substance : Furosemide
Indication : Diuretic
Schedule :3
Route of Administration : Parenteral

ORGANIC NITRATES
Substance : Glyceryl Trinitrate
Indication : Vasodilator
Schedule : 3

Route of Administration : Oral

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)

ANTI-EMETIC
Substance : Cyclizine
Indication : Antihistamine, anti-emetic
Schedule : 3
Route of Administration : Parenteral

CO-ENZYME
Substance : Thiamine (Vitamin B1)
Indication : Nutritional supplement/Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Schedule : 3
Route of Administration : Parenteral

ANALGESIC
Substance : Paracetamol
Indication : Analgesic/Anti-pyrexia
Route of Administration : Parenteral

*ANTI-SPASMODIC
Substance : Hyoscine butylbromide
Indication : Anti-spasmodic
Route of Administration : Parenteral

**ARTERIAL SMOOTH MUSCLE AGENT
Substance : Hydralazine
Indication : Hypertension.in pregnancy
Route of Administration : Oral

BETA BLOCKER
Substance : Labetalol
Indication : Hypertension.in pregnancy
Route of Administration : Parenteral

**CLASS III ANTI-ARRHYTHMIC
Substance : Sotalol
Indication : Anti-arrhythmic

Route of Administration : Oral/Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Ringers Lactate
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Polygeline
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Sodium Bicarbonate 8,5 %
Indication : Metabolic acidosis
Route of Administration : Parenteral

**VASODILATOR
Substance : Isosorbide dinitrate
Indication : Acute pulmonary Syndrome/Acute pulmonary oedema
Route of Administration : Parenteral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

[Schedule 3 Annexure 1C added by GNR 1375 in G. 44019 of 18 December 2020.]

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa

*SELECTIVE β2 AGONISTS
Substance : Salbutamol
Indication : Bronchodilator
Route of Administration : Inhalant

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

[Schedule 3 Annexure 1D added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 883 in G. 45176 of 17 September 2021.]

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Dextran
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Hydroxyethyl Starch
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Sodium chloride
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Ringers Lactate
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Polygeline
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Sodium Bicarbonate 8,5 %
Indication : Metabolic acidosis
Route of Administration : Parenteral

*CARBOHYDRATES

Substance : Dextrose

Indication : Nutrition/Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics

Route of Administration : Parenteral

*CO-ENZYME

Substance : Thiamine (Vitamin B1)

Indication : Nutritional supplement/Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)

Route of Administration : Parenteral

*OTHER MINERAL SUPPLEMENTS

Substance : Magnesium sulphate

Indication : Mineral supplement; prevention and control of seizures and hypertension in toxaemia of pregnancy

Route of Administration : Parenteral

SELECTIVE β2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Inhalant

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

[Schedule 3 Annexure 1E added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Dextran

Indication : Plasma expanders

Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Hydroxyethyl Starch

Indication : Plasma expanders

Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Sodium chloride
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Ringers Lactate
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Polygeline
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS
Substance : Sodium Bicarbonate 8,5 %
Indication : Metabolic acidosis
Route of Administration : Parenteral

*CARBOHYDRATES
Substance : Dextrose
Indication : Nutrition/Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics
Route of Administration : Parenteral

*CO-ENZYME
Substance : Thiamine (Vitamin B1)
Indication : Nutritional supplement/Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Route of Administration : Parenteral

OTHER MINERAL SUPPLEMENTS
Substance : Magnesium sulphate
Indication : Mineral supplement; prevention and control of seizures and hypertension in toxaemia of pregnancy. Ventricular anti-arrhythmic
Route of Administration : Parenteral

ORGANIC NITRATES

Substance : Glyceryl trinitrate

Indication : Vasodilator

Route of Administration : Oral

SELECTIVE β2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Inhalant

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

[Schedule 3 Annexure 1F added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Dextran

Indication : Plasma expanders

Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Hydroxyethyl Starch

Indication : Plasma expanders

Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Sodium chloride

Indication : Plasma expanders

Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Ringers Lactate

Indication : Plasma expanders

Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Polygeline
Indication : Plasma expanders
Route of Administration : Parenteral

PLASMA SUBSTITUTES AND COLLOID SOLUTIONS

Substance : Sodium Bicarbonate 8,5 %
Indication : Metabolic acidosis
Route of Administration : Parenteral

*CARBOHYDRATES

Substance : Dextrose
Indication : Nutrition/Acute Symptomatic Hypoglycaemic Treatment in adults and paediatrics
Route of Administration : Parenteral

*CO-ENZYME

Substance : Thiamine (Vitamin B1)
Indication : Nutritional supplement/Vitamin B (Emergency treatment of Wernicke's encephalopathy and Beriberi)
Route of Administration : Parenteral

OTHER MINERAL SUPPLEMENTS

Substance : Magnesium sulphate
Indication : Mineral supplement; prevention and control of seizures and hypertension in toxaemia of pregnancy
Route of Administration : Parenteral

SELECTIVE β2 AGONISTS

Substance : Salbutamol
Indication : Bronchodilator
Route of Administration : Inhalant

ANNEXURE 3: OPTOMETRIST

[Schedule 3 Annexure 3 added by GN 620 in G. 40041 of 3 June 2016; amended by GN 748 in G. 41009 of 28 July 2017, GNR 219 & GNR 220 in G. 43051 of 28 February 2020.]

OPTOMETRIST (Bachelor's 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 recognised by the Health Professions Council of South Africa as an authorised prescriber.

OPTOMETRIST

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)

BETA-BLOCKER

Substance : Betaxolol

Indication : Open-Angle Glaucoma in Adults

Route of Administration : Topical Application (Drops)

SYMPATHOMIMETIC

Substance : Brimonidine

Indication : Open-Angle Glaucoma in Adults

Route of Administration : Topical Application (Drops)

BETA-BLOCKER

Substance : Levobunolol

Indication : Open-Angle Glaucoma in Adults

Route of Administration : Topical Application (Drops)

ANNEXURE 4: PODIATRIST

[Schedule 3 Annexure 4 added by GNR 220 in G. 43051 of 28 February 2020; amended by GNR 1375 in G. 44019 of 18 December 2020.]

PODIATRIST registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974).

PODIATRIST

SYMPATHOMIMETIC

Substance : Adrenaline/Epinephrine

Indication : Sympathomimetic catecholamine for the management of shock

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Bupivacaine Hydrochloride 2 %

Indication : Local Anaesthesia

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Bupivacaine Hydrochloride 2 % with Adrenaline

Indication : Local Anaesthesia

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Levobupivacaine Hydrochloride with Adrenaline

Indication : Local Anaesthesia

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Lidocaine (Lignocaine) Hydrochloride

Indication : Local Anaesthesia

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Lidocaine (Lignocaine) Hydrochloride with Adrenaline

Indication : Local Anaesthesia

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Mepivacaine Hydrochloride

Indication : Local Anaesthesia

Route of Administration : Parenteral

SCHEDULE 4

[Schedule 4 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, GNR 2082 of 5 November 1976; amended by GNR 279 of 25 February 1977, GNR 437 of 1 April 1977, GNR 1194 of 1 July 1977, GNR 1674 of 18 August 1978 (as amended GNR 2410 of 8 December 1978), GNR 1926 of 31 August 1979, GNR 658 of 27 March 1981, GNR 2416 of 12 November 1982, GNR 1289 of 14 June 1985, GN 154 of 31 January 1986; substituted by GN 225 of 17 February 1989; amended by GNR 2841 of 7 December 1990, GNR 2169 of 6 September 1991, GNR 580 of 21 February 1992, GNR 141 of 5 February 1993, GNR 775 of 7 May 1993; repealed, inserted, amended by s 21 of Act 94 of 1991; amended by GNR 1556 of 16 September 1994, GNR 673 of 12 May 1995, GNR 42 of 19 January 1996, GNR 1496 of 13 September 1996, GNR 1203 of 15 October 1999, GNR 1077 of 3 November 2000; repealed by s 27 of Act 90 of 1997; inserted by GNR 509 in G. 24727 of 10 April 2003; substituted by GN 935 in G. 31387 of 5 September 2008, GNR 1230 in G. 32838 of 31 December 2009; amended by GNR 227 in G. 35149 of 15 March 2012, GNR 674 in G. 36827 of 13 September 2013, GNR 690 in G. 36850 of 20 September 2013, GNR 104 in G. 37318 of 11 February 2014, GNR 352 in G. 37622 of 8 May 2014, GNR 234 in G. 38586 of 20 March 2015, GN 254 in G. 39815 of 15 March 2016, GN 620 in G. 40041 of 3 June 2016, GN 748 in G. 41009 of 28 July 2017, GN 1261 in G. 41256 of 17 November 2017, GNR 1098 in G. 41971 of 12 October 2018, GNR 1262 in G. 42052 of 23 November 2018, GNR 755 in G. 42477 of 23 May 2019, GNR 219 & GNR 220 in G. 43051 of 28 February 2020, GNR 586 in G. 43347 of 22 May 2020, GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176

of 17 September 2021, GN 2685 in G. 47373 of 28 October 2022, GNR 3261 in G. 48358 of 24 March 2023, GN 6466 in G. 53099 of 1 August 2025.]

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.

[Numbering as published in original Gazette.]

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 Authority, 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)
   Annexure 1B: Emergency Care Provider (Emergency Care Practitioner)
   Annexure 1C: Basic Ambulance Assistant
   Annexure 1D: Ambulance Emergency Assistant
   Annexure 1E: Emergency Care Technician
   Annexure 1F: Emergency Care Assistant
   (ii) Annexure 2: Dental Therapist
   (iii) Annexure 3: Optometrist.
   (iv) Annexure 5: Oral Hygienists

[Annexures numbering as published in original Gazette.]

Abacavir.

Abatacept.

Abciximab.

Abemaciclib.

Abiraterone.

Acalabrutinib.

Acarbose.

Acediasulfone.

Acetarsone diethylamine salt, when intended for injection.

Acyclovir, except when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections (S1)

Adalimumab.

Adenosine.

Adrenaline, when intended for injection. (S2, S3)

Afatinib.

Agalsidase alfa.

Agalsidase beta.

Aglepristone.

Alatrofloxacin.

Albendazole,

a. except when intended for the treatment of intestinal parasites as a single oral dose; (S2)
b. except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Albutrepenonacog alfa.

Alclometasone.

Alcuronium.

Aldesleukin.

Alectinib.

Alefacept.

Alemtuzumab.

Alfuzosin.

Alglucosidase alfa.

Alginic Acid, its salts and complexes thereof, when intended for use in gastric regurgitation, gastro-oesophageal reflux and reflux associated with hiatus hernia in infants and young children under the age of 6 years (S0)

Alirocumab.

Alizapride.

Almitrine.

Alosetron.

Alfacalcidol.

Alpelisib.

Alphachymotrypsin (a-chymotrypsin), when intended for ophthalmic use.

Alprostadil.

Alteplase (recombinant human tissue-type plasminogen activator) (r-tPA).

Altrenogest for use in animals.

Amantadine.

Ambrisentan.

Amethocaine,—see Tetracaine.

Amifostine.

Amikacin.

Aminoacridine.

Aminoglutethimide.

Aminolevulinic.

Aminophenazone.

Aminopyrine (amidopyrine).

Aminosalicylic acid.

Amiodarone.

Amiphenazole.

Amivantamab.

Amodiaquine.

Amoxicillin.

Ampicillin except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

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

Amphotericin B.

Amprenavir.

Amrinone.

Amsacrine.

Anagrelide.

Anastrozole.

Anecortave.

Anidulafungin.

Anticoagulants, except preparations intended for application to the skin. (S1)

Antihemophilic factor.

Antimalarials, unless listed elsewhere in the Schedules.

Antimicrobial substances, natural or synthetic including substances purporting to be suitable for the treatment of microbial infections unless listed elsewhere in the Schedules, and except—

a. the following substances when intended for topical application to the epidermis, nares and external ear:
    (i) bacitracin; (S1)
    (ii) gramicidin; (S1)
    (iii) griseofulvin; (S2)
    (iv) mupirocin; (S2)
    (v) natamycin; (S2)
    (vi) polymyxin B; (S1)
    (vii) tyrothricin; (S1)
b. when intended for use as—
    (i) disinfectants, being topical agents or preparations used to treat inanimate objects, materials or surfaces, and that destroys or inhibits the growth of pathogenic micro-organisms so treated in the non-sporing or vegetative state, rendering them harmful to neither health nor the quality of perishable goods; (S0)
    (ii) antiseptics, being topical agents or preparations used on skin and other living tissues, and that destroys or inhibits the growth of pathogenic micro-organisms so

treated in the non-sporing or vegetative state, protecting health and preventing infection; (S0) and

(iii) germicides, being topical agents or preparations used to treat inanimate objects, materials or surfaces and/or on skin and other living tissues, destroying or killing pathogenic micro-organisms so treated in the non-sporing or vegetative state, thereby protecting health, the quality of perishable goods, and preventing infection. (S0)

Antisera, unless listed elsewhere in the Schedules when intended for veterinary use, except antisera registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Apalutamide.

Apixaban.

Apomorphine, when indicated for the treatment of erectile dysfunction. (S2)

Apraclonidine.

Apramycin.

Apremilast.

Aprotinin.

Aprepitant.

A-b arteetheR

Arabinosylcytosine.

Arprinocid, except when intended and registered as an anticoccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Arsenamide, when intended for injection.

Arsenic,

a. when intended for injection;

b. except in oral dosage form. (S1, S2)

Artemether and its derivatives.

Artemisinin.

Artemotil.

Artesunate.

Asciminib.

L-Asparaginase.

Astemizole.

AtazanaviR

Atezolizumab.

Atipamizole.

Atorvastatin.

Atosiban.

Atovaquone, except when co-formulated with the proguanil and intended and labelled for the chemoprophylaxis of malaria in those weighing 11 kilograms or more. (S2)

Atracurium besilate.

Atropine,

a. when intended for use in injections (S2)
b. except when intended for use in ophthalmic preparations (S3)

Auranofin.

