MEDICINES AND RELATED SUBSTANCES ACT
NO. 101 OF 1965

[View Regulation]

[ASSENTED TO 19 JUNE, 1965]
[DATE OF COMMENCEMENT: 1 APRIL, 1966]

(Afrikaans text signed by the State President)

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as amended by

Drugs Control Amendment Act, No. 29 of 1968

Drugs Control Amendment Act, No. 88 of 1970

Drugs Laws Amendment Act, No. 95 of 1971

Drugs Control Amendment Act, No. 65 of 1974

Medicines and Related Substances Control Amendment Act, No. 19 of 1976

Health Laws Amendment Act, No. 36 of 1977

Medicines and Related Substances Control Amendment Act, No. 17 of 1979

Medicines and Related Substances Control Amendment Act, No. 20 of 1981

Transfer of Powers and Duties of the State President Act, No. 97 of 1986

[with effect from 3 October, 1986]

Businesses Act, No. 71 of 1991

[with effect from 24 May, 1991]

Medicines and Related Substances Control Amendment Act, No. 94 of 1991

General Law Amendment Act, No. 49 of 1996

[with effect from 4 October, 1996]

Abolition of Restrictions on the Jurisdiction of Courts Act, No. 88 of 1996

[with effect from 22 November, 1996]

Medicines and Related Substances Control Amendment Act, No. 90 of 1997

Medicines and Related Substances Amendment Act, No. 59 of 2002

Judicial Matters Amendment Act, No. 66 of 2008

[with effect from 17 February, 2009]

Medicines and Related Substances Amendment Act No. 72 of 2008

Medicines and Related Substances Amendment Act, No. 14 of 2015

GENERAL NOTE

There is a discrepancy between the English and Afrikaans texts of section 1 of Act No. 94 of 1991, which affects section 1 of this Act.

The definition of "landdros" in section 1 of the Afrikaans text of this Act has been amended by the Judicial Matters Amendment Act, No. 66 of 2008. We suggest that reference be made to the Afrikaans Act for this definition.

In terms of s. 24 **of** Act No. 14 of 2015**, 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, are substituted by the words "medicine" and "medicines", respectively.**

EDITORIAL NOTE

Please note that details of Government Notices published in *Government Gazettes* that amend the Schedules to the Act are annotated at the beginning of the Schedules.

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 rationalization 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 No. 65 of 1974, by s. 15 of Act No. 17 of 1979, by s. 22 of Act No. 94 of 1991, by s. 29 of Act No. 90 of 1997 and by s. 13 of Act No. 59 of 2002.]

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—

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

distributed to members of the public; or

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;

[Definition of "advertisement" amended by s. 1 (a) of Act No. 20 of 1981 and substituted by s. 1 (a) of Act No. 72 of

2008 and by s. 1 (a) of Act No. 14 of 2015.]

"advisory committee" . . . . . .

[Definition of "advisory committee" inserted by s. 1 (a) of Act No. 72 of 2008. (Editorial Note: S. 1 (a) of Act No. 72 of 2008 does not give instructions to insert the definition of "advisory committee", however we suggest this was intended) and deleted by s. 1 (b) of Act No. 14 of 2015.]

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

"appeal board" . . . . . .

[Definition of "appeal board" deleted by s. 1 (a) of Act No. 94 of 1991.]

"approved name", in relation to a medicine, means the international non-proprietary 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 No. 194 of 1993);

[Definition of "approved name" substituted by s. 1 (a) of Act No. 90 of 1997.]

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

[Definition of "Authority" inserted by s. 1 (b) of Act No. 72 of 2008.]

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

[Definition of "Board" inserted by s. 1 (c) of Act No. 14 of 2015.]

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

[Definition of "certificate of registration" inserted by s. 1 (b) of Act No. 20 of 1981.]

"cosmetic" . . . . . .

[Definition of "cosmetic" inserted by s. 1 (c) of Act No. 72 of 2008 and deleted by s. 1 (d) of Act No. 14 of 2015.]

"council" . . . . . .

[Definition of "council" deleted by s. 1 (d) of Act No. 72 of 2008.]

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

[Definition of "dentist" substituted by s. 1 (b) of Act No. 90 of 1997.]

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

[Definition of "Director-General" inserted by s. 1 (c) of Act No. 20 of 1981 and substituted by s. 1 (b) of Act No. 94 of 1991 and by s. 1 (c) of Act No. 90 of 1997.]

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

[Definition of "export" inserted by s. 1 (a) of Act No. 17 of 1979.]

"foodstuff" . . . . . .

[Definition of "foodstuff" inserted by s. 1 (e) of Act No. 72 of 2008 and deleted by s. 1 (e) of Act No. 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;

[Definition of "immediate container" inserted by s. 1 (b) of Act No. 17 of 1979.]

"inspector" means a person authorized 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;

[Definition of "interchangeable multi-source medicine" inserted by s. 1 (d) of Act No. 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;

[Definition of "IVD" inserted by s. 1 (f) of Act No. 72 of 2008 and substituted by s. 1 (f) of Act No. 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 No. 90 of 1993), and includes an additional magistrate and an assistant magistrate;

[Definition of "magistrate" inserted by s. 1 (a) of Act No. 59 of 2002.]

"Medical Act" . . . . . .

[Definition of "Medical Act" deleted by s. 1 (e) of Act No. 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 No. 15 of 1973)—

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

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;

[Definition of "medical device" inserted by s. 1 (c) of Act No. 94 of 1991 and substituted by s. 1 (g) of Act No. 72 of 2008 and by s. 1 (h) of Act No. 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;

[Definition of "medical device or IVD establishment" inserted by s. 1 (h) of Act No. 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;

[Definition of "medical practitioner" substituted by s. 1 (c) of Act No. 17 of 1979, by s. 1 (d) of Act No. 94 of 1991 and by s. 1 (f) of Act No. 90 of 1997.]

"medicinal purpose" . . . . . .

[Definition of "medicinal purpose" deleted by s. 1 (e) of Act No. 94 of 1991.]

"medicine"—

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

includes any veterinary medicine;

[Definition of "medicine" substituted by s. 1 (d) of Act No. 17 of 1979, by s. 1 (i) of Act No. 72 of 2008 and by s. 1 (g) of Act No. 14 of 2015.]

"Minister" means the Minister of Health;

[Definition of "Minister" substituted by s. 1 (d) of Act No. 20 of 1981, by s. 1 (f) of Act No. 94 of 1991 and by s. 1 (g) of Act No. 90 of 1997.]

"nurse" means a person registered as such under the Nursing Act, 1978 (Act No. 50 of 1978);

[Definition of "nurse" inserted by s. 1 (g) of Act No. 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;

[Definition of "pharmacist" substituted by s. 1 (e) of Act No. 17 of 1979 and by s. 1 (h) of Act No. 94 of 1991.]

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

[Definition of "pharmacist intern" inserted by s. 1 (h) of Act No. 90 of 1997.]

"pharmacist's assistant" means a person registered as such under the Pharmacy Act, 1974;

[Definition of "pharmacist's assistant" inserted by s. 1 (f) of Act No. 17 of 1979, deleted by s. 1 (i) of Act No. 94 of 1991 and inserted by s. 1 (h) of Act No. 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;

[Definition of "pharmacologist" substituted by s. 1 (j) of Act No. 94 of 1991.]

"pharmacy Board" . . . . . .

[Definition of "pharmacy Board" deleted by s. 1 (k) of Act No. 94 of 1991.]

"practitioner" means a person registered as such under the Allied Health Professions Act, 1982 (Act No. 63 of 1982);

[Definition of "practitioner" inserted by s. 1 (l) of Act No. 94 of 1991 and substituted by s. 1 (i) of Act No. 90 of 1997 and by s. 1 (b) of Act No. 59 of 2002.]

"prescribed" means prescribed by or under this Act;

"product" . . . . . .

[Definition of "product" inserted by s. 1 (j) of Act No. 72 of 2008 and deleted by s. 1 (i) of Act No. 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;

[Definition of "public" inserted by s. 1 (e) of Act No. 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" " . . . . . .

[Definition of "registrar" deleted by s. 1 (k) of Act No. 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;

[Definition of "Scheduled substance" substituted by s. 1 (m) of Act No. 94 of 1991.]

"Schedule 1 substance" . . . . . .

[Definition of "Schedule 1 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 2 substance" . . . . . .

[Definition of "Schedule 2 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 3 substance" . . . . . .

[Definition of "Schedule 3 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

"Schedule 4 substance" . . . . . .

[Definition of "Schedule 4 substance" deleted by s. 1 (n) of Act No. 94 of 1991.]

“Schedule 5 substance” . . . . . .

[Definition of “Schedule 5 substance” deleted by s. 1 (n) of Act No. 94 of 1991.]

“Schedule 6 substance” . . . . . .

[Definition of “Schedule 6 substance” deleted by s. 1 (n) of Act No. 94 of 1991.]

“Schedule 7 substance” . . . . . .

[Definition of “Schedule 7 substance” deleted by s. 1 (n) of Act No. 94 of 1991.]

“Schedule 8 substance” . . . . . .

[Definition of “Schedule 8 substance” deleted by s. 1 (n) of Act No. 94 of 1991.]

“Schedule 9 substance” . . . . . .

[Definition of “Schedule 9 substance” deleted by s. 1 (n) of Act No. 94 of 1991.]

“Secretary” . . . . . .

[Definition of “Secretary” deleted by s. 1 (f) of Act No. 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 authorize, 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” . . . . . .

[Definition of “the territory” deleted by s. 1 (o) of Act No. 94 of 1991 and by s. 1 of Act No. 49 of 1996.]

“trainee pharmacist” . . . . . .

[Definition of “trainee pharmacist” deleted by s. 1 (o) of Act No. 94 of 1991.]

“unqualified assistant” . . . . . .

[Definition of “unqualified assistant” deleted by s. 1 (g) of Act No. 17 of 1979.]

“veterinarian” means a person registered as such under the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982);

[Definition of “veterinarian” substituted by s. 1 (p) of Act No. 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 Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 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.

[Definition of “veterinary medicine” added by s. 1 (h) of Act No. 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.

[Definition of “vigilance” inserted by s. 1 (j) of Act No. 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 purpose 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.

[Sub-s. (2) substituted by s. 1 (i) of Act No. 17 of 1979, by s. 1 (g) of Act No. 20 of 1981 and by s. 1 (j) of Act No. 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.

[Sub-s. (3) substituted by s. 1 (j) of Act No. 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 (1) of Act No. 65 of 1974. Sub-s (4) added by s. 1 (k) of Act No. 90 of 1997.]

2. Establishment of South African Health Products Regulatory Authority.—(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.

[Sub-s. (1) substituted by s. 2 (b) of Act No. 14 of 2015.]

(2) The Authority is—

a juristic person;

Subject: to the Public Finance Management Act, 1999 (Act No. 1 of 1999); and

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.

[S. 2 amended by s. 2 (1) of Act No. 65 of 1974, by s. 2 of Act No. 94 of 1991 and by s. 2 of Act No. 90 of 1997, substituted by s. 2 of Act No. 72 of 2008 and amended by s. 2 (a) of Act No. 14 of 2015.]

(5) The Authority acts through its Board.

[Sub-s. (5) added by s. 2 (c) of Act No. 14 of 2015.]

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 No. 14 of 2015.]

2B. Functions of Authority.—(1) The Authority must, in order to achieve its objects—

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;

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

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

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;

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

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

(2) The Authority may—

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

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 No. 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—

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;

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

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

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

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

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 No. 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—

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

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 No. 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 No. 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—

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

is an unrehabilitated insolvent;

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

has been removed from an office of trust.

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

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

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

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 No. 17 of 2002);

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

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 No. 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 No. 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 No. 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—

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

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

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

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

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 No. 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.

[Sub-s. (1) substituted by s. 4 (a) of Act No. 14 of 2015.]

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

is an unrehabilitated insolvent;

is mentally unfit; or

has been convicted of an offence committed after the Constitution of the Republic of South Africa, 1993 (Act No. 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—

serious misconduct;

permanent incapacity; or

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

(4) The Chief Executive Officer—

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

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

[Para. (b) substituted by s. 4 (b) of Act No. 14 of 2015.]

is accountable to and reports to the Board;

[Para. (c) substituted by s. 4 (b) of Act No. 14 of 2015.]