Avilamycin, except when listed elsewhere in the Schedules and 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).

Avoparcin, except when listed elsewhere in the Schedules and 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).

Axitinib.

Azacitidine.

Azathioprine.

Azithromycin.

Azlocillin.

Aztreonam.

Baclofen.

Bacitracin, except when intended for topical application to the epidermis, nares and external ear. (S1) and except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Baloxavir.

Bambermycin, except when listed elsewhere in the Schedules and 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).

Baricitinib.

Barium sulfate.

Basiliximab.

Bacampicillin.

Bazedoxifene.

Beclomethasone dipropionate, except when intended for inhalation or nasal administration. (S3)

Bedaquiline.

Bedinvetmab.

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

Belatacep.

Belimumab.

Bemegride.

Bemiparin.

Bendamustine.

Benethamine penicillin.

Benralizumab.

Benzathine benzylpenicillin.

Benzathine phenoxymethylpenicillin.

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)

Benzylpenicillin.

Besifloxacin.

Betamethasone.

Bethanechol.

Betiatide.

Bevacizumab.

Bicalutamide.

Bictegravir.

Bifonazole, except when intended for application to the skin. (S1)

Bimatoprost.

Biolimus.

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 IqG, IqA, or IqM;

(viii) Human plasma albumin;

(ix) Neiserria meningitides 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.

Biperiden.

Bleomycin.

Blinatumomab.

Boceprevir.

Bortezomib.

Botulinum toxin.

Brentuximab.

Bretylium tosilate.

Brigatinib.

Brolucizumab.

Bromocriptine.

Budesonide,

a. except when intended for the prophylaxis and treatment of seasonal and perennial allergic rhinitis in adults and children aged 12 years and older; (S2)
b. except when intended inhalation or nasal administration, unless listed in another Schedule. (S3)

Bufenoide.

Bumadizone.

Bupivicaine.

Buserelin.

Busulfan.

Butoconazole, except—

a. when intended for application to the skin; (S1) and

b. when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1)

Cabazitaxel.

Cabergoline.

Cabotegravir.

Cabozantinib.

Calcitonin.

Calcitriol.

Calcium,

a. when indicated for the treatment of hyperphosphataemia; (S0)
b. except in oral preparations or mixtures containing more than1300 mg of calcium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)
c. except in preparations thereof for injection; (S3)
d. except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Calcium acetate, when indicated for treatment of hyperphosphataemia.

Cambendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Canakinumab.

Carglumic.

Carnidazole, except when listed elsewhere in the Schedules and except injections thereof intended for use in pigeons and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Candicidin.

Cannabidiol, except—

a. in complementary medicines containing no more than 600 mg cannabidiol per sales pack, providing a maximum daily dose of 20 mg of cannabidiol, and making a general health enhancement, health enhancement or relief of minor symptoms (low-risk) claim; (S0) or
b. processed products made from cannabis raw plant material intended for ingestion containing 0,0075 percent or less of cannabidiol where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product. (S0)

Capecitabine.

Capreomycin.

Capsaicin, when intended for transdermal application.

Carbachol, except ophthalmic preparations thereof, when intended for glaucoma. (S3)

Carbadox, except when listed elsewhere in the Schedules and 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).

Carbenicillin.

Carbetocin.

Carbidopa.

Carboplatin.

Carbuterol, when intended for injection. (S2, S3)

Carfilzomib.

Carmustine.

Capreomycin.

Casirivimab.

Caspofungin.

Casopitant.

Catridecacog.

Cefaclor.

Cefadroxil.

Cefalexin.

Cefaloridine.

Cefalosporin.

Cefalotin.

Cefamandole.

Cefazolin.

Cefepime.

Cefguinome.

Cefixime.

Cefmetazole.

Cefodizime.

Cefonicid.

Cefoperazone.

Cefotaxime.

Cefotetan.

Cefovecin.

Cefoxitin.

Cefpirome.

Cefpodoxime.

Cefprozil.

Cefradine.

Cefsulodin.

Ceftaroline.

Ceftazidime.

Ceftibuten.

Ceftiofur.

Ceftizoxime.

Ceftobiprole.

Ceftolozane.

Ceftriaxone.

Cefuroxime.

Cefalotin.

Ceritinib.

Cerivastatin.

Certoparin.

Ceruletide.

Cetrorelix.

Cetuximab.

Chlorambucil.

Clodantoin.

Chlormadinone.

Chlormethine.

Chloroquine.

Choriogonadotropin alfa.

Chorionic gonadotrophin.

Chloramphenicol.

Chlorguinaldol.

Chlortetracycline, except when listed elsewhere in the Schedules and except injections thereof intended 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).

Chymopapain, when intended for injection.

Ciclacillin.

Cilastatin.

Ciclosporin.

Cinacalcet.

Cinoxacin.

Ciplofloxacin.

Ciprofloxacin.

Cisapride.

Cisatracurium.

Cisplatin.

Cladribine.

Clanobutin.

Clarithromycin.

Clavulanic acid.

Clazuril, except when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Clemizole penicillin.

Clenbuterol.

Clioquinol.

Clindamycin.

Clobetasol.

Clobetasone.

Clofazimine.

Clomifene.

Cloprostenol, when intended for veterinary use.

Closantel, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Clotrimazole, except when intended for application to the skin (S1) and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1)

Cloxacillin, except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Cobimetinib.

Cobicistat.

Colfosceril.

Colistimethate.

Colistin,

a. when presented as a finished pharmaceutical product; and
b. except when compounded by a pharmacist in terms of section 14(4) of the Act, a veterinarian, or by a holder of a section 22C(1)(a) licence, or presented as the raw material. (S6)

Contrast media, unless listed elsewhere in the Schedules.

Copper,

a. in preparations thereof for injection; (S0)
b. except in oral preparations or mixtures containing more than 4 mg of Copper per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Corifollitropin alfa.

Corticosteroids (natural or synthetic), unless listed elsewhere in the Schedules, except—

a. triamcinolone when intended for application to oral lesions; (S2) and
b. when contained in preparations intended for nasal administration. (S2, S3)

Co-tetroxazine.

Co-trifamole.

Co-trimoxazole.

Crisaborole.

Crisanlizumab.

Crizotinib.

Cyclofenil.

Cyclophosphamide and its derivatives, unless listed in another Schedule.

Cycloserine.

Cyprenorphine.

Cyproterone acetate.

Cytarabine.

Dabigatran.

Dabrafenib.

Dacarbazine.

Dacliximab.

Daclizumab.

Dacomitinib.

Dactinomycin.

Dalteparin.

Danaparoid.

Danofloxacin.

Dantrolene.

Dapagliflozin.

Dapivirine.

Dapsone and its derivatives, unless listed elsewhere in the Schedules.

Daptomycin.

Daratumumab.

Darbepoetin Alfa.

Darolutamide.

Darunavir.

Dasatinib.

Daunorubicin.

Decitabine.

Deconexent (DHA) 380, when indicated for the treatment of hypertriglyceridaemia.

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

Deferasirox.

Deferipone.

Deferiprone.

Deferoxamine.

Degarelix.

Demecarium.

Demeclocycline.

Denosumab.

Deoxycholic acid.

Desirudin.

Deslorelin.

Desmopressin.

Desonide.

Desoximetasone.

Dexamethasone.

Dexlansoprazole.

Diatrizoic acid.

Diazoxide.

Dichlorophen,

a. except in preparations and mixtures when intended for application to the skin; (S0)
b. except in preparations containing 0,5 percent or less of dichlorophen when intended for use in terms of the provisions of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972);
c. except when intended for use and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Diclazuril, except when intended registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Diclodronic acid.

Dicloxacillin.

Didanosine.

Diethylcarbamazine.

Diflorasone.

Difloxacin.

Diflucortolone.

Dihydralazine.

Dihydrostreptomycin except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Dihydrotachysterol.

Diiodohydroxyquinoline, except when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Di-isopropyl fluorophosphate.

Dilazep.

Diloxanide furoate.

Dimethyl fumarate.

Dimethyl sulphoxide.

Dimetridazole, except when listed elsewhere in the Schedules and except when intended for use in pigeons, as an anti-spirochaete preparation for pigs and to promote growth in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Diminazene, except when intended and registered as an antibabesial in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

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

Dinitrophenol.

Dinoprostone.

Diphemethoxidine.

Difenidol.

Disophenol, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Disopyramide.

Distigmine.

Ditazole.

Dobutamine.

Docetaxel.

Dolasetron.

Dolutegravit.

Domperidone.

Dopa.

Dopamine.

Doravirine.

Doripenem.

Doxapram.

Doxepin, when intended for application to the skin. (S5)

Doxorubicin.

Doxycycline, except

a. when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older. (S2)
b. 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).

Dronedarone.

Drospirenone,

a. when intended for hormone replacement therapy;
b. except when intended for oral contraception. (S3)

Drotrecognin.

Dulaglutide.

Dupilumab.

Durvalumab.

Dutasteride.

Dydrogesterone.

Econazole, except—

a. when intended for application to the skin, (S1) and
b. when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1)

Efraloctocog alfa.

Enilconazole, except when intended for application to the skin. (S1)

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).

Entrectinib.

Edoxudine.

Edrophonium.

Efalizumab.

Efavirenz.

Eftrenonacog alfa (Human coagulation Factor IX).

Eicosapent (EPA) 460, when indicated for the treatment of hypertriglyceridaemia.

Eletriptan.

Eltrombopag.

Elvitegravir.

Eptacog alfa.

Etravirine.

Emetine, except substances, preparations and mixtures containing less than 0,2 percent of alkaloids, calculated as emetine. (S2)

Empagliflozin.

Emtricitabine.

Encainide.

Enoxacin.

Enoxaparin.

Enrofloxacin.

Entacapone.

Entecavir.

Enzalutamide.

Epicillin.

Epinephrine, when intended for injection. (S2, S3)

Epirizole.

Epirubicin (4-epidoxorubicin).

Eplerenone.

Epoetin beta, polyethylene glycol

Eptifibatide.

Eptinezumab.

Erenumab.

Ergometrine maleate.

Ergot alkaloids (natural or synthetic), except preparations and mixtures thereof when intended for the treatment of migraine. (S2)

Eribulin.

Erlotinib.

Ertapenem.

Erythromycin.

Esomeprazole.

Esomeprazole, except when indicated for the temporary, short-term relief of heartburn and hyperacidity, subject to—

a. a maximum daily dose of 20 milligrams;
b. a maximum treatment period of 14 days (S2)

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)

Estramustine.

Estriol,

a. when intended for hormone replacement therapy;
b. when intended for veterinary use;
c. except when intended for oral contraception; (S3)
d. except when intended for human vaginal use; (S2)

Etamiyan.

Etanercept.

Etelcalcetide.

Etidronic acid.

Etiproston.

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

Ethambutol.

Ethionamide.

Etofamide.

Etoglucid.

Etoposide.

Everolimus.

Evolocumab.

Exemestane.

Ezetimibe.

Famciclovir.

Famotidine, except when intended for the short term symptomatic relief of heartburn caused by excess acid, where the maximum dose is 10 milligrams, the maximum daily dose (per 24 hours) is 20 milligrams and the maximum treatment period is 2 weeks (S2)

Fampridine.

Faricimab.

Fazadinium.

Febantel, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Fenchlorphos, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Fenoldopam.

Fenoterol, when intended for the prevention or delay of labour, and preparations thereof for injection. (S2, S3)

Fenticonazole.

Fertirelin.

Ferucarbitran.

Fidaxomicin.

Filgrastim.

Finasteride.

Fingolimod.

Flecainide.

Florfenicol.

Flosequinan.

Flucloxacillin.

Fluconazole, except as a single dose of 150 mg when indicated for the following fungal infections in adults:

a. Vaginal candidiasis, recurrent
b. Candidial balanitis associated with vaginal candidiasis. (S2)

Flucytosine.

Fludarabine.

Fludrocortisone acetate.

Flugestone.

Flumethasone.

Flunisolide, except when intended for inhalation or nasal administration. (S2, S3).

Fluocinolone.

Fluocinonide.

Fluocortolone.

Fluorides,

a. except in oral medicinal preparations and mixtures intended for ingestion containing not more than 0,25 milligrams of fluorine per dosage unit; (S1)
b. except in toothpaste containing not more than 0,15 percent fluoride; (S0) and
c. except in mouth rinses containing not more than 0,15 percent fluoride. (S0)

Fluorometholone.

5-Fluorouracil.

Fluprednidene.

Flurbiprofen,

a. when intended for ophthalmic use; (S4)
b. except when in the form of lozenges, indicated for the relief of pain associated with sore throats, subject to:
    (i) a maximum of 8,75 milligrams per lozenge;
    (ii) a maximum treatment period of 3 days; and
    (iii) a maximum pack size of 15 lozenges (S1)
c. except when intended for application to the skin, provided that in the case of application by transdermal patch:
    (i) use is restricted to adults and children 12 years and older; and
    (ii) the treatment period is limited to a maximum of 4 weeks (S0)
d. except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2).

Flurbiprofen, when intended for ophthalmic use. (S1, S2, S3)

Flutamide.

Fluticasone except when intended for inhalation or nasal administration. (S2, S3).

Fluticasone furoate, except—

a. when intended for nasal administration, as an aqueous spray, in the short-term (less than 6 months) prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—
   (i) a maximum daily dose of 55 micrograms per nostril; and
   (ii) a maximum pack size limit of 120 doses (S2)
b. when intended for inhalation or nasal administration. (S3)

Fluticasone propionate, except—

a. when intended for nasal administration as an aqueous spray, in the short-term (less than 6 months prophylaxis and treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12 years of age, subject to—
   (i) a maximum daily dose of 100 micrograms per nostril; and
   (ii) a maximum pack size limit of 120 doses (S2)
b. when intended for inhalation or nasal administration. (S3)

Fluvastatin.

Follitropin alfa.

Follitropin delta.

Fondaparinux.

Formoterol.

Fosamprenavir.

Fosaprepitant.

Fosfomycin.

Fosphenytoin sodium.

Fostemsavir.

Fotemustine.

Framycetin.

Fremanezumab.

Frovatriptan.

Frunevetmab.

Ftorafur.

Fulvestrant.

Furaltadone, except when listed elsewhere in the Schedules and except when intended as a single oral dosage for gastro-intestinal infections and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Furazolidone.

Fusidic acid, except when intended for topical application. (S2)

Gadobutrol.

Gadodiamide.

Gadofosveset.

Gadoversetamide.

Galactose, when used as a contrast agent.

Galantamine.

Galcanezumab.

Gallamine.

Gamma benzene hexachloride, except when intended to be used for the second line treatment of lice in a pack size not exceeding 60ml. (S2)

Gamithromycin.

Ganciclovir.

Ganirelix.

Gatifloxacin.

Gefitinib.

Gemcitabine.

Gemtuzumab.

Gemifloxacin.

Gentamicin.

Gestrinone.

Glatiramer.

Glofitamab.

Glucagon.

Glycosaminoglycan polysulfate (previously mucopolysaccharide poly-sulphuric acid ester), except when intended for application to the skin. (S1)

Golimumab.

Gonadorelin.

Goserelin.

Gramicidin except when intended for topical application to the epidermis, nares and external ear. (S1)

Granisetron.

Granulocyte Colony Stimulating Factor (G-CSF).

Grapiprant.

Griseofulvin except when intended for topical application to the epidermis, nares and external ear. (S2)

Grepafloxacin.

Guselkumab.

Halcinonide.

Halofantrine.

Halofenate.

Halofuginone, except when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Halogenated hydroxyquinolines, except when intended for application to the skin. (S2)

Halometasone.

Halquinol.

Hemin.

Heparin.

Heptaminol.

Hexoprenaline, when intended for the prevention or delay of labour and preparations thereof for injection. (S2, S3)

Histrelin.

Hormones (natural or synthetic, including recombinant forms), with either hormonal, prohormonal or anti-hormonal action, unless listed elsewhere in the Schedules, and except—

a. when specifically intended for emergency postcoital contraception; (S2)
b. when intended for oral contraception; (S3)

c. insulin; (S3)

epinephrine; (S2, S3, S4)

corticotrophin (adrenocorticotrophic hormone; ACTH); (S5)

human growth hormone (human somatotropin) – all forms; (S5)

a. zeranol, natural estrogen, and progesterone, when intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).
b. BST (Bovine somatropin), when intended and registered as a production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Human C1-esterase inhibitor.

Human coagulation factors.

Human fibrinogen, when indicated for use as a haemostatic.

Human normal immunoglobulin.

Human thrombin, when indicated for use as a haemostatic.

Human Plasma.

Human Plasma Proteins.

Human von Willebrand Factor.

Hyaluronidase.

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),

Hycanthone.

Hydrocortisone and hydrocortisone acetate, except when used in

a. maximum concentration of 1 percent in preparations intended for application to the skin, and
b. in a maximum concentration of 1 percent used in combination with miconazole for topical application in the treatment of athlete's foot. (S2)

Hydroxycarbamide. (Hydroxyurea)

Hydroxychloroquine.

Ibandronic acid.

Ibrutinib.

Ibuprofen,

a. Ibuprofen, when intended for the treatment of a haemodynamically significant patent ductus arterious in infants less than 34 weeks of gestational age;
b. except when contained in preparations intended for application to the skin; containing 5% m/m or less of ibuprofen; (S0, S1)
c. except when contained in transdermal patches containing 200mg of ibuprofen per patch or less, and indicated for use by patients aged 16 years and older; (S1)
d. except when contained in oral medicinal preparations supplied in a solid dose form as divided doses contained in packs not exceeding 24 dosage units or divided doses and containing ibuprofen as the only active therapeutic substance, intended for the treatment of mild to moderate pain or fever of inflammatory origin or for the treatment of post-traumatic conditions in adults and children over 12 years of age where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children 12 years and older does not exceed 20 milligrams per kilogram of body weight; (S1)
e. except when contained in oral medicinal preparations intended for human use only, in combination with one or more other active therapeutic substances and intended for the treatment of mild to moderate pain or fever of inflammatory origin for a maximum treatment period of 10 days where the recommended daily dose of ibuprofen in the case of adults does not exceed 1,2 grams and in children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

f. except when contained in oral medicinal preparations, intended for human use only, as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 millilitres in volume or in oral solid preparations in packs exceeding 24 dosage units or divided doses, when intended for adults and children over the age of 1 year; for the treatment of mild to moderate pain of inflammatory origin for a maximum treatment period of 10 days, or for the treatment of fever of inflammatory origin or for the treatment of post-traumatic conditions where the recommended daily dose of ibuprofen for adults does not exceed 1,2 grams and for children over the age of 1 year and up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight; (S2)

g. except for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

h. except when intended for veterinary use (S3).

Ibutilide.

Ibritumomab.

Icatibant.

Icosapent ethyl.

Idarubicin.

Idarucizumab.

Idebenone.

Idoxuridine, except when intended for application to the skin. (S1)

Idursulfase.

Ifosfamide.

Iloprost.

Imatinib.

Imdevimab.

Imidocarb, except when intended and registered as an antibabesial for the treatment of babesiosis in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Imiglucerase.

Imiquimod.

Imipenem.

Inclisiran.

Indacaterol.

Indinavir.

Indium chloride pentetreotide.

Infliximab.

Ingenol mebutate.

Inosine pranobex.

Interferon alpha.

Interferon beta.

Interferon gamma.

Intra-uterine devices.

Intra-uterine systems, drug eluting, unless listed elsewhere in the Schedules.

Intrifiban.

Iobitridol.

Iocarmic acid.

Iodamide sodium.

Iodised oil, when used as a contrast agent.

Iodixanol.

Iofendylate.

Ioglicic acid.

Iohexol.

Iomeprol.

Iopamidol.

Iopanoic acid.

Iopromide.

Iotalamate sodium.

Iotrolan.

Ioversol.

Ioxitalamic acid.

Ioxoglate sodium.

Ipilimumab.

Irinotecan.

Isepamicin.

Isoconazole, except when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1)

Isoflupredone.

Isoniazid.

Isopirin.

Isoprenaline (isoproterenol), when intended for injection. (S2, S3)

Isoxsuprine.

Itopride.

Itraconazole.

Ixabepilone.

Ixazomib.

Ixekizumab.

Josamycin.

Kanamycin.

Ketoconazole, except—

a. preparations and mixtures containing not more than 1,0 percent of ketoconazole when intended for the prevention and treatment of dandruff; (S0) or
b. when intended for application to the skin. (S0, S1)

Ketorolac, except when intended for ophthalmic use. (S3)

Lamivudine.

Lanreotide.

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

a. a maximum daily dose of 15 milligrams (S2); and
b. a maximum treatment period of 14 days (S2)

Lanthanum.

Lapatinib.

Laronidase.

Laropiprant.

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

Latamoxef.

Latanoprost.

Latanoprostene.

Ledipasvir.

Leflunomide.

Lenalidomide.

Lenograstim.

Lenvatinib.

Lepirudin.

Lesinurad.

Letermovir.

Letrozole.

Leuprolide acetate.

Levallorphan.

Levamisole, except when intended and registered as an anthelmintic and an immunomodulator in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Levobupivacaine.

Levodopa.

Levofloxacin.

Levonorgestrel,

a. when administered via an Intra Uterine System;
b. except when intended for oral contraception; (S3)
c. except when intended for emergency post coital contraception. (S2)

Levosimendan.

Liarozole.

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.

Lincomycin.

Linezolid.

Lipegfilgrastim.

Liraglutide.

Lixisenatide.

Local anaesthetics, when intended for ophthalmic or parenteral use except–

a. when intended for topical use; (S1)
b. oxybuprocaine, proxymetacaine and tetracaine when contained in eye drops intended for emergency treatment of “arc eyes”; (S2).

Lokivetmab.

Lomefloxacin.

Lomustine.

Lopinavir.

Loracarbef.

Loteprednol.

Lovastatin.

Lubiprostone.

Lumefantrine.

Luprositol, when intended for veterinary use.

Lurasidone.

Lutropin alfa.

Lymecycline.

Lysozyme, except preparations and mixtures when intended for application to the skin. (S1)

Macitentan.

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

Mafenide.

Mangafodipir trisodium.

Mandelic acid.

Maraviroc.

Marbofloxacin.

Maropitant, when intended for veterinary use.

Mavacoxib.

Mecamylamine.

Mecillinam.

Medical gases, when used in combination with nitrous oxide, but excluding such medical gasses when used alone or in combinations that exclude nitrous oxide. (S0)

Medroxyprogesterone.

Mefloquine.

Meglumine diatrizoate.

Meglumine gadobenate.

Meglumine gadoterate.

Meglumine iodipamide.

Meglumine ioglycamate.

Meglumine iotalamate.

Meglumine iotroxate.

Meglumine pentetate.

Melagatran.

Melarsoprol.

Melatonin, exept when used for the treatment of desyncronosis (jet-lag) in doses not exceeding 6mg daily. (S2).

Melphalan and its derivatives, unless listed in another Schedule.

Memantine.

Meningococcal Group B vaccine.

Menotrophin.

Mepacrine.

Mephentermine.

Mepirizole.

Mepivicaine.

Mepolizumab.

Meropenem.

6-Mercaptopurine and its derivatives, unless listed in another Schedule.

Mercury, preparations and mixtures that contain mercury metal and that are intended for medicinal use, except preparations of mercuric oxides containing less than 3 percent of mercury. (S2)

Mesna, when intended for injection. (S2)

Metamizole (dipyrone).

Metaproterenol (orciprenaline), when intended for the prevention or delay of labour, and preparations thereof for injection. (S2, S3)

Metergoline.

Methacholine.

Methampyrone (dipyrone).

Methenamine (hexamine), except when intended for application to the skin. (S1)

Methotrexate.

Methoxsalen.

Methyl-5-aminolevulinate.

Methylnaltrexone.

Methylprednisolone.

Methysergide.

Metoclopramide.

Metomidate.

Metrizoic acid.

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)

Mexiletine.

Mezlocillin.

Micafungin.

Miconazole,

a. except when intended for application to the skin; (S1) and

b. except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis; (S1) and
c. except when intended for human use in preparations containing 2 percent or less of miconazole, when intended for the topical treatment of fungal infections of the mouth (oral candidiasis). (S2)

Midostaurin.

Mifamurtide.

Mifepristone.

Miglitol.

Miglustat.

Milrinone.

Miltefosine.

Minocycline.

Minoxidil, except when intended for application to the scalp in preparations containing not more than 2 % (w/v) and which are registered in terms of the Act. (S2)

Misoprostol.

Mitomycin C.

Mitoxantrone.

Mivacurium.

Mizolastine.

Mofebutazone.

Molgramostim.

Molnupiravir.

Mometasone furoate, except when intended for inhalation or nasal administration. (S2, S3)

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).

Moracizine.

Morazone.

Morinamide promolate.

Morphethylbutyne.

Mosunetuzumab.

Moxifloxacin.

Mucoglucuronan.

Muromonab.

Mupirocin, except when intended for topical application to the epidermis, nares and external ear. (S2)

Mycophenolic acid.

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).

Nadroparin.

Nalidixic acid.

Nalorphine.

Naloxone.

Naltrexone.

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

Naratriptan.

Natalizumab.

Natamycin, except when intended for topical application to the epidermis, nares and external ear. (S2)

Nefopam.

Nelfinavir.

Neomycin, except when registered in terms of the provisions of the Fertilizers Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Neostigmine.

Neotizide.

Neratinib.

Netilmicin.

Netobimin.

Netupitant.

Nevirapine.

Niacin (Nicotinic Acid, Vitamin B3) and derivatives thereof,

a. when intended for hypercholesterolaemia and for the management of dyslipidaemias; (S0)
b. except in oral preparations or mixtures containing more than 35 mg of Niacin per recommended daily dose alone or in combination with other active pharmaceutical ingredients (S1)

Niacin when intended for hypercholesterolaemia.

Nicarbazin, except when intended and registered as an anti-coccidian preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Nicorandil.

Nifuratel.

Nifuroxazide.

Nifurtoinol.

Nikethamide.

Nilotinib.

Nilutamide.

Nimesulide.

Nimorazole.

Nimotuzumab.

Nimustine.

Nintedanib.

Niraparib.

Niridazole.

Nirmatrelvir.

Nitric oxide.

Nitrofurantoin, except preparations thereof intended for application to the skin. (S1)

Nitrofurazone, except when intended for application to the skin. (S1)

Nitrofural, except preparations thereof intended for application to the skin. (S1)

Nitrous oxide, alone or in combination with other medical gases.

Nitrovin, except when listed elsewhere in the Schedules and 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).

Nitroxoline.

Nitroxynil, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Nivolumab.

Nizatidine, except when intended for oral administration for short-term symptomatic relief of heartburn and hyperacidity, where the maximum dose is 150 milligrams, the maximum daily dose is 300 milligrams and the maximum treatment period is two weeks (S2)

Nomegestrol.

Nonacog beta pegol.

Noradrenaline (norepinephrine).

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)

Norfloxacin.

Norgestrel,

a. when intended for hormone replacement therapy;
b. except when intended for oral contraception. (S3)

Novobiocin.

Nystatin,

a. when intended for systemic use or the initial treatment of vaginal candidiasis;

b. except when presented as oral drops containing not more than100 000 I.U. per ml. (S2)
c. except when intended for application to the skin, (S1) and
d. except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1)
e. except when intended and registered as a stock remedy for pigeons in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Obidoxime.

Obinutuzumab.

Oclacitinib.

Ocrelizumab.

Ocriplasmin.

Octocog alfa.

Octreotide.

Ofatumumab.

Ofloxacin.

Olaquindox, except when listed elsewhere in the Schedules and 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).