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

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;

must manage and direct the activities of the Authority;

must appoint and supervise staff of the Authority; and

must compile business and financial plans and reports in terms of the Public Finance Management Act, 1999 (Act No. 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 No. 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 No. 65 of 1974, by s. 1 of Act No. 36 of 1977, by s. 2 of Act No. 17 of 1979, by s. 46 of Act No. 97 of 1986 and by s. 3 of Act No. 94 of 1991, substituted by s. 3 of Act No. 90 of 1997 and by s. 3 of Act No. 72 of 2008. Sub-s. (9) substituted by s. 4 (c) of Act No. 14 of 2015.]

4. . . . . . .

[S. 4 amended by s. 4 (1) of Act No. 65 of 1974 and by s. 4 of Act No. 90 of 1997, substituted by s. 4 of Act No. 72 of 2008 and repealed by s. 5 of Act No. 14 of 2015.]

5. . . . . . .

[S. 5 amended by s. 46 of Act No. 97 of 1986 and repealed by s. 5 of Act No. 72 of 2008.]

6. . . . . . .

[S. 6 amended by s. 5 of Act No. 65 of 1974, by s. 3 of Act No. 17 of 1979, by s. 46 of Act No. 97 of 1986, by s. 4 of Act No. 94 of 1991 and by s. 1 of Act No. 49 of 1996, substituted by s. 5 of Act No. 90 of 1997, amended by s. 2 (a)-(*b*) of Act No. 59 of 2002 and repealed by s. 5 of Act No. 72 of 2008.

7. . . . . . .

[S. 7 amended by s. 6 of Act No. 65 of 1974 and repealed by s. 5 of Act No. 72 of 2008.]

8. . . . . . .

[S. 8 repealed by s. 5 of Act No. 72 of 2008.]

9. . . . . . .

[S. 9 amended by s. 7 of Act No. 65 of 1974 and by s. 6 of Act No. 90 of 1997 and repealed by s. 5 of Act No. 72 of 2008.]

10. . . . . . .

[S. 10 substituted by s. 8 (1) of Act No. 65 of 1974 (English only), amended by s. 4 of Act No. 17 of 1979 and by s. 46 of Act No. 97 of 1986 and repealed by s. 5 of Act No. 94 of 1991.]

11. . . . . . .

[S. 11 amended by s. 9 of Act No. 65 of 1974, by s. 5 of Act No. 17 of 1979 and by s. 46 of Act No. 97 of 1986 and repealed by s. 6 of Act No. 94 of 1991.]

12. . . . . . .

[S. 12 substituted by s. 10 (1) of Act No. 65 of 1974, amended by s. 7 of Act No. 90 of 1997, substituted by s. 3 of Act No. 59 of 2002 and repealed by s. 5 of Act No. 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—

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

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 (1) of Act No. 65 of 1974 (English only) and substituted by s. 2 of Act No. 20 of 1981, by s. 6 of Act No. 72 of 2008 and by s. 6 of Act No. 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 medicines, 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 medicines, 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—

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

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).

[Para. (b) substituted by s. 7 of Act No. 14 of 2015.]

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

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

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, and 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 (1) of Act No. 29 of 1968 and by s. 12 (1) of Act No. 65 of 1974, amended by s. 6 of Act No. 17 of 1979, s. 7 (a)-(*c*) of Act No. 94 of 1991, by s. 8 (a)-(*b*) of Act No. 90 of 1997 and substituted by s. 7 of Act No. 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—

the prescribed particulars;

samples of the relevant medicines;

where practicable, samples of medical devices or IVDs; and

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

[Sub-para. (ii) amended by s. 8 (a) of Act No. 14 of 2015.]

(iii)

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

[Sub-para. (iii) substituted by s. 8 (a) of Act No. 14 of 2015.]

(iv)

. . . . . .

[Sub-para. (iv) deleted by s. 8 (b) of Act No. 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.

[Para. (c) substituted by s. 8 (c) of Act No. 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—

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

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 No. 29 of 1968, substituted by s. 13 of Act No. 65 of 1974, amended by s. 8 of Act No. 94 of 1991 and by s. 9 (a)-(*f*) of Act No. 90 of 1997 and substituted by s. 8 of Act No. 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 No. 20 of 1981 and substituted by s. 9 of Act No. 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 No. 20 of 1981 and substituted by s. 10 of Act No. 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 —

notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 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;

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;

[Para. (b) substituted by s. 11 of Act No. 72 of 2008.]

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 No. 90 of 1997.]

16. Cancellation of registration.—(1) If the Authority—

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;

[Para. (a) amended by s. 9 of Act No. 14 of 2015.]

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

[Para. (b) amended by s. 9 of Act No. 14 of 2015.]

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,

[Para. (c) added by s. 9 of Act No. 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 No. 29 of 1968, by s. 14 of Act No. 65 of 1974 (English only) and by s. 4 (b) of Act No. 20 of 1981 and substituted by s. 12 of Act No. 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—

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;

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 No. 29 of 1968, substituted by s. 15 of Act No. 65 of 1974, amended by s. 5 of Act No. 20 of 1981 and substituted by s. 13 of Act No. 72 of 2008.]

18. Labels and advertisements.—(1) No person shall sell any—

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

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

[Sub-s. (1) substituted by s. 10 of Act No. 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.

[Sub-s. (2) substituted by s. 10 of Act No. 14 of 2015.]

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

(4) The Authority may authorize 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 No. 65 of 1974 and by s. 7 of Act No. 17 of 1979, amended by s. 11 of Act No. 90 of 1997 and substituted by s. 14 of Act No. 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 No. 90 of 1997 and substituted by s. 15 of Act No. 72 of 2008 and by s. 11 of Act No. 14 of 2015.]

(Date of commencement: 2 May, 2004.)

18B. Sampling of medicines, medical devices or IVDs.—(1) No person shall sample any medicine, medical devices or IVD.

(2) Use of medicine, 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 products, 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 No. 56 of 1974), or any professional or person authorized to use the device.

[S. 18B inserted by s. 12 of Act No. 90 of 1997 and substituted by s. 16 of Act No. 72 of 2008.]

18C. Marketing of medicines, medical devices or IVDs.—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 No. 90 of 1997, substituted by s. 4 of Act No. 59 of 2002 and by s. 17 of Act No. 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.