Olaratumab.

Oleandomycin.

Olipudase alfa.

Olodaterol.

Oloparib.

Omalizumab.

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

a. a maximum daily dose of 20mg
b. a maximum treatment period of 14 days (S2)

Ondansetron.

Oprelvekin.

Orbifloxacin.

Ornidazole, except when intended for application to the skin. (S1)

Ornipressin.

Orphenadrine, except when contained in preparations intended for use as a muscle relaxant. (S2)

Osaterone, when intended for veterinary use.

Oseltamivir.

Osimertinib.

Oxamniquine.

Oxfendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Oxacillin.

Oxaliplatin.

Oxetacaine (Oxethazaine),

a. when intended for ophthalmic or parenteral use;
b. except in oral preparations containing an antacid. (S1)

Oxolinic acid.

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)

Oxyclozanide, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Oxyphenbutazone, except when intended and registered for the synchronization of oestrus in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Oxytetracycline, except when listed elsewhere in the Schedules and except 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).

Oxytocin.

Paclitaxel.

Palbociclib.

Palivizumab.

Palonosetron.

Pamidronate disodium.

Pamidronic acid.

Pancuronium.

Panituzumab.

Panobinostat.

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)

Paricalcitol.

Paromomycin.

Pasireotide.

Pazopanib.

Pegfilgrastim.

Pembrolizumab.

Pemetrexed.

Penciclovir, except when intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections (S1)

Penethamate hydriodide, except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Peginterferon alpha.

Peginterferon beta 1a.

Penicillamine.

Pentamidine.

Pentostatin.

Perfluorooctane, when intended for intraocular use. (S2)

Pergolide.

Perhexiline.

Pertuzumab.

Phenacetin, except preparations and mixtures intended for external use and containing not more than 0,1 percent phenacetin as stabilizer.

Phenamidine, except when intended and registered as an antibabesial in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Pheneticillin.

Phenindione.

Phenopyrazone.

Phenoxybenzamine.

Phenoxymethylpenicillin, except when intended for the prophylaxis of rheumatic fever. (S3)

Phenylephrine,

a. when intended for injection;
b. except ophthalmic preparations containing 0,2 percent or less; (S0)
c. except for oral dosage forms, nasal dosage forms, or ophthalmic dosage forms containing more than 0,2 percent. (S1)

Phospholipids, when intended for parenteral administration. (S0)

Phthalylsulfathiazole.

Physostigmine, except ophthalmic preparations thereof when intended for glaucoma. (S3)

Picrotoxin.

Pilocarpine, except ophthalmic preparations thereof intended for glaucoma. (S3)

Pimecrolimus.

Pimobendan.

Pipemidic acid.

Piperacillin, anhydrous.

Pirenzepine.

Pirfenidone.

Piribedil.

Pirlimycin.

Piromidic acid.

Pivampicillin.

Pivmecillinam.

Pixantrone.

Plerixafor.

Podophyllum resin, preparations and mixtures containing more than 20 percent of podophyllum resin. (S1)

Polatuzumab.

Polydimethylsiloxane – see Silicone oil.

Polyethylene glycol — epoetin beta.

Polyglycerylene-dextran.

Polymixin B, except when intended for topical application to the epidermis, nares and external ear. (S1)

Polynoxylin.

Polysterene sulfonic acid when intended for therapeutic purposes.

Pomalidomide.

Ponesimod.

Poractant alpha.

Posaconazole.

Potassium dichromate, except preparations and mixtures containing not more than 15 micrograms of potassium dichromate per dosage unit.

Pradofloxacin, when intended for veterinary use.

Pralidoxime.

Pralsetinib.

Pramipexole.

Prasugrel.

Pravastatin.

Praziquantel, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Prednisolone.

Pretomanid.

Prilocaine,

a. when intended for ophthalmic or parenteral use; (S4)
b. except in topical preparations containing 10 % or less of prilocaine. (S1)

Primaguine.

Procainamide.

Procaine benzylpenicillin, except when listed elsewhere in the Schedules and except intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Procarbazine.

Progesterone.

Proguanil, except when co-formulated with atovaquone and intended and labelled for the chemoprophulaxis of malaria in those weighing 11 kilograms or more. (S2)

Propafenone.

Propentofylline, except when intended for veterinary use. (S1)

Propylhexedrine, except when used as a vasoconstrictor and decongestant in nose preparations and inhalants (S1)

Protein C (isolated from human plasma).

Proyliodone.

Proteolytic (fibrinolytic) enzymes, when intended for injection, and unless listed elsewhere in the Schedules (S1)

Protionamide.

Proxymetacaine, except when contained in eye drops intended for emergency treatment of arc eyes (S2)

Prucalopride.

Pyrazinamide.

Pyricarbate.

Pyridostigmine.

Pyrimethamine.

Quinine, except preparations and mixures containing not more than 1 percent. (S2)

Quinoronium, except when intended and registered as an antibabesial in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Quinagolide.

Quinupristin.

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.

Ractopamine.

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) 14 C – Urea;

(iii) 18F – Fludeoxyglucose (2 – deoxy – 2 – [18F] 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.

Rafoxanide, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Raltegravir.

Raltitrexid.

Ramucirumab.

Ranibizumab.

Ranolazine.

Rapacuronium.

Rasagiline.

Rasburicase.

Ravulizumab.

Recombinant human epidermal growth factor (rhEGF).

Regorafenib.

Remdesivir.

Resorantel, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Respiratory syncytial virus antigen (recombinant).

Retapamulin.

Revefanacin.

Ribavirin.

Ribociclib.

Rifabutin.

Rifampicin.

Rifapentine.

Rifaximin.

Rilpivirine.

Riluzole.

Rimiterol, when intended for injection. (S2, S3)

Riociguat.

Risdiplam.

Ritodrine.

Ritonavir.

Rotigotine.

Rituximab.

Rivaroxaban.

Rizatriptan, except when in oral solid dosage forms providing 5mg or less and presented as packs of no more than 2 oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with rizatriptan. (S2)

Robenacoxib.

Rocuronium.

Roflumilast.

Rolitetracycline except when listed elsewhere in the Schedules and except injections thereof intended 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).

Romiplostim.

Ropinirole.

Ropivacaine.

Rosoxacin.

Rosuvastatin.

Roxadustat.

Roxithromycin.

Roxatidine.

Ruxolitinib.

Safinamide.

R-salbutamol, except when intended and registered as a stock remedy in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Salbutamol, when intended for injection. (S2, S3)

Salinomycin, except when listed elsewhere in the Schedules and except when intended as an anti-coccidial preparation and to promote growth and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Salmefamol, when intended for injection. (S2, S3)

Salmeterol.

Saquinavir.

Sarafloxacin.

Saroglitazar magnesium.

Sarolaner, except when intended and registered for the control of ticks and fleas in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Satralizumab.

Secukinumab.

Selegiline.

Selenium,

a. in preparations thereof for injection when intended for veterinary use;
b. except in oral preparations or mixtures containing more than 200 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

Selexipag.

Semaglutide.

Semuloparin.

Serelaxin.

Sermorelin.

Sertaconazole, except when intended for application to the skin. (S1)

Sertindole.

Sevelamer.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine.

Sildenafil.

Silicone oil (polydimethylsiloxane) when intended for intraocular use.

Silodosin.

Siltuximab.

Simoctogog alfa.

Simvastatin.

Siponimod.

Sirolimus.

Sisomicin.

Sodium aurothiomalate.

Sodium cromoglycate, when intended for veterinary use. (S2)

Sodium dihydroazapentacene polysulphonate.

Sodium fluoride; except oral medicinal preparations and mixtures thereof containing 40 milligrams or more per daily dose. (S1)

Sodium nitroprusside.

Sodium polystyrine sulphonic acid, when indicated for therapeutic use.

Sofosbuvir.

Solcoseryl, except preparations intended for application to the skin, to the mucous membranes of the mouth and to the lips and except ophthalmic preparations thereof. (S0, S3)

Somapacitan.

Sorafenib.

Sparfloxacin.

Spectinomycin.

Stavudine.

Stents, Drug Eluting, unless listed elsewhere in the Schedules.

Stiripentol.

Streptokinase.

Strychnine, except—

a. preparations and mixtures containing 0,2 percent or less of strychnine; (S2) and

b. subject thereto that it shall only be supplied for the control of problem predatory mammals—

(i) on a written prescription issued by a State Veterinarian, for use in the particular State Veterinarian's area of jurisdiction, and in a quantity not exceeding 5 grams; and

(ii) subject to the State Veterinarian obtaining prior written approval for such use from the Director of the concerned provincial conservation institution or authority in his area of jurisdiction, a copy of such written approval being attached to the written prescription.

Styramate.

Sugammadex.

Sulbactam.

Sulfabenzamide.

Sulfacetamide.

Sulfadiazine, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sulfadiazine silver, except when intended for application to the skin in the short term treatment of minor burns, provided that the pack size is limited to a maximum of 50 grams (S2)

Sulfasalazine.

Sulphonamides except when intended for application to the eyes, nares and vagina. (S2)

Sufadimidine (sulfadimethoxine) except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sulfamethazine except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sulfadoxine except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sulfafurazole (sulfisoxazole).

Sulfaguanidine except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sulfamethizole.

Sulfamethoxazole except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sulfametopyrazine.

Sulfamoxole.

Sulfanilamide.

Sulfathiazole, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sulfisomidine.

Sulfamerazine.

Sulfapyridine.

Sultamicillin.

Sulfonamides, unless listed elsewhere in the Schedules, and except—

a. substances, preparations and mixtures intended for application to the eyes, nares and vagina; (S2) and
b. when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sumatriptan, except when in oral solid dosage forms providing 50 mg or less and presented as packs of no more than two oral solid dosage forms, indicated for the acute relief of migraine attacks, with or without aura, in patients previously diagnosed by a medical practitioner and initiated on treatment with sumatriptan. (S2)

Sunitinib.

Suramin.

Surfactant associated proteins.

Suxamethonium.

Suxethonium.

Streptokinase.

Streptomycin.

Tacrine.

Tacrolimus.

Tadalafil.

Tafamidis.

Tafluprost.

Talampicillin.

Talazoparib.

Taliglucerase alfa.

Tamoxifen.

Tamsulosin.

Taurolidine.

Tasonermin.

Tazobactam.

Tedizolid.

Tegafur.

Tegaserod.

Teicoplanin.

Telaprevir.

Telbivudine.

Telithromycin.

Temozolomide.

Temsirolimus.

Tenecteplase.

Teniposide.

Tenofovir.

Terbinafine, except when intended for application to the skin. (S1)

Terconazole.

Terfenadine.

Teriflunomide.

Terizidone.

Teriparatide.

Terlipressin.

Tetanus toxoid.

Tetrabenazine.

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).

Tetracycline, except when listed elsewhere in the Schedules and except injections thereof intended 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).

Tetramisole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Thalidomide.

Theophylline and its derivatives, unless listed elsewhere in the Schedules, and preparations intended for injection. (S2)

Thiamphenicol.

Thioacetazone.

Thiabendazole, except—

a. when intended for application to the skin; (S1) and
b. when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Tioguanine.

Thiostrepton.

Thymopentin.

Thyrotropin alfa.

Tiamulin, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Tibolone.

Ticarcillin.

Tigecycline.

Tildipirosin, when intended for veterinary use.

Tilmicosin.

Tiludronic acid.

Tin fluoride (stannous fluoride), when intended for injection.

Tinidazole.

Tinzaparin.

Tioconazole, except when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1)

Tiopronin.

Tipiracil.

Tipranavir.

Tirilazad.

Tivozanib.

Tobramycin.

Tocainide.

Tocilizumab.

Tofacitinib.

Tolcapone.

Tolrestat.

Toltrazuril, except when intended and registered as an anti-coccidial preparation in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Topotecan.

Toremifene.

Tozinameran.

Trabectedin.

Trametinib.

Tranexamic acid.

Trastuzumab.

Trastuzumab deruxtecan.

Trastuzumab emtansine.

Travoprost.

Tremelimumab.

Treosulfan.

Triclabendazole, except when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Thiotepa.

Trifluridine.

Triflusal.

Trimetaphan.

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).

Trimetrexate.

Trioxysalen.

Triptorelin.

Tromantadine.

Trometamol.

Tropisetron.

Tuberculin.

Tubocurarine.

Tulathromycin.

Turoctocog Alpha.

Tylosin, except when listed elsewhere in the Schedules and except when intended for addition to drinking water and feedstuff for administration to poultry and pigs and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Tyropanoic acid.

Tyrothricin, except when intended for topical application to the epidermis, nares and external ear. (S1)

Unoprostone.

Upadacitinib.

Urapidil.

Urethane.

Urokinase.

Urofollitropin.

Ustekinumab.

(Vaccines, see—Biologicals)

Valaciclovir.

Valganciclovir.

Valnemulin.

Vancomycin.

Vardenafil.

Varicella Zoster Virus glycoprotein E antigen.

Vasoactive intestinal polypeptide.

Vasopressin.

Vecuronium.

Vedolizumab.

Velaglucerase alfa.

Velpatasvir.

Vemurafenib.

Venetoclax.

Vericiguat.

Vernakalant.

Verteporfin.

Vidarabine.

Vilanterol.

Vinblastine.

Vincristine.

Vindesine.

Vinorelbine.

Virginiamycin, except when listed elsewhere in the Schedules and 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).

Vismodegib.

Voriconazole.

Vorinostat.

Vorozole.

Warfarin.

Zalcitabine.

Zanamivir.

Zanubrutinib.

Zidovudine.

Zinc bacitracin, except when listed elsewhere in the Schedules and 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).

Ziv-aflibercept.

Zofenopril.

Zolmitriptan.

Zoledronic acid.

Zotarolimus.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Schedule 4 Annexure 1A added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021.]

PARAMEDIC (National Diploma in Emergency Medical Care graduates only) registered with the Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates)

ANTI-ARRHYTHMICS
Substance : Adenosine
Indication : Endogenous Purine Nucleoside/Supraventricular Anti-arrhythmic
Schedule : 4
Route of Administration : Parenteral

ANTI-ARRHYTHMICS
Substance : Amiodarone
Indication : Class III Anti-arrhythmic/Atrial & Ventricular
Schedule : 4
Route of Administration : Parenteral

ANTI-ARRHYTHMICS

Substance : Lignocaine Hydrochloride (Systemic)
Indication : Class I B-Ventricular Anti-arrhythmic
Schedule : 4
Route of Administration : Parenteral

ADRENERGIC

Substance : Adrenaline/Epinephrine
Indication : Sympathomimetic catecholamine
Schedule : 4
Route of Administration : Parenteral

ANTI-CHOLINERGIC

Substance : Atropine arrhythmic
Indication : Competitive Anti-Cholinergic, Bradycardia, Anti-
Schedule : 4
Route of Administration : Parenteral

PARAMEDIC (National Diploma in Emergency Medical Care graduates)

SELECTIVE β2 AGONISTS

Substance : Salbutamol
Indication : Bronchodilator
Schedule : 4
Route of Administration : Parenteral

SELECTIVE β2 AGONISTS

Substance : Fenoterol
Indication : Bronchodilator
Schedule : 4
Route of Administration : Parenteral

CORTICOSTEROIDS

Substance : Hydrocortisone
Indication : Glucocorticoid / Steroidal Anti-Inflammatory
Schedule : 4
Route of Administration : Parenteral

HYPERGLYCAEMIC AGENT

Substance : Glucagon
Indication : Hyperglycaemic agent
Schedule : 4
Route of Administration : Parenteral

CORTICOSTEROIDS

Substance : Methylprednisolone
Indication : Glucocorticoid / Steroidal Anti-Inflammatory
Schedule : 4
Route of Administration : Parenteral

ANTI-EMETIC

Substance : Metoclopramide Monohydrochloride
Indication : Propulsive Anti-emetic/Dopamine Antagonist
Schedule : 4
Route of Administration : Parenteral

OPIOID ANTAGONIST

Substance : Naloxone Hydrochloride
Indication : Opioid Antagonist/Narcotic Antagonist
Schedule : 4
Route of Administration : Parenteral

OPIOID ANTAGONIST

Substance : Nitrous Oxide
Indication : Analgesic Gas
Schedule : 4
Route of Administration : Inhalant

*ANTI-FIBRINOLYTIC

Substance : Tranexamic acid
Indication : Major haemorrhage in trauma
Route of Administration : Parenteral

**OXYTOCIN

Substance : Oxytocin
Indication : Post-partum haemorrhage
Route of Administration : Parenteral

CORTICOSTEROID

Substance : Prednisolone

Indication : Glucocorticoid/Steroidal anti-inflammatory

Route of Administration : Oral

LOCAL ANAESTHETIC

Substance : Lignocaine hydrochloride

Indication : Local anaesthesia

Route of Administration : Parenteral

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Schedule 4 Annexure 1B added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE PRACTITIONER

(Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)

ANTI-ARRHYTHMICS

Substance : Adenosine

Indication : Endogenous Purine Nucleoside / Supraventricular Anti-arrhythmic

Schedule : 4

Route of Administration : Parenteral

ANTI-ARRHYTHMICS

Substance : Amiodarone

Indication : Class III Anti-arrhythmic/Atrial & Ventricular

Schedule : 4

Route of Administration : Parenteral

ANTI-ARRHYTHMICS

Substance : Lignocaine Hydrochloride (Systemic)

Indication : Class I B-Ventricular Anti-arrhythmic

Schedule : 4

Route of Administration : Parenteral

ADRENERGIC

Substance : Adrenaline/Epinephrine

Indication : Sympathomimetic catecholamine

Schedule : 4

Route of Administration : Parenteral

ANTI-CHOLINERGIC

Substance : Atropine

Indication : Competitive Anti-Cholinergic, Bradycardia, Anti- arrhythmic

Schedule : 4

Route of Administration : Parenteral

SELECTIVE β2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Schedule : 4

Route of Administration : Parenteral

SELECTIVE β2 AGONISTS

Substance : Fenoterol

Indication : Bronchodilator

Schedule : 4

Route of Administration : Parenteral

CORTICOSTEROIDS

Substance : Hydrocortisone

Indication : Glucocorticoid / Steroidal Anti-Inflammatory

Schedule : 4

Route of Administration : Parenteral

CORTICOSTEROIDS

Substance : Methylprednisolone

Indication : Glucocorticoid / Steroidal Anti-Inflammatory

Schedule : 4

Route of Administration : Parenteral

HYPERGLYCAEMIC AGENT

Substance : Glucagon

Indication : Hyperglycaemic agent

Schedule : 4
Route of Administration : Parenteral

ANTI-EMETIC
Substance : Metoclopramide Monohydrochloride
Indication : Propulsive Anti-emetic/ Dopamine Antagonist
Schedule : 4
Route of Administration : Parenteral

OPIOID ANTAGONIST
Substance : Naloxone Hydrochloride
Indication : Opioid Antagonist/Narcotic Antagonist
Schedule : 4
Route of Administration : Parenteral

OPIOID ANTAGONIST
Substance : Nitrous Oxide
Indication : Analgesic Gas
Schedule : 4
Route of Administration : Inhalant (50:50 combination with Medical Oxygen)

THROMBOLYTIC AGENTS
Substance : Streptokinase
Indication : Enzymes
Schedule : 4
Route of Administration : Parenteral

THROMBOLYTIC AGENTS
Substance : Tenecteplase
Indication : Enzymes
Schedule : 4
Route of Administration : Parenteral

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)

ANTITHROMBOTIC AGENTS
Substance : Heparin Sodium
Indication : Anticoagulant
Schedule : 4
Route of Administration : Parenteral

ANTITHROMBOTIC AGENT

Substance : Enoxaparin
Indication : Anticoagulant
Schedule : 4
Route of Administration : Parenteral

MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)

Substance : Suxamethonium Chloride
Indication : Depolarizing Muscle Relaxant
Schedule : 4
Route of Administration : Parenteral

MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)

Substance : Vecuronium
Indication : Competitive Muscle Relaxant
Schedule : 4
Route of Administration : Parenteral

MUSCLE RELAXANTS (NEURO BLOCKING AGENTS)

Substance : Rocuronium
Indication : Non-Depolarizing Muscle Relaxants
Schedule : 4
Route of Administration : Parenteral

**CORTICOSTEROID

Substance : Betamethasone
Indication : Pre-term birth
Route of Administration : Parenteral

*ANTICHOLINESTERASE

Substance : Neostigmine
Indication : Reversal of neuromuscular blockade
Route of Administration : Parenteral

*CHOLINESTERASE INHIBITOR

Substance : Sugammadex
Indication : Reversal of neuromuscular blockade
Route of Administration : Parenteral

*SEROTONIN ANTAGONIST

Substance : Ondansetron

Indication : Post-operative nausea and vomiting

Route of Administration : Parenteral

*ANTI-FIBRINOLYTIC

Substance : Tranexamic acid

Indication : Major haemorrhage in trauma

Route of Administration : Parenteral

OXYTOCIN

Substance : Oxytocin

Indication : Post-partum haemorrhage

Route of Administration : Parenteral

CORTICOSTEROID

Substance : Prednisolone

Indication : Glucocorticoid/Steroidal anti-inflammatory

Route of Administration : Oral

LOCAL ANAESTHETIC

Substance : Lignocaine hydrochloride

Indication : Local anaesthesia

Route of Administration : Parenteral

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

[Schedule 4 Annexure 1C added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 883 in G. 45176 of 17 September 2021.]

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa

*SELECTIVE β2 AGONISTS

Substance : Fenoterol

Indication : Bronchodilator

Route of Administration : Parenteral

OPIOID ANTAGONIST

Substance : Nitrous oxide

Indication : Analgesic Gas

Route of Administration : Inhalant (50:50 combination with Medical Oxygen)

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

[Schedule 4 Annexure 1D added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 883 in G. 45176 of 17 September 2021.]

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

*ADRENERGIC

Substance : Adrenaline/Epinephrine

Indication : Sympathomimetic catecholamine

Route of Administration : Parenteral

*CORTICOSTEROIDS

Substance : Methylprednisolone

Indication : Glucocorticoid/Steroidal Anti-Inflammatory

Route of Administration : Parenteral

*CORTICOSTEROIDS

Substance : Hydrocortisone

Indication : Glucocorticoid/Steroidal Anti-Inflammatory

Route of Administration : Oral

*HYPERGLYCAEMIC AGENT

Substance : Glucagon

Indication : Hyperglycaemic agent

Route of Administration : Parenteral

*OPIOID ANTAGONIST

Substance : Naloxone hydrochloride

Indication : Oploid Antagonist/Narcotic Antagonist

Route of Administration : Parenteral

OPIOID ANTAGONIST

Substance : Nitrous oxide

Indication : Analgesic Gas

Route of Administration : Inhalant (50:50 combination with Medical Oxygen)

SELECTIVE β2 AGONISTS

Substance : Fenoterol

Indication : Bronchodilator

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Lignocaine hydrochloride

Indication : Local anaesthesia

Route of Administration : Parenteral

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

[Schedule 4 Annexure 1E added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

*ADRENERGIC

Substance : Adrenaline/Epinephrine

Indication : Sympathomimetic catecholamine

Route of Administration : Parenteral

CORTICOSTEROIDS

Substance : Methylprednisolone

Indication : Glucocorticoid/Steroidal Anti-Inflammatory

Route of Administration : Parenteral

CORTICOSTEROIDS

Substance : Hydrocortisone

Indication : Glucocorticoid/Steroidal Anti-Inflammatory

Route of Administration : Parenteral

HYPERGLYCAEMIC AGENT

Substance : Glucagon

Indication : Hyperglycaemic agent

Route of Administration : Parenteral

ANTI-ARRHYTHMICS

Substance : Amiodarone

Indication : Class III Anti-arrhythmic/Atrial & Ventricular

Route of Administration : Parenteral

*ANTI-EMETIC

Substance : Metoclopramide monohydrochloride

Indication : Propulsive Anti-emetic/Dopamine Antagonist

Route of Administration : Parenteral

SELECTIVE β2 AGONISTS

Substance : Salbutamol

Indication : Bronchodilator

Route of Administration : Parenteral

SELECTIVE β2 AGONISTS

Substance : Fenoterol

Indication : Bronchodilator

Route of Administration : Parenteral

ANTI-CHOLINERGIC

Substance : Atropine

Indication : Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic

Route of Administration : Parenteral

OPIOID ANTAGONIST

Substance : Naloxone hydrochloride

Indication : Opioid Antagonist/Narcotic Antagonist

Route of Administration : Parenteral

OPIOID ANTAGONIST

Substance : Nitrous oxide

Indication : Analgesic Gas

Route of Administration : Inhalant (50:50 combination with Medical Oxygen)

**OXYTOCIN

Substance : Oxytocin

Indication : Post-partum haemorrhage

Route of Administration : Parenteral

CORTICOSTEROID

Substance : Prednisolone

Indication : Glucocorticoid/Steroidal anti-inflammatory

Route of Administration : Oral

LOCAL ANAESTHETIC

Substance : Lignocaine hydrochloride

Indication : Local anaesthesia

Route of Administration : Parenteral

ANNEXURE 1F: EMERGENCY CARE ASSISTANT

[Schedule 4 Annexure 1F added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa

*ADRENERGIC

Substance : Adrenaline/Epinephrine

Indication : Sympathomimetic catecholamine

Route of Administration : Parenteral

CORTICOSTEROIDS

Substance : Methylprednisolone

Indication : Glucocorticoid/Steroidal Anti-Inflammatory

Route of Administration : Parenteral

CORTICOSTEROIDS

Substance : Prednisolone

Indication : Glucocorticoid/Steroidal anti-inflammatory

Route of Administration : Oral

CORTICOSTEROIDS

Substance : Hydrocortisone

Indication : Glucocorticoid/Steroidal Anti-Inflammatory

Route of Administration : Parenteral

HYPERGLYCAEMIC AGENT

Substance : Glucagon

Indication : Hyperglycaemic agent

Route of Administration : Parenteral

ANTI-CHOLINERGIC

Substance : Atropine

Indication : Competitive Anti-Cholinergic, Bradycardia, Anti- arrhythmic

Route of Administration : Parenteral

OPIOID ANTAGONIST

Substance : Naloxone hydrochloride

Indication : Opioid Antagonist/Narcotic Antagonist

Route of Administration : Parenteral

OPIOID ANTAGONIST

Substance : Nitrous oxide

Indication : Analgesic Gas

Route of Administration : Inhalant (50:50 combination with Medical Oxygen)

SELECTIVE β2 AGONISTS

Substance : Fenoterol

Indication : Bronchodilator

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Lignocaine hydrochloride

Indication : Local anaesthesia

Route of Administration : ParenteralSubstance

ANNEXURE 2: DENTAL THERAPIST

[Schedule 4 Annexure 2 added by GNR 674 in G. 36827 of 13 September 2013, amended by GN 6466 in G. 53099 of 1 August 2025.]