[Sub-s. (2) substituted by s. 12 of Act No. 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 No. 65 of 1974 (English only) and substituted by s. 18 of Act No. 72 of 2008.]

20. Publication or distribution of false advertisements concerning medicines, medical devices or IVDs.—(1) No person shall—

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

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).

[Para. (b) substituted by s. 13 of Act No. 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 No. 65 of 1974 (English only) and substituted by s. 19 of Act No. 72 of 2008.]

21. Authority may authorize sale of unregistered medicines, medical devices or IVDs for certain purposes.—(1) The Authority may in writing authorize 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 No. 65 of 1974 (English only) and substituted by s. 20 of Act No. 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—

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;

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 No. 65 of 1974, by s. 8 of Act No. 17 of 1979 amended by s. 6 of Act No. 20 of 1981 and substituted by s. 21 of Act No. 72 of 2008.]

22A. Control of medicines, Scheduled substances, medical devices and IVDs.—(1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine, Scheduled substance, medical device or IVD, except in accordance with the prescribed conditions.

[Sub-s. (1) substituted by s. 14 (b) of Act No. 14 of 2015.]

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

[Sub-s. (2) substituted by s. 22 (a) of Act No. 72 of 2008.]

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

(4) Any Schedule 1 substance shall not be sold—

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—

prescribe such substance;

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—

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

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);

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;

[Para. (b) substituted by s. 22 (b) of Act No. 72 of 2008.]

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 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;

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;

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

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);

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

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—

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;

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;

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

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

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;

[Para. (e) substituted by s. 22 (c) of Act No. 72 of 2008.]

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;

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;

where a Schedule 5 substance is used for—

(i)
its anxiolytic, anti-depressant 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;

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

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;

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;

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;

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 percent of the quantity specified in the prescription or order in question;

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;

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

the sale of a 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;

[Para. (p) substituted by s. 5 (a) of Act No. 59 of 2002.]

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;

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 No. 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.

[Sub-s. (8) substituted by s. 5 (b) of Act No. 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 prescribed conditions for the treatment or prevention of a medical condition in a particular patient, or for the purposes of education, analysis or research;

[Sub-para. (i) substituted by s. 5 (c) of Act No. 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 determined by the Director-General.

[Para. (a) substituted by s. 5 (d) of Act No. 59 of 2002.]

(*b*) A permit 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;

[Sub-para. (i) substituted by s. 5 (e) of Act No. 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 in 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).

[Para. (b) substituted by s. 5 (f) of Act No. 59 of 2002.]

(*c*) Notwithstanding paragraph (b), no such importation or exportation shall take place unless authorised by the Director-General.

[Para. (c) substituted by s. 5 (g) of Act No. 59 of 2002.]

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

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

[Para. (a) substituted by s. 22 (d) of Act No. 72 of 2008.]

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

to the conditions, as detailed on the permit, having been complied with, the triplicate copy of the permit 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 pharmacist's assistant shall not handle any specified Schedule 5 or Schedule 6 substance except as contemplated in subsection (5) (a) and (b); and

[Para. (a) substituted by s. 5 (h) of Act No. 59 of 2002.]

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 No. 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.

[Sub-s. (15) substituted by s. 22 (e) of Act No. 72 of 2008.]

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

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

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 prescriber;

[Para. (b) substituted by s. 5 (i) of Act No. 59 of 2002.]

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;

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—

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

"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 No. 65 of 1974, amended by s. 9 of Act No. 17 of 1979 and by s. 7 of Act No. 71 of 1991, substituted, and subsequently re-substituted (after amendment), by s. 9 of Act No. 94 of 1991 and by s. 13 of Act No. 90 of 1997 and amended by s. 14 (a) of Act No. 14 of 2015.]

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

[Sub-s. (1) substituted by s. 15 (b) of Act No. 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 No. 94 of 1991, substituted by s. 23 of Act No. 72 of 2008 and amended by s. 15 (a) of Act No. 14 of 2015.]

22C. Licensing.—(1) Subject to the provisions of this section—

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 No. 56 of 1974), a licence to compound and dispense medicines, on the prescribed conditions;

[Para. (a) substituted by s. 16 (a) of Act No. 14 of 2015.]

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.

[Sub-s (1) amended by s. 6 (a) of Act No. 59 of 2002 and substituted by s. 24 (a) of Act No. 72 of 2008. Para. (b) substituted by s. 16 (a) of Act No. 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.

[Sub-s. (2) substituted by s. 6 (b) of Act No. 59 of 2002 and by s. 24 (b) of Act No. 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.

[Sub-s. (3) substituted by s. 24 (c) of Act No. 72 of 2008.]

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

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

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

[Sub-s. (4) amended by s. 24 (d) of Act No. 72 of 2008.]

(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).

[Sub-s. (5) substituted by s. 6 (c) of Act No. 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.

[Sub-s. (6) substituted by s. 6 (d) of Act No. 59 of 2002, by s. 24 (e) of Act No. 72 of 2008 and by s. 16 (b) of Act No. 14 of 2015.]

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

[S. 22C inserted by s. 14 of Act No. 90 of 1997. Sub-s. (7) substituted by s. 6 (e) of Act No. 59 of 2002.]

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 No. 90 of 1997 and by s. 25 of Act No. 72 of 2008.]

22E. Suspension and cancellation of licence.—(1) If the holder of a licence under section 22C—

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;

[Para. (a) substituted by s. 26 (a) of Act No. 72 of 2008.]

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

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

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.

[Para. (d) amended by s. 26 (b) of Act No. 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)—

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

revoke the licence in question.

[Sub-s. (2) substituted by s. 26 (c) of Act No. 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 No. 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—

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; and

[Para. (a) substituted by s. 7 (b) of Act No. 59 of 2002.]

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.

[Sub-s. (1) amended by s. 7 (a) of Act No. 59 of 2002.]

(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—

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;

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

where the product has been declared not substitutable by the Authority.

[S. 22F inserted by s. 14 of Act No. 90 of 1997. Para. (c) substituted by s. 27 of Act No. 72 of 2008.]

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.

[Sub-s. (1) substituted by s. 8 (a) of Act No. 59 of 2002.]

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

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

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

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

[Para. (c) added by s. 8 (b) of Act No. 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 a wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).