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

DENTAL THERAPIST (Bachelor's degree in Dental Therapy)

LOCAL ANAESTHETIC

Substance : Lignocaine / Lidocaine hydrochloride 2 percent with Vasoconstrictor (Adrenaline)

Indication : Dental local anaesthesia

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Lignocaine / Lidocaine hydrochloride 3 percent without a Vasoconstrictor (Adrenaline)

Indication : Dental local anaesthesia

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Mepivacaine hydrochloride 2 percent with a Vasoconstrictor (Adrenaline)

Indication : Dental local anaesthesia

Route of Administration : Parenteral

LOCAL ANAESTHETIC

Substance : Mepivacaine hydrochloride 3 percent without a Vasoconstrictor (Adrenaline)

Indication : Dental local anaesthesia

Route of Administration : Parenteral

ANTI-MICROBIALS (Beta-Lactams)

Substance : Penicillins

Indication : Dental orofacial and odontogenic infections (Non prophylactic)

Route of Administration : Oral

PENICILLINS AND BETA-LACTAMS COMBINATION

Substance : Amoxicillin + clavulanic acid

Indication : Dental infections, abscesses

Route of Administration : Oral

MACROLIDES
Substance : Erythromycin
Indication : For patients allergic to Penicillin
Route of Administration : Oral

ANTI-PROTOZOAL
Substance : Metronidazole
Indication : Dental orofacial and odontogenic infections (Non prophylactic)
Route of Administration : Oral

AUTONOMIC SYMPATHOMIMETICS
Substance : Adrenaline
Indication : Emergency medicine for drug related anaphylactic shock
Route of Administration : Parenteral

ANNEXURE 3: OPTOMETRIST

[Schedule 4 Annexure 3 added by GN 620 in G. 40041 of 3 June 2016; amended by GN 748 in G. 41009 of 28 July 2017, GNR 219 & GNR 220 in G. 43051 of 28 February 2020, GN 2685 in G. 47373 of 28 October 2022.]

OPTOMETRIST (Bachelor's 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 recognised by the Health Professions Council of South Africa as an authorised prescriber.

OPTOMETRIST 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)

ANTIBACTERIAL
Substance : Tetracycline
Indication : Trachoma
Route of Administration : Oral

ANTIBACTERIAL
Substance : Doxycycline
Indication : Trachoma
Route of Administration : Oral

ANTIBACTERIAL
Substance : Azithromycin
Indication : Trachoma
Route of Administration : Oral

ANTIBIOTICS
Substance : Fuscidic acid
Indication : For Blepharitis and stye
Route of Administration : Topical drops or ointment

ANTIBIOTICS

Substance : Neomycin
Indication : For Blepharitis only
Route of Administration : Topical drops or ointment

ANTIBIOTICS
Substance : Bacitracin
Indication : For Blepharitis only
Route of Administration : Ointment

ANTIBIOTICS
Substance : Polymyxin B
Indication : For Blepharitis only
Route of Administration : Ointment

PROSTAGLANDIN ANALOGUES (PGAs)
Substance : Latanoprost, Travoprost, Bimatoprost
Indication : Glaucoma
Route of Administration : Drops

[‡]ANNEXURE 4: PODIATRIST

[Schedule 4 Annexure 4 amended by GNR 1375 in G. 44019 of 18 December 2020.]

[[‡]Schedule 4 Annexure 4 amended only; no other text published in the Gazette.]

PODIATRIST registered with the Health Professions Council of South Africa in terms of the Health Professions Act, 1974 (Act 56 of 1974).

Vericiguat.

ANNEXURE 5: ORAL HYGIENISTS

[Schedule 4 Annexure 5 added by GNR 3261 in G. 48358 of 24 March 2023.]

ORAL HYGIENISTS registered with the Health Professions Council of South Africa (HPCSA) in terms of the Health Professions Art, 1974 (Act 56 of 1974)

ORAL HYGIENISTS

LOCAL ANAESTHETIC
Substance : Lignocaine/Lidocaine hydrochloride with or without Adrenaline or Noradrenaline
Indication : Dental surface anaesthesia (local anaesthetic)

Route of Administration : Local injection

LOCAL ANAESTHETIC
Substance : Mepivacaine with or without Adrenaline
Indication : Dental surface anesthesia (local anaesthetic)
Route of administration : Local injection

LOCAL ANAESTHETIC
Substance : Articaine with Adrenaline
Indication : Dental surface anaesthesia (local anaesthetic)
Route of administration : Local injection

LOCAL ANAESTHETIC
Substance : Prilocaine with or without Adrenaline
Indication : Dental surface anaesthesia (local anaesthetic)
Route of administration : Local injection

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

[Schedule 5 and Specified Schedule 5 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, GNR 2082 of 5 November 1976; amended by GNR 143 of 4 February 1977, GNR 279 of 25 February 1977, GNR 437 of 1 April 1977, GNR 1674 of 18 August 1978 (as amended GNR 2410 of 8 December 1978), GNR 1926 of 31 August 1979, (as amended GN 271 of 15 February 1980), GNR 2416 of 12 November 1982, GNR 1289 of 14 June 1985, GN 154 of 31 January 1986; substituted by GN 225 of 17 February 1989, amended by GNR 2841 of 7 December 1990, GNR 580 of 21 February 1992 , GNR 775 of 7 May 1993, repealed, inserted, amended by s 21 of Act 94 of 1991; amended by GNR 1556 of 16 September 1994, GNR 673 of 12 May 1995, GNR 42 of 19 January 1996, R 1203 of 15 October 1999 and by R 1077 of 3 November 2000, repealed by s 27 of Act 90 of 1997; inserted by GNR 509 in G. 24727 of 10 April 2003; substituted by GN 935 in G. 31387 of 5 September 2008, GNR 1230 in G. 32838 of 31 December 2009; amended by GNR 227 in G. 35149 of 15 March 2012, R 674 in G. 36827 of 13 September 2013, R 690 in G. 36850 of 20 September 2013, GNR 104 in G. 37318 of 11 February 2014, GNR 234 in G. 38586 of 20 March 2015, GN 254 in G. 39815 of 15 March 2016, GN 748 in G. 41009 of 28 July 2017, GN 1261 in G. 41256 of 17 November 2017, GNR 1098 in G. 41971 of 12 October 2018, GNR 1262 in G. 42052 of 23 November 2018, GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021, GN 2685 in G. 47373 of 28 October 2022, GNR 3261 in G. 48358 of 24 March 2023, GN 6466 in G. 53099 of 1 August 2025.]

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)
Annexure 1B: Emergency Care Provider (Emergency Care Practitioner)
Annexure 1E: Emergency Care Technician

[Numbering as published in original *Gazette*.]

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 **

Acitretin.

Agomelatine.

Alfaxalone.

Alprazolam**.

Amisulpride.

Amitryptyline and its derivatives.

Amoxapine.

Anaesthetic preparations containing pregnanedione derivatives.

Androstanolone.

Androstenediol.

Aponal.

Apronalide.

Aripriprazole.

Armodafanil.

Atomoxetine.

Asenapine.

Azacyclonol.

Barbituric acid** and its derivatives**, unless listed in another Schedule, excluding—

a. amobarbital, cyclobarbital, pentobarbital and secobarbital (S6), and
b. preparations and mixtures containing not more than 90 milligrams of phenobarbital* per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S3)

Benactyzine and its derivatives unless listed in another Schedule.

Benfluramate.

Benzoctamine.

Benzodiazepines** and their derivatives**, unless listed in another Schedule and except flunitrazepam. (S6)

Benzquinamide.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene:

a. any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure); and

b. any salt or substance falling under the above; and
c. except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
d. except when contained in appliances for inhalation in which the substance is absorbed onto solid material; (S1, S7) and
e. excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof; and
f. except substances listed in Schedule 7. (S1, S2, S6)

Bolandiol.

Bolasterone.

Boldenone.

Brexpiprazole.

Bromides; preparations and mixtures thereof containing 80 milligrams or more of bromine as bromide per recommended daily dose, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as 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 and for anaytical laboratory purposes (S2)

Bromazepam**.

Bromisovalum.

Brotizolam**.

Bupropion.

Buspirone.

Butriptyline.

Butyrophenones.

Carbromal.

Cariprazine.

Chloral derivatives, unless listed in another Schedule.

Chlordiazepoxide**.

Chlormethiazole.

Chlormezanone, except mixtures thereof where the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (S2)

Chloroform, all substances, preparations and mixtures containing more than 20 percent of chloroform. (S1), except for industrial purposes including the manufacturing and compounding of products not intended for medicinal use. (S0, S1)

Chlorpromazine.

Chlorprothixene.

Citalopram.

Clobazam**.

Clomacran.

Clomipramine.

Clonazepam**.

Clopenthixol.

Clorazepic acid**.

Clostebol.

Clothiapine.

Clozapine.

Corticotrophin (adrenocorticotrophic hormone; ACTH).

Cyclobenzaprine.

Cyproheptadine, except when indicated for allergic rhinitis or antipruritic use. (S2)

Danazol.

Dapoxetine.

Deanol and its derivatives, unless listed in another Schedule, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as 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, and for analytical laboratory purposes (S1)

Dehydrochloromethyltestosterone.

Desflurane.

Desipramine.

Desvenlafaxine.

Detomidine.

Dexfenfluramine.

Dexmedetomidine.

Dextropropoxyphene; preparations and mixtures for oral use containing not more than 135 milligrams of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5 percent in undivided preparations (S6)

Diazepam**.

Dibenzepin.

Diprenorphine.

Donepezil.

Dosulepin.

Dothiepin.

Doxepin, except when intended for application to the skin. (S4)

Droperidol.

Drostanolone.

Duloxetine.

Ecothiopate.

Emylcamate.

Enflurane.

Epitiostanol.

Escitalopram.

Esketamine.

Estazolam**.

Ethchlorvynol**.

Ether (diethyl ether); all substances, preparations and mixtures containing more than 20 percent of ether, (S1), except for industrial purposes including the manufacturing and compounding of products not intended for medicinal use.

Ethinamate** and its derivatives**, unless listed in another Schedule.

Ethylestrenol.

Etifoxine.

Etodroxizine, except preparations and mixtures thereof when used solely as an antihistamine. (S2)

Etomidate.

Etretinate.

Fencamfamine**.

Fenfluramine.

Flumazenil**.

Fluoxetine.

Fluoxymesterone.

Flupenthixol.

Fluphenazine.

Flurazepam**.

Fluspirilene.

Fluvoxamine.

Formebolone.

Furazabol.

Haloperidol.

Halothane.

Hedonal and its esters, except when specifically packaged, labelled and used for industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, which are intended to be ingested by man or animals as 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, and for anaytical laboratory purposes.

Human growth hormone (human somatotropin) – all forms, whether natural or synthetic, including recombinant forms, with either hormonal, prohormonal or anti-hormonal action).

5-Hydroxy Tryptophan,

a. except in oral preparations with a maximum daily dose not exceeding 220 mg of 5-Hydroxy tryptophan, alone or in combination with other active pharmaceutical ingredients; (S1)
b. except in oral preparation with a maximum daily dose not exceeding 220 mg of 5-Hydroxy tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement. (S0)

Hydroxyzine.

Hygromycin B, except when listed elsewhere in the Schedules and except when intended as an anthelmintic for pigs and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Imipramine and its derivatives, unless listed elsewhere in the Schedules.

Iproniazid.

Isoflurane.

Isotretinoin.

Ketamine.

Ketazolam**.

Lemborexant.

Lithium salts, except when intended for application to the skin. (S2)

Lofepramine.

Loprazolam**.

Lorazepam**.

Lormetazepam**.

Loxapine.

Maprotiline.

Mazindol**.

Mebolazine.

Mechlorethamine and its derivatives, unless listed elsewhere in the Schedules.

Meclofenoxate.

Medazepam**.

Medetomidine.

Melitracene.

Mephenoxalone.

Meprobamate**.

Mesterolone.

Metandienone.

Metenolone.

Methandranone.

Methandriol.

Methoxyflurane.

Methyltestosterone.

Metrifonate.

Mianserin.

Mibolerone.

Midazolam**.

Milnacipran.

Mirtazapine.

Mitrazapine.

Moclobemide.

Modafinil.

Molindone.

Nalbuphine.

Nandrolone.

Nefazodone.

Nitrazepam**.

Nomifensine.

Norclostebol.

Norethandronlone.

Nortriptyline.

Olanzapine.

Oxabolone.

Oxandrolone.

Oxazepam**.

Oxymesterone.

Oxymetholone.

Oxypertine.

Paliperidone.

Paraldehyde.

Pargyline.

Paroxetine.

Pemoline** and its complexes**.

Perampanel.

Phenethylhydrazine.

Phenazepam.

Phenothiazine and its derivatives,

a. unless listed in another Schedule;
b. except preparations and mixtures containing promethazine or dimethothiazine or their salts when used solely as an antihistaminic; (S2) and
c. except preparations containing promethazine or its salts when intended specifically for the treatment of travel sickness or application to the skin; (S2) and
d. except phenothiazine when intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Phentermine**.

Pimethixene, except preparations and mixtures thereof when used solely as an antihistaminic. (S2)

Pimozide.

Pipradrol**.

Pizotifen, except preparations and mixtures thereof when used solely as an antihistaminic or when intended for the prophylaxis of migraine. (S2)

Prasterone (Dehydroepiandrosterone, DHEA).

Prazepam**.

Prolintane.

Pregabalin.

Prochlorperazine maleate.

Propofol.

Protriptyline.

Quazepam**.

Quetiapine.

Quinbolone.

Quinupramine.

Reboxetine.

Rimonabant.

Risperidone.

Rivastigmine.

Romifidine.

Sertindole.

Sertraline.

Sevoflurane.

Sibutramine.

Stanozolol.

Stenbolone.

Sulphonmethane.

Sulpiride.

Temazepam**.

Testolactone.

Testosterone, except subcutaneous implants thereof when specifically intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Thioguanosine.

Thiopentone.

Thiothixene.

Tiapride.

Tiletamine.

Tizanidine.

Tramadol.

Tranylcypromine.

Trazodone.

Trenbolone, except subcutaneous implants thereof when specifically intended and registered as a veterinary production improver in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Tretinoin, when intended for oral preparation. (S3)

Triazolam**.

Trifluoroperazine.

Trihexyphenidyl.

Trimipramine.

L-tryptophan,

a. except in oral preparations with a maximum daily dose not exceeding 220 mg of L-tryptophan, alone or in combination with other active pharmaceutical ingredients; (S1)
b. except in oral preparation with a maximum daily dose not exceeding 220 mg of L-tryptophan alone or in combination with other active pharmaceutical ingredients, with general health claims as a health supplement; (S0)

Varenicline.

Venlafaxine.

Viloxazine.

Vortioxetine.