[Para. (b) substituted by s. 8 (c) of Act No. 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 No. 90 of 1997.]

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

[Sub-s. (1) substituted by s. 28 of Act No. 72 of 2008 and by s. 17 (b) of Act No. 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.

[Sub-s. (2) substituted by s. 28 of Act No. 72 of 2008 and by s. 17 (b) of Act No. 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 No. 90 of 1997 and amended by s. 17 (a) of Act No. 14 of 2015.]

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—

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

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.

[Sub-s. (3) amended by s. 22 of Act No. 65 of 1974 (English only) and substituted by s. 29 of Act No. 72 of 2008.]

24. Appeal against decision of the 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 No. 65 of 1974, substituted by s. 11 of Act No. 94 of 1991 and by s. 15 of Act No. 90 of 1997, amended by s. 9 (a)-(*g*) of Act No. 59 of 2002 and substituted by s. 30 of Act No. 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—

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

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 No. 72 of 2008.]

25. Privileges of Authority and committees.— The Authority, persons contracted by the Authority to perform work 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 No. 88 of 1996, by s. 10 of Act No. 59 of 2002 and by s. 32 of Act No. 72 of 2008.]

26. Inspectors.—(1) The Chief Executive Officer may authorize 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 authorized 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 (1) of Act No. 65 of 1974, amended by s. 1 of Act No. 19 of 1976 and by s. 10 of Act No. 17 of 1979 and substituted by s. 33 of Act No. 72 of 2008.]

27. Analysts, pharmacologists, engineers, technicians and pathologists.— The 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 (1) of Act No. 65 of 1974, by s. 11 of Act No. 17 of 1979 and by s. 34 of Act No. 72 of 2008.]

28. Powers of inspectors.—(1) An inspector may, at all reasonable times—

enter upon—

(i)
any place or premises from which a person, authorized 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

[Sub-para. (i) substituted by s. 35 (a) of Act No. 72 of 2008 and by s. 18 (a) of Act No. 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);

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);

[Para. (b) substituted by s. 35 (b) of Act No. 72 of 2008 and by s. 18 (b) of Act No. 14 of 2015.]

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;

[Para. (c) substituted by s. 35 (b) of Act No. 72 of 2008 and by s. 18 (b) of Act No. 14 of 2015.]

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.

[Sub-s. (1) amended by s. 26 (a) of Act No. 65 of 1974 and by s. 16 of Act No. 90 of 1997 and substituted by s. 11 (a) of Act No. 59 of 2002. Para. (d) inserted by s. 35 (c) of Act No. 72 of 2008 and substituted by s. 18 (b) of Act No. 14 of 2015.]

(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;

[Sub-para. (i) substituted by s. 18 (c) of Act No. 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.

[Sub-para. (iii) substituted by s. 18 (d) of Act No. 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.

[Sub-s. (2) amended by s. 26 (a) of Act No. 65 of 1974, substituted by s. 12 (a) of Act No. 17 of 1979 and by s. 35 (d) of Act No. 72 of 2008. Para. (b) substituted by s. 18 (e) of Act No. 14 of 2015.]

(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.

[Sub-s. (3) substituted by s. 12 (b) of Act No. 17 of 1979 and by s. 18 (f) of Act No. 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.

[Sub-s. (4) substituted by s. 26 (b) of Act No. 65 of 1974, by s. 35 (e) of Act No. 72 of 2008 and by s. 18 (f) of Act No. 14 of 2015.]

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

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

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

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

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

[Sub-s. (5) added by s. 11 (b) of Act No. 59 of 2002.]

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

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

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).

[Sub-s. (6) added by s. 11 (b) of Act No. 59 of 2002.]

29. Offences.—Any person who—

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

[Para. (a) substituted by s. 17 (a) of Act No. 90 of 1997.]

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

[Para. (b) substituted by s. 17 (a) of Act No. 90 of 1997.]

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

[Para. (c) substituted by s. 17 (a) of Act No. 90 of 1997.]

contravenes the provisions of section 20 (1); or

[Para. (d) substituted by s. 17 (a) of Act No. 90 of 1997.]

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

[Para. (e) substituted by s. 17 (a) of Act No. 90 of 1997 and by s. 36 (a) of Act No. 72 of 2008.]

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

[Para. (f) substituted by s. 17 (a) of Act No. 90 of 1997.]

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

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

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

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

[Para. (h) substituted by s. 27 (a) of Act No. 65 of 1974 and amended by s. 36 (b) of Act No. 72 of 2008 and by s. 19 (a) of Act No. 14 of 2015.]

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

[Para. (i) substituted by s. 27 (b) of Act No. 65 of 1974, by s. 36 (c) of Act No. 72 of 2008 and by s. 19 (b) of Act No. 14 of 2015.]

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

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;

[Para. (k) added by s. 27 (d) of Act No. 65 of 1974 and substituted by s. 17 (b) of Act No. 90 of 1997.]

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

[Para. (l) added by s. 12 of Act No. 94 of 1991.]

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 imposed in terms of the said section,

[Para. (m) added by s. 12 of Act No. 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.

[Sub-s. (1) substituted by s. 13 of Act No. 94 of 1991 and by s. 18 (a) of Act No. 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.

[Sub-s. (2) amended by s. 28 (a) of Act No. 65 of 1974 and substituted by s. 37 (a) of Act No. 72 of 2008 and by s. 20 (a) of Act No. 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.

[Sub-s. (3) substituted by s. 28 (b) of Act No. 65 of 1974, by s. 37 (b) of Act No. 72 of 2008 and by s. 20 (b) of Act No. 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.

[Sub-s. (4) added by s. 18 (b) of Act No. 90 of 1997.]

31. Procedure and evidence.—(1) In any criminal proceedings under this Act—

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;

[Para. (a) amended by s. 29 of Act No. 65 of 1974 and substituted by s. 38 (a) of Act No. 72 of 2008 and by s. 21 (a) of Act No. 14 of 2015.]

. . . . . .

[Para. (b) deleted by s. 19 (a) of Act No. 90 of 1997.]

a certificate stating the result of a test, examination or analysis carried out in terms of the provisions of section twenty-eight 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;

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.

[Para. (d) amended by s. 29 of Act No. 65 of 1974 and substituted by s. 38 (b) of Act No. 72 of 2008 and by s. 21 (b) of Act No. 14 of 2015.]

(2) . . . . . .

[Sub-s. (2) substituted by s. 13 of Act No. 17 of 1979 and deleted by s. 19 (b) of Act No. 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 No. 65 of 1974 (English only) and repealed by s. 20 of Act No. 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—

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

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

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—

State funds received through the Department of Health;

fees raised and interest on overdue fees;

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 No. 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 No. 90 of 1997 and substituted by s. 39 of Act No. 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 or for the benefit of his employer.

[S. 34 substituted by s. 14 of Act No. 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 sections 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.

[Sub-s. (1) substituted by s. 22 (a) of Act No. 90 of 1997.]

(2) The Director-General may in writing authorize 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.

[Sub-s. (2) amended by s. 22 (b) of Act No. 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 inserted by s. 2 of Act No. 19 of 1976, substituted by s. 15 of Act No. 94 of 1991. Sub-s. (3) added by s. 40 of Act No. 72 of 2008.]

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

(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;

[Para. (i) substituted by s. 22 (a) of Act No. 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);

[Para. (ii) substituted by s. 22 (a) of Act No. 14 of 2015.]

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

[Para. (iii) substituted by s. 22 (a) of Act No. 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;

[Para. (iv) substituted by s. 22 (a) of Act No. 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;

[Para. (v) substituted by s. 22 (a) of Act No. 14 of 2015.]

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

[Para. (vi) substituted by s. 22 (a) of Act No. 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;

[Para. (vii) substituted by s. 22 (a) of Act No. 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;

[Para. (viii) substituted by s. 22 (a) of Act No. 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;

[Para. (ix) substituted by s. 22 (a) of Act No. 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;

[Para. (x) substituted by s. 22 (a) of Act No. 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;

[Para. (xi) substituted by s. 22 (a) of Act No. 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);

[Para. (xii) substituted by s. 41 (b) of Act No. 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, sterilization, disinfection, recall, decomposition, decommissioning or decontamination of medical devices and IVDs;

[Para. (xiii) substituted by s. 41 (c) of Act No. 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;

[Para. (xv) substituted by s. 22 (b) of Act No. 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;

[Para. (xvii) substituted by s. 22 (c) of Act No. 14 of 2015.]

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

[Para. (xviii) substituted by s. 22 (c) of Act No. 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;

[Para. (xix) substituted by s. 22 (c) of Act No. 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;

[Para. (xxii) substituted by s. 22 (d) of Act No. 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;

[Para. (xxiii) substituted by s. 22 (d) of Act No. 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;

[Para. (xxiv) substituted by s. 12 (a) of Act No. 59 of 2002 and by s. 22 (d) of Act No. 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;

[Para. (xxvii) substituted by s. 12 (b) of Act No. 59 of 2002 and by s. 22 (e) of Act No. 14 of 2015.]

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

[Para. (xxviii) substituted by s. 22 (e) of Act No. 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;

[Para. (xxix) substituted by s. 22 (e) of Act No. 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;

[Para. (xxx) substituted by s. 22 (e) of Act No. 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;

[Para. (xxxi) substituted by s. 41 (d) of Act No. 72 of 2008 and by s. 22 (e) of Act No. 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;

[Para. (xxxii) substituted by s. 22 (e) of Act No. 14 of 2015.]

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

[Para. (xxxiii) substituted by s. 41 (e) of Act No. 72 of 2008.]

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

[Para. (xxxiv) substituted by s. 22 (f) of Act No. 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;

[Para. (xxxvii) substituted by s. 41 (f) of Act No. 72 of 2008.]

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

[Para. (xxxviii) substituted by s. 22 (g) of Act No. 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);

[Para. (xl) inserted by s. 41 (g) of Act No. 72 of 2008 and substituted by s. 22 (h) of Act No. 14 of 2015.]

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

[Para. (xli) inserted by s. 41 (g) of Act No. 72 of 2008 and substituted by s. 22 (h) of Act No. 14 of 2015.]

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

[Para. (xlii) inserted by s. 41 (g) of Act No. 72 of 2008 and substituted by s. 22 (h) of Act No. 14 of 2015.]

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

[Para. (xliv), previously para. (xl) renumbered by s. 41 (g) of Act No. 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.

[Sub-s. (1) amended by s. 41 (a) of Act No. 72 of 2008. Para. (xlv), previously para. (xli) renumbered by s. 41 (g) of Act No. 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—

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

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.

[Para. (b) substituted by s. 41 (h) of Act No. 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.

[Sub-s. (5) substituted by s. 41 (i) of Act No. 72 of 2008 and by s. 22 (i) of Act No. 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.

[Sub-s. (6) substituted by s. 41 (j) of Act No. 72 of 2008 and by s. 22 (i) of Act No. 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 No. 29 of 1968, by s. 1 of Act No. 88 of 1970 and by s. 7 of Act No. 95 of 1971, substituted by s. 31 (1) of Act No. 65 of 1974, amended by s. 3 of Act No. 19 of 1976, by s. 14 of Act No. 17 of 1979, by s. 7 of Act No. 20 of 1981, by s. 7 of Act No. 71 of 1991 and by s. 16 of Act No. 94 of 1991 and substituted by s. 23 of Act No. 90 of 1997. Sub-s. (8) substituted by s. 41 (k) of Act No. 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 No. 65 of 1974 (English only) and substituted by s. 42 of Act No. 72 of 2008 and by s. 23 of Act No. 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—

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

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 No. 94 of 1991.]

37. . . . . . .

[S. 37 substituted by s. 33 of Act No. 65 of 1974 and by s. 18 of Act No. 94 of 1991 and repealed by s. 24 of Act No. 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 No. 65 of 1974, repealed, and subsequently re-inserted (after amendment), by s. 19 of Act No. 94 of 1991, substituted by s. 25 of Act No. 90 of 1997 and by s. 43 of Act No. 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 No. 94 of 1991 and inserted by s. 26 of Act No. 90 of 1997.]

(Date of commencement: 1 July, 2005.)

40. Short title.—This Act shall be called the Medicines and Related Substances Act, 1965.

[S. 40 substituted by s. 35 of Act No. 65 of 1974 and by s. 28 of Act No. 90 of 1997.]