Xylazine.

Zaleplon.

Zimelidine.

Ziprasidone.

Zolazepam.

Zolpidem**.

Zopiclone.

Zotepine.

Zuclopenthixol.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Schedule 5 Annexure 1A added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021.]

PARAMEDIC (National Diploma in Emergency Medical Care graduates only) registered with the Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates)

BENZODIAZEPINE DERIVATIVE
Substance : Diazepam
Indication : Anti Convulsant/Sedative/Hypnotic
Schedule : 5
Route of Administration : Parenteral

BENZODIAZEPINE DERIVATIVE
Substance : Midazolam
Indication : Anti Convulsant/Sedative/Hypnotic
Schedule : 5
Route of Administration : Parenteral

BENZODIAZEPINE DERIVATIVE
Substance : Lorazepam
Indication : Anti Convulsant/Sedative/Hypnotic
Schedule : 5
Route of Administration : Parenteral

BENZODIAZEPINE ANTAGONIST

Substance : Flumazenil
Indication : Benzodiazepine Antagonist
Schedule : 5
Route of Administration : Parenteral

NON-SELECTIVE ANTIHISTAMINE
Substance : Promethazine
Indication : Antihistamine
Schedule : 5
Route of Administration : Parenteral

*INDUCTION AGENTS
Substance : Ketamine
Indication : Analgesia
Route of Administration : Parenteral

ANALGESIC INHALANT
Substance : Methoxyflurane (Penthrox Inhaler)
Indication : Analgesia
Route of Administration : Inhalant

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Schedule 5 Annexure 1B added by GNR 674 in G. 36827 of 13 September 2013; amended by GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE PRACTITIONER
(Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (B Tech: Emergency Medical Care)

BENZODIAZEPINE DERIVATIVE
Substance : Diazepam
Indication : Anti Convulsant/Sedative/Hypnotic
Schedule : 5
Route of Administration : Parenteral

BENZODIAZEPINE DERIVATIVE
Substance : Midazolam
Indication : Anti Convulsant/Sedative/Hypnotic

Schedule : 5
Route of Administration : Parenteral

BENZODIAZEPINE DERIVATIVE
Substance : Lorazepam
Indication : Anti Convulsant/Sedative/Hypnotic
Schedule : 5
Route of Administration : Parenteral

BENZODIAZEPINE ANTAGONIST
Substance : Flumazenil
Indication : Benzodiazepine Antagonist
Schedule : 5
Route of Administration : Parenteral

NON-SELECTIVE ANTIHISTAMINE
Substance : Promethazine
Indication : Antihistamine
Schedule : 5
Route of Administration : Parenteral

INDUCTION AGENTS
Substance : Ketamine
Indication : Dissociative Anaesthesia/Analgesic/Mild Bronchodilator
Schedule : 5
Route of Administration : Parenteral

INDUCTION AGENTS
Substance : Etomidate
Indication : Induction Agent
Schedule : 5
Route of Administration : Parenteral

ANALGESIC INHALANT
Substance : Methoxyflurane (Penthrox Inhaler)
Indication : Analgesia
Route of Administration : Inhalant

ANNEXURE 1C: BASIC AMBULANCE ASSISTANT

[Schedule 5 Annexure 1C added by GN 883 in G. 45176 of 17 September 2021.]

BASIC AMBULANCE ASSISTANT registered with Health Professions Council of South Africa

ANALGESIC INHALANT
Substance : Methoxyflurane (Penthrox Inhaler)
Indication : Analgesia
Route of Administration : Inhalant

ANNEXURE 1D: AMBULANCE EMERGENCY ASSISTANT

[Schedule 5 Annexure 1D added by GN 883 in G. 45176 of 17 September 2021.]

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

ANALGESIC INHALANT
Substance : Methoxyflurane (Penthrox Inhaler)
Indication : Analgesia
Route of Administration : Inhalant

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

[Schedule 5 Annexure 1E added by GNR 1375 in G. 44019 of 18 December 2020; amended by GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

BENZODIAZEPINE DERIVATIVE
Substance : Diazepam
Indication : Anti-convulsant/Sedative/Hypnotic
Route of Administration : Parenteral

*BENZODIAZEPINE DERIVATIVE
Substance : Midazolam
Indication : Anti-convulsant/Sedative/Hypnotic
Route of Administration : Parenteral

*BENZODIAZEPINE DERIVATIVE
Substance : Lorazepam
Indication : Anti-convulsant/Sedative/Hypnotic
Route of Administration : Parenteral

BENZODIAZEPINE ANTAGONIST
Substance : Flumazenil
Indication : Benzodiazepine Antagonist
Route of Administration : Parenteral

NON-SELECTIVE ANTIHISTAMINE
Substance : Promethazine
Indication : Antihistamine
Route of Administration : Parenteral

EMERGENCY CARE ASSISTANT registered with Health Professions Council of South Africa
BENZODIAZEPINE DERIVATIVE
Substance : Diazepam
Indication : Anti-convulsant/Sedative/Hypnotic
Route of Administration : Parenteral

*BENZODIAZEPINE DERIVATIVE
Substance : Midazolam
Indication : Anti-convulsant/Sedative/Hypnotic
Route of Administration : Parenteral

*BENZODIAZEPINE DERIVATIVE
Substance : Lorazepam
Indication : Anti-convulsant/Sedative/Hypnotic
Route of Administration : Parenteral

BENZODIAZEPINE ANTAGONIST
Substance : Flumazenil
Indication : Benzodiazepine Antagonist
Route of Administration : Parenteral

ANALGESIC INHALANT
Substance : Methoxyflurane (Penthrox Inhaler)
Indication : Analgesia
Route of Administration : Inhalant

ANNEXURE 1F: AMBULANCE EMERGENCY ASSISTANT

[Schedule 5 Annexure 1F added by GN 883 in G. 45176 of 17 September 2021.]

AMBULANCE EMERGENCY ASSISTANT registered with Health Professions Council of South Africa

ANALGESIC INHALANT

Substance	: Methoxyflurane (Penthrox Inhaler)
Indication	: Analgesia
Route of Administration	: Inhalant

SCHEDULE 6

[Schedule 6 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, GNR 2082 of 5 November 1976; amended by GNR 437 of 1 April 1977, GNR 1674 of 18 August 1978, GNR 1926 of 31 August 1979, GNR 658 of 27 March 1981, GNR 2416 of 12 November 1982, GNR 1289 of 14 June 1985; substituted by GN 225 of 17 February 1989, repealed, inserted, amended by s 21 of Act 94 of 1991; amended by GNR 1557 of 16 September 1994, GNR 1203 of 15 October 1999; repealed by s 27 of Act 90 of 1997; inserted by GNR 509 in G. 24727 of 10 April 2003; amended by GNR 491 in G. 31010 of 25 April 2008; substituted by GN 935 in G. 31387 of 5 September 2008, GNR 1230 in G. 32838 of 31 December 2009; amended by GNR 227 in G. 35149 of 15 March 2010, GNR 674 in G. 36827 of 13 September 2013, GNR 104 in G. 37318 of 11 February 2014, GNR 352 in G. 37622 of 8 May 2014, GNR 234 in G. 38586 of 20 March 2015, GN 254 in G. 39815 of 15 March 2016, GN 620 in G. 40041 of 3 June 2016, GN 748 in G. 41009 of 28 July 2017, GN 1261 in G. 41256 of 17 November 2017, GNR 755 in G. 42477 of 23 May 2019, GNR 586 in G. 43347 of 22 May 2020, GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021, GNR 3261 in G. 48358 of 24 March 2023, GN 5181 in G. 51171 of 6 September 2024, GN 6466 in G. 53099 of 1 August 2025.]

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)
Annexure 1B: Emergency Care Provider (Emergency Care Practitioner)
Annexure 1E: Emergency Care Technician

[Annexure numbering as published in original *Gazette*.]

Acetorphine.

Acetyldihydrocodeine.

Acetylmethadol.

Alfentanil.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Amineptine.

Amobarbital.

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene derivatives, being any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure):

a. except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
b. except when contained in appliances for inhalation in which the substance is absorbed in solid material: (S1) and
c. excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof; (S1, S2, S5) and
d. except substances listed in Schedule 7. (S1, S2, S5)

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Buprenorphine.

Butalbital.

Butorphanol.

Carfentanil, when intended for veterinary use. (S7)

Cathine ((+)-norpseudoephedrine / D-norpseudoephedrine).

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne.

Chlorphentermine.

Clonitazene.

Coca leaf and any salt, compound, derivative or preparation of coca leaf and any salt, compound, derivative or preparation thereof that is chemically equivalent or identical to any of these substances, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except decocainized coca leaf and extractions of coca leaf where such extractions contain no cocaine or ecgonine. (S0)

Codeine (methylmorphine),

a. single component codeine preparations;
b. 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)

Codoxime.

Colistin,

a. when compounded by a pharmacist in terms of section 14(4) of the Act, a veterinarian, or by a holder of a section 22C(1)(a) licence, or presented as the raw material: and
b. except when presented as a finished pharmaceutical product. (S4)

Cyclobarbital.

Desomorphine.

Dexamfetamine (Dexamphetamine) in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder. (S7)

Dextromoramide.

Dextropropoxyphene, except preparations and mixtures for oral use containing 135 milligrams or less of dextropropoxyphene, calculated as the base, per dosage unit or with a concentration of not more than 2,5 percent in undivided preparations (S5)

Dextrorphan.

Diampromide.

Diethylpropion (amfepramone).

Diethylthiambutene.

Dihydrocodeine—

a. single component dihydrocodeine preparations;
b. 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. 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)

Dihydroetorphine.

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene.

Dioxaphethyl butyrate.

Diphenoxin (or diphenoxylic acid), except mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5 percent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S2)

Diphenoxylate, except preparations containing not more than 2,5 milligrams of diphenoxylate, calculated as the base, and not less than 25 micrograms of atropine sulphate per dosage unit. (S2)

Dipipanone.

(D-norpseudoephedrine - see cathine)

Drotebanol.

Ecgonine, and the esters and derivatives thereof that are convertible to ecgonine and cocaine.

Ephedra alkaloids (natural or synthetic), unless listed separately in the Schedules,

a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedra alkaloids per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer; (S2)
b. except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids (S1)

Ephedrine,

a. except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures, in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, containing not more than 30 milligrams of ephedrine per dose, with a maximum daily dose not exceeding 120 milligrams, subject to a maximum pack size of 360 milligrams and limited to one pack per customer; (S2)
b. except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine. (S1)

Ethylmethylthiambutene.

Ethylmorphine,

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

Etonitazene.

Etorphine and analogues.

Etoxeridine.

Fenproporex.

Fentanyl, when intended for therapeutic purposes (S7)

Flunitrazepam.

Furethidine.

Glutethimide.

Hydrocodone (dihydrocodeinone).

Hydromorphinol (14-hydroxydihydromorphine).

Hydromorphone (dihydromorphinone).

Hydroxypethidine.

Ibogaine.

Isomethadone.

Ketobemidone.

Levomoramide.

Levophenacylmorphan.

Levorphanol.

Lisdexamfetamine (Lisdexamphetamine), in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder. (S7)

Mecloqualone.

Mefenorex.

Meptazinol.

Metazocine.

Methadone.

Methadone-intermediate.

Methorphan, including levomethorphan and racemethorphan, but excluding dextromethorphan. (S2)

Methyldesorphine.

Methyldihydromorphine.

Methylphenidate and its derivatives, unless listed in another Schedule.

Metopon.

Moramide-intermediate.

Morpheridine.

Morphine, except preparations and mixtures of morphine containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (S2).

Morphine methobromide and other pentavalent nitrogen morphine derivatives.

Morphine-N-oxide and its derivatives.

Myrophine (myristylbenzylmorphine).

Nefopam.

Nicocodine.

Nicodicodine.

Nicomorphine.

Noracymethadol.

Norcodeine.

Norlevorphanol.

Normethadone.

Normorphine (demethylmorphine or N-demethylated morphine).

((+)-Norpseudoephedrine see D-norpseudoephedrine / Cathine)

Norpipanone.

Opium and opiates and any salt, compound, derivative or preparation of opium or opiates, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except mixtures containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (S2)

Opium-poppy and poppy straw, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or whether obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis.

Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).

Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).

Pentazocine.

Pentobarbital.

Pethidine, pethidine-intermediate A, pethidine-intermediate B and pethidine-intermediate C. (S7)

Phenadoxone.

Phenampromide.

Phenazocine.

Phendimetrazine.

Phenomorphan.

Phenoperidine.

Phenylpropanolamine (norephedrine),

except products registered in terms of the Act, not intended for export and oral preparations and mixtures where the recommended daily dose for adults does not exceed 100 milligrams and for children 6 to 12 years does not exceed 50 milligrams, when in combination with another pharmacologically active substance and intended for the symptomatic relief of nasal and sinus congestion, subject to a maximum pack size of 300 milligrams for adults and 150 milligrams for children, limited to one pack per customer. (S2)

Piminodine.

Piritramide.

Proheptazine.

Properidine.

Propiram.

Pseudoephedrine, except contained in products registered in terms of the Act, and not intended for export, being oral preparations and mixtures containing not more than 60 milligrams or controlled-release oral preparations and mixtures containing not more than 120 milligrams of pseudoephedrine per dose, and not more than 240 milligrams per day, 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)

Racemoramide.

Racemorphan.

Remifentanil.

Secobarbital.

Sufentanil.

p-Synephrine,

a. except preparations and mixtures registered in terms of the Act and intended for application to the skin, ears and nares containing 1 percent or less of p-synephrine and containing 0,2 percent or less for application to the eyes; (S0)
b. except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is 50 milligrams or less and for children 6 to 12 years is 25 milligrams or less, with a maximum pack size of 5 days; (S1)
c. except oral preparations and mixtures registered in terms of the Act and intended for the symptomatic relief of nasal and sinus congestion, where the recommended daily dose for adults is more than 50 milligrams and for children 6 to 12 years is more than 25 milligrams (S2)

Tapentadol.