SCHEDULE 0

[Schedule 0 inserted by Government Notice No. R.509 in *Government Gazette* 24727 of 10 April, 2003, substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008 and amended by Government Notice No. R.1230 in *Government Gazette* 32838 of 31 December, 2009.]

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.

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 No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975, No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by Government Notices No. R.278 of 25 February, 1977, No. R.437 of 1 April, 1977, No. R.1194 of 1 July, 1977, No. R.1674 of 18 August, 1978 (as amended by Government Notice No. R.2410 of 8 December, 1978), No. R.1926 of 31 August, 1979, No. R.2416 of 12 November, 1982 and No. R.1289 of 14 June, 1985 (as amended by Government Notice No. 155 of 31 January, 1986), substituted by Government Notice No. 225 of 17 February, 1989, amended by Government Notices No. R.2841 of 7 December, 1990, No. R.2169 of 6 September, 1991, No. R.348 of 5 March, 1993 and No. R.775 of 7 May, 1993, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991, amended by Government Notice No. R.1556 of 16 September, 1994, by Government Notice No. R.673 of 12

May, 1995, by Government Notice No. R.42 of 19 January, 1996, by Government Notice No. R.1496 of 13 September, 1996, by Government Notice No. R.1098 of 15 August, 1997, by Government Notice No. R.1099 of 15 August, 1997, by Government Notice No. R.1203 of 15 October, 1999 and by Government Notice No. R.1077 of 3 November, 2000, repealed by s. 27 of Act No. 90 of 1997, inserted by Government Notice No. R.509 in *Government Gazette* 24727 of 10 April, 2003, amended by Government Notice No. R.491 in *Government Gazette* 31010 of 25 April, 2008, substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008, Government Notice No. R.1230 in *Government Gazette* 32838 of 31 December, 2009, amended by Government Notice No. R.227 in *Government Gazette* 35149 of 15 March, 2012, amended by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013, amended by Government Notice No. R.690 in *Government Gazette* 36850 of 20 September, 2013, amended by Government Notice No. R.104 in *Government Gazette* 37318 of 11 February, 2014, amended by Government Notice No. R.352 in *Government Gazette* 37622 of 8 May, 2014, amended by Government Notice No. R.234 in *Government Gazette* 38586 of 20 March, 2015, amended by Government Notice No. 254 in *Government Gazette* 39815 of 15 March, 2016 and amended by Government Notice No. 620 in *Government Gazette* 40041 of 3 June, 2016.]

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.

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.

In terms of section 22A (4) (a) (v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act No. 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 1 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

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

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

(iii)
Annexure 2:
Dental Therapist;

(iv)
Annexure 3:
Optometrist.

Acetanilide and alkyl acetanilides.

Acetarsol, when intended for human vaginal use.

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:

preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine-containing nose and eye preparations; and

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; in concentrations equivalent to 0,01 percent or less of arsenic trioxide. (S2)

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,

when intended for topical use;

in oral preparations containing 2 % or less of benzocaine;

in lozenges containing 30 mg or less of benzocaine, per dosage unit;

except when intended for ophthalmic or parenteral use. (S4)

Benzydamine; preparations and mixtures containing—

3 percent or less of benzydamine, when intended for application to the skin (S3); or

0,15 percent or less of benzydamine, when 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)

Bifidobacterium adolescentis,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim;

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium animalis *subsp*. Animalis,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium animalis *subsp*. Lactis,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium bifidum,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium breve,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium lactis,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium longum *subsp*. Infantis,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Bifidobacterium longum *subsp*. Longum,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

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,

when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) or

when intended for application to the skin. (S4)

Calcium,

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)

except in preparations thereof for injection; (S3)

except when indicated for the treatment of hyperphosphataemia; (S4)

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).

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 50 µg of Chromium per recommended daily dose alone or in combination with other active pharmaceutical ingredients. (S0)

Clotrimazole,

when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) and

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,

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)

except in preparations thereof for injection. (S3)

Cyanocobalamin—see Vitamin B12.

Diclofenac, when intended for application to the skin. (S2, S3)

Diosmine.

Dithiazanine.

Econazole,

when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) or

when intended for application to the skin. (S4)

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

Ephedra alkaloids (natural or synthetic), unless listed separately in the Schedules, intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids, and not intended for export. (S2, S6)

Ephedrine, preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1 percent or less of ephedrine, and not intended for export. (S2; S6)

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)

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,

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)

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.

except when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)

except when intended for ophthalmic use. (S4)

Fluorescein, when intended for ophthalmic use by the topical route only. (S3)

Fluorides,

in oral medicinal preparations or mixtures intended for ingestion containing 0,25 milligrams or less of fluorine per dosage unit; Schedule 0 *inscription removed*

except in toothpaste containing less than 0,15 percent fluoride; (S0) and

except in mouth rinses containing less than 0,15 percent fluoride. (S0)

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,

when intended for topical application to the skin;

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

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

except when intended for parenteral use (S4)

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).

Ibuprofen,

when contained in preparations intended for application to the skin; (S2, S3, S4).

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. (S2, S3)

Icodextrin.

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

Indanazoline.

Indometacin,

when intended for application to the skin; (S3)

except when intended for the emergency treatment of acute gout attacks; (S2)

Iron,

in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

except in preparations thereof for injection; (S3)

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, when intended for

application to the skin,

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,

when intended for application to the skin; (S3)

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)

except when intended for the emergency treatment of acute gout attacks; (S2)

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)

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,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus brevis,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1×10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus caucasicus,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing $\geq 1 \times 10^9$ cfu per dosage unit with

the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus casei,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus fermentum,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1974 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

(Editorial Note: Wording as per the original *Government Gazette*. It is suggested that the phrase "Foodstuffs, Cosmetic and Disinfectant Act, 1974 (Act No. 54 of 1972)" is intended to be "Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972)".)

Lactobacillus gasseri,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human*

intestines and thereby improve the functioning of the digestive tract/gut"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1974 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

(Editorial Note: Wording as per the original *Government Gazette*. It is suggested that the phrase "Foodstuffs, Cosmetic and Disinfectant Act, 1974 (Act No. 54 of 1972)" is intended to be "Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972)".)