Thebacon.

Thebaine.

Thiafentanyl.

Tilidine.

Tetrahydrocannabinol, except:

a. in raw cannabis plant material cultivated and possessed in accordance with a permit issued in terms of the Plant Improvement Act (Act 11 of 2018) and processed products manufactured from such material, intended for agricultural or industrial purposes, including the manufacture of consumer items or products which have no pharmacological action or medicinal purpose; or
b. …
c. when raw cannabis plant material is cultivated, possessed, and consumed by an adult, in private for personal consumption.

Trimeperidine.

Zipeprol.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Schedule 6 Annexure 1A added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021.]

PARAMEDIC (National Diploma in Emergency Medical Care graduates only) registered with the Health Professions Council of South Africa

PARAMEDIC (National Diploma in Emergency Medical Care graduates)

ANALGESICS

Substance	: Morphine Sulphate
Indication	: Opioid/Narcotic
Schedule	: 6
Route of Administration	: Parenteral

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Schedule 6 Annexure 1B added by GNR 674 in G. 36827 of 13 September 2013; amended by GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021.]

EMERGENCY CARE PRACTITIONER

(Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa

EMERGENCY CARE PRACTITIONER (Bachelor of Technology Degree in Emergency Medical Care) registered with the Health Professions Council of South Africa

ANALGESICS

Substance	: Morphine Sulphate
Indication	: Opioid/Narcotic
Schedule	: 6
Route of Administration	: Parenteral

ANNEXURE 1E: EMERGENCY CARE TECHNICIAN

[Schedule 6 Annexure 1E added by GNR 1375 in G. 44019 of 18 December 2020.]

EMERGENCY CARE TECHNICIAN registered with Health Professions Council of South Africa

*ANALGESIC

Substance	: Morphine sulphate
Indication	: Opioid/Narcotic
Route of Administration	: Parenteral

SCHEDULE 7

[Schedule 7 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, GNR 2082 of 5 November 1976; amended by GNR 437 of 1 April 1977, GNR 1567 of 12 August 1977, GNR 1674 of 18 August 1978 (as amended GNR 2410 of 8 December 1978), GNR 1926 of 31 August 1979, GNR 658 of 27 March 1981, GNR 2416 of 12 November 1982, GNR 1289 of 14 June 1985; substituted by GN 225 of 17 February 1989; amended by GNR 2841 of 7 December 1990, GNR 775 of 7 May 1993; repealed, inserted, amended by s 21 of Act 94 of 1991; amended by GNR 1496 of 13 September 1996, GNR 1203 of 15 October 1999, GNR 1077 of 3 November 2000; repealed by s 27 of Act 90 of 1997; inserted by GNR 509 in G. 24727 of 10 April 2003; amended by GNR 491 in G. 31010 of 25 April 2008; substituted by GN 935 in G. 31387 of 5 September 2008; amended by GN 227 in G. 35149 of 15 March 2012, GNR 690 in G. 36850 of 20 September 2013, GNR 352 in G. 37622 of 8 May 2014, GNR 234 in G. 38586 of 20 March 2015, GN 254 in G. 39815 of 15 March 2016, GN 748 in G. 41009 of 28 July 2017, GN 1261 in G. 41256 of 17 November 2017, GNR 755 in G. 42477 of 23 May 2019, GNR 219 in G. 43051 of 28 February 2020, GNR 586 in G. 43347 of 22 May 2020, GNR 1375 in G. 44019 of 18 December 2020, GN 883 in G. 45176 of 17 September 2021, GN 2685 in G. 47373 of 28 October 2022, GNR 3261 in G. 48358 of 24 March 2023, GN 6466 in G. 53099 of 1 August 2025.]

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.

(Trivial or unofficial names are marked *)

5F – APINACA (5F AKB-48).

Acetylfentanyl.

AB-CHMINACA.

AB-FUBINACA.

AB-PINACA.

ADB-CHMINACA (MAB-CHMINACA).

ADB-FUBINACA.

AH-7921.

Alpha-PHP.

AM-2201.

Aminorex.

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

1-Benzylpiperazine. (BZP)

Beta-aminopropylbenzene and beta-aminoisopropylbenzene, except any compound structurally derived from either beta-aminopropylbenzene or beta-aminoisopropylbenzene by substitution in the side chain or by ring closure therein (or by both such substitution and such ring closure), and presented as:

a. preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and
b. appliances for inhalation in which the substance is absorbed onto solid material; (S1)
c. excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine; (S1, S2, S5)
d. except substances listed in S1, S2, S5, and S6.

Brolamfetamine ((+)-4-bromo-2,5-dimethoxy-α-methylphenethylamine) *(DOB).

4-bromo-2,5-dimethoxyphenethylamine (2C-B) *(Nexus).

Brorphine.

Bufotenine (N,N-dimethylserotonin).

Butyrfentanyl.

Carfentanil, except when intended for veterinary use. (S6)

Catha edulis (“khat”), the whole plant or any portion or product thereof.

Cathinone((-)-(S)-2-aminopropiophenone).

1-(4-chloro-2,5-dimethoxyphenyl)propan-2-amine (DOC).

Clonazolam.

4-CMC (4-chloromethcathinone; clephedrone).

CUMYL-4CN-8INACA.

CUMYL-PEGACLONE.

Dexamfetamine (Dexamphetamine) except in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder (S6)

Diclazepam.

Diethyltryptamine [3-(2-(diethylamino) ethyl) indole] *(DET).

(+)-2,5-dimethoxy-α-methylphenethylamine *(DMA).

2,5-dimethoxy-α-4-dimethylphenethylamine *(DOM, STP) and its derivatives.

2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7).

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)

3-(1, 2-dimethylheptyl)-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran-1-ol *(DMHP).

(+)-N,α-dimethyl-3, 4-(methylenedioxy) phenethylamine *(MDMA).

Dimethyltryptamine [3-(2-(dimethylamino) ethyl) indole] *(DMT).

Dipentylone.

Diphenidine.

(+)-4-ethyl-2,5-dimethoxy-a-phenethylamine *(DOET).

N-Ethylnorpentylone (ephylone).

Ethylone.

Ethylphenidate.

Etilamfetamine(N-ethylamphetamine).

Etizolam.

Etryptamine.

Eutylone.

Fenetylline.

Fentanyl-analogues (unless listed in another Schedule) including:

(i) acetyl-alpha-methylfentanyl;

(ii) alpha-methylfentanyl;

(iii) alpha-methylfentanyl-acetanilide;

(iv) alpha-methylthiofentanyl;

(v) benzyl-fentanyl;

(vi) beta-hydroxyfentanyl;

(vii) beta-hydroxy-3-methylfentanyl;

(viii) 3-methylfentanyl and its two isomeric forms:
cis-N-(3-methyl-1-(2-phenethyl)-4-piperidyl) propionanilide; and
trans-N-(3-methyl-1 -(2-phenethyl)-4-piperidyl) propionanilide;

(ix) 3-methylthiofentanyl;

(x) para-fluorofentanyl; and

(xi) thiofentanyl. (S6)

(xii) 4-anilino-N-phenethylpiperidine (ANPP);

(xiii) N-phenethyl-4-piperidone (NPP).

(xiv) Acryloylfentanyl (acrylfentanyl).

(xv) 4-fluoroisobutyrfentanyl (4-FIBF, pFIBF).

(xvi) Furanylfentanyl

(xvii) Tetrahydrofuranylfentanyl (THF-F).

(xviii) Cyclopropylfentanyl. (N-Phenyl-N-[l-(2-phenylethyl)piperidin-4-ylJcyclopropanecarboxamide)

[Wording as published in original *Gazette*.]

(xix) Methoxyacetyl fentanyl. (2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide)

(xx) Ortho-fluorofentanyl. (N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide)

(xxi) Parafluorobutyrlfentanyl (N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide)

(xxii) Crotonylfentanyl.

(xxiii) Valeryfentanyl.

Flualprazolam.

Flubromazolam.

4-fluoroamphetamine (4-FA).

2-Fluorodeschloroketamine.

4F-MDMB-BINACA.

5F-AMB-PINACA (5F-AMB, 5F-MMB-PINACA).

5F-MDMB-PICA (5F-MDMB-2201).

FUB-AMB (MMB-FUBINACA, AMB-FUBINACA).

Gamma-hydroxybutyrate *(GHB).

Harmaline (3,4-dihydroharmine).

Harmine [7-methoxy-1-methyl-9H-pyrido (3,4-b)-indole].

Heroin (diacetylmorphine).

3-hexyl-7, 8, 9, 10-tetrahydro-6,6,0-trimethyl-6H-dibenzo[b,d]-pyran-1-01 *(Parahexyl).

Isotonitazene.

Lefetamine *(SPA).

Lisdexamfetamine (Lisdexamphetamine), except in medicines registered in terms of the Act and intended for the treatment of Attention-Deficit Hyperactivity Disorder. (S7)

Lysergide (Lysergic acid diethylamide) *(LSD).

4- MEC.

MDMB – CHMICA.

5F-MDMB-PINACA (5F-ADB).

Mephedrone.

Mescaline (3,4,5-trimethoxyphenethylamine).

Mesocarb.

Methamphetamine and methamphetamine racemate.

Methaqualone and any preparation containing methaqualone.

Methcathinone.

Methiopropamine (MPA).

Methoxetamine (MXE).

2-methoxy-α-methyl-4,5-(methylenedioxy)phenethylamine *(MMDA).

p-methoxy-α-methylphenethylamine *(PMA).

3-Methoxyphencyclidine.

Methyl alpha-phenylacetoacetate (MAPA).

4 methylaminorex.

((Methylenedioxyamphetamine *(MDA) and its analogues—see tenamphetamine.)

3.4-methylenedoxypyrovalerone (MDPV).

Methylone (beta-keto-MDMA).

Methyprylon.

Metonitazene.

MDMB-4en-PINACA.

MT -45.

N-ethylhexedrone.

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

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

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

Nabilone. (S8)

Norfentanyl.

Ocfentanil.

Para-methoxymethylamphetamine (PMMA).

Para-methyl-4-methylaminorex (4,4-DMAR).

5F-PB-22.

Pentedrone.

Pethidine-analogues, including:

(i) 1-methyl-4-phenyl-4-propionoxy-piperidine *(MPPP);

(ii) 1-methyl-4 phenyl-1,2,5,6-tetrahydropiperidine *(MPTP); and

(iii) 1-phenylethyl-4-phenyl-4-acetyloxy-piperidine *(PEPAP).

except pethidine-intermediate A, pethidine-intermediate B and pethidine-intermediate C. (S6)

Phencyclidine *(PCP) and its congeners, including:

(i) eticyclidine (N-ethyl-1 -phenylcyclohexylamine) *(PCE);

(ii) rolycyclidine (1-(1-phenylcyclohexyl) pyrrolidine) *(PHP or PCPY); and

(iii) tenocyclidine (1-[1-(2-thienyl) cyclohexyl] piperidine) *(TCP).

Phenmetrazine.

Pholcodine.

Psilocin (4-hydroxy-NN-dimethyltryptamine).

Psilocybine (4-phosphoryloxy-NN-dimethyltryptamine).

Pyrovalerone (4’-methyl-2-(1-pyrrolidinyl) valerophenone).

α-pyrrolidinovalerophenone (α-PVP).

Synthetic cannabinoids (synthetic substances with cannabis-like effects), including but not limited to—

- cannabicyclohexanol;
- JWH-018;
- JWH-073;
- JWH-200;
- CP-47,497;
- CP 47,497-C6;
- CP 47,497-C7;
- CP 47,497-C8;
- CP 47,497-C9;
- HU-210

Tenamfetamine (methylenedioxyamphetamine) *(MDA) and its analogues:

(i) (+)-N-ethyl-α-methyl-3,4-(methylenedioxy) phenethylamine *(N-ethyl MDA);

(ii) (+)-N-[α-methyl-3,4-(methylenedioxy) phenethyl] hydroxylamine *(N-hydroxy MDA).

1-(3-trifluoromethylphenyl) piperazine *(TFMPP).

(+)-3, 4, 5-trimethoxy-α-methylphenethylamine *(TMA).

U47700.

UR-144.

XLR-11.

SCHEDULE 8

[Schedule 8 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, GNR 2082 of 5 November 1976, amended by GNR 437 of 1 April 1977, GNR 1567 of 12 August 1977, GNR 1674 of 18 August 1978 (as amended GN 2410 of 8 December 1978), GNR 1926 of 31 August 1979, GNR 658 of 27 March 1981, GNR 2416 of 12 November 1982, GNR 1289 of 14 June 1985; substituted by GN 225 of 17 February 1989; amended by GNR 1133 of 2 June 1989, GNR 2841 of 7 December 1990, GNR 775 of 7 May 1993; repealed, inserted, amended by s 21 of Act 94 of 1991; amended by GNR 1556 of 16 September 1994, GNR 1203 of 15 October 1999, GNR 1077 of 3 November 2000; repealed by s 27 of Act 90 of 1997; inserted by GNR 509 in G. 24727 of 10 April 2003; substituted by GN 935 in G. 31387 of 5 September 2008; amended by GNs 254 in G. 39815 of 15 March 2016, GN 1261 in G. 41256 of 17 November 2017, GNR 1375 in G. 44019 of 18 December 2020.]

a. 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)

Nabilone. (S7)

SCHEDULE 9

...

[Schedule 9 added by s 36 of Act 65 of 1974; substituted by GNR 420 of 7 March 1975, GNR 2244 of 28 November 1975, GNR 575 of 2 April 1976, GNR 2082 of 5 November 1976; amended by GNR 437 of 1 April 1977, GNR 2416 of 12 November 1982, GNR 1289 of 14 June 1985; substituted by GN 225 of 17 February 1989; amended by GNR 775 of 7 May 1993; repealed, inserted, amended by s 21 of Act 94 of 1991; repealed by s 27 of Act 90 of 1997.]