Lactobacillus helveticus,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus johnsonii,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus lactis,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus paracasei,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus plantarum,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus reuteri,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus rhamnosus,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lactobacillus salivarius,

in pharmaceutical preparations and mixtures with medicinal claim(s);

except in pharmaceutical preparations and mixtures for one or more strains containing ≥1 x 10^9 cfu per dosage unit with the general health claim:

"*When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut*"; (S0)

except for use in ready-to-drink single serving infant formula sold in liquid form, in terms of the provisions of the Foodstuffs, Cosmetic and Disinfectant Act, 1972 (Act No. 54 of 1972) containing no less than 1 x 10^8 cfu probiotics per daily serving, provided no medicinal or general health claim is made.

Lidocaine,

when intended for topical use;

in oral preparations containing 2 % or less of lidocaine, per dosage unit;

except when intended for ophthalmic or parenteral use; (S4)

except when intended for the treatment of neuropathic pain associated with previous herpes zoster infection. (S4)

Lignocaine,—see Lidocaine.

Local anaesthetics, except

when intended for ophthalmic or parental use; (S4)

oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of "arc eyes"; (S2) and

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,

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)

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.

Miconazole,

when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; (S4) and

when intended for application to the skin. (S4)

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

when contained in preparations intended for application to the skin; (S2, S3)

when contained in oral medicinal preparations 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)

Niacin (Nicotinic Acid, Vitamin B3) and derivatives thereof,

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)

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,

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;

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)

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)

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)

except when registered as metered sprays containing not more than 1 mg per dose; (S2)

except when registered as oral solid dosage forms containing not more than 2 mg; (S2)

except when registered as inhalers containing not more than 10 mg per cartridge; (S2)

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,

when intended for application to the skin; and

when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis; and

except when presented as oral drops containing not more than 100 000 I.U. per ml; (S2)

except when intended for systemic use or the initial treatment of vaginal candidiasis. (S4)

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),

in oral preparations containing an antacid;

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—

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)

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)

when contained in rectal suppositories; (S2)

when contained in modified release formulations; (S2)

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, except ophthalmic preparations containing 0,2 percent or less. (S0)

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,

in topical preparations containing 10 % or less of prilocaine;

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,

for oral use, and

when intended for application to the skin, and

except when intended for soft contact lens cleaners; (S0) and

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.

Riboflavin—see Vitamin B2.

Selenium,

in oral preparations or mixtures containing more than 60 µg of Selenium per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S0)

in preparations thereof for injection when intended for veterinary use.

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

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

Tetracaine,

when intended for topical use;

in oral preparations containing 2 % or less of tetracaine, per dosage unit;

except when contained in eye drops intended for the emergency treatment of "arc eyes"; (S2)

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,

when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis; and

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)

L-tryptophan,

when intended for medicinal use in dosages of less than 5mg/kg/day or

intended as supplementation for nutritional purposes. (S5)

Vitamin B1 (Thiamine) and derivatives thereof,

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)

except in preparations thereof for injection. (S3)

Vitamin B2 (Riboflavin) and derivatives thereof,

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)

except in preparations thereof for injection. (S3)

Vitamin B5 (Pantothenic Acid) and derivatives thereof,

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)

except in preparations thereof for injection. (S3)

Vitamin B6 (Pyridoxine) and derivatives thereof,

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)

except in preparations thereof for injection. (S3)

Vitamin B12 (Cyanocobalamin) and derivatives thereof,

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)

except in preparations thereof for injection. (S3)

Vitamin C (Ascorbic Acid),

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)

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,

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)

except in injection preparations; (S3)

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,

in injection preparations when intended for veterinary use;

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)

except when intended for topical use; (S0)

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,

except when intended for oral ingestion, where the daily dose is less than 50 milligrams of elemental zinc; (S0),

except when intended for topical use by humans; (S0),

when intended for veterinary use as an 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).

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Annex. 1A added by GNR. 674 in *Government Gazette* 36827 of 13 September, 2013.]

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

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Annex. 1B added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

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

ANNEXURE 2: DENTAL THERAPIST

[Annex. 2 added by GNR. 674 in *Government Gazette* 36827 of 13 September, 2013.]

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

DENTAL THERAPIST (Bachelors degree in Dental Therapy)	
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY	
Substance	: Paracetamol
Indication	: Dental pain
Schedule	: 1
Route of Administration	: Oral
SURFACE ANAESTHETIC	
Substance	: Lidocaine/ Lignocaine Hydrochloride
Indication	: Dental surface anaesthesia
Schedule	: 1
Route of Administration	: Topical

DENTAL THERAPIST (Bachelors degree in Dental Therapy)	
ANTI-VIRAL	
Substance	: Acyclovir
Indication	: Viral infection of lips
Schedule	: 1
Route of Administration	: Topical
VITAMINS AND MINERALS	
Substance	: —
Indication	: Applicable to Dentistry
Schedule	: 1

Route of Administration	: Oral
MOUTH AND THROAT PREPARATIONS	
Substance	: —
Indication	: Applicable to Dentistry
Schedule	: 1
Route of Administration	: Oral

ANNEXURE 3: OPTOMETRIST

[Annex. 3 added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013 and substituted by Government Notice 620 in *Government Gazette* 40041 of 3 June, 2016.]

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

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

SCHEDULE 2

[Schedule 2 added by s. 36 of Act No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975, No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by Government Notices No. R.278 of 25 February, 1977, No. R.437 of 1 April, 1977, No. R.1988 of 30 September, 1977, No. R.1674 of 18 August, 1978 (as amended by Government Notice No. R.2410 of 8 December, 1978), No. R.1926 of 31 August, 1979, No. R.2507 of 9 November, 1979, No. R.2416 of 12 November, 1982, No. R.1289 of 14 June, 1985 (as amended by Government Notice No. 155 of 31 January, 1986) and No. 154 of 31 January, 1986, substituted by Government Notice No. 225 of 17 February, 1989, amended by Government Notices No. R.1132 of 2 June, 1989, No. R.1862 of 10 August, 1990, No. R.2841 of 7 December, 1990, No. R.2169 of 6 September, 1991, No. R.141 of 5 February, 1993 and No. R.775 of 7 May 1993, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991, amended by Government Notices Nos. R.1556 and R.1557 of 16 September, 1994, by Government Notice No. R.673 of 12 May, 1995, by Government Notice No. R.1496 of 13 September 1996, by Government Notice No. R.1203 of 15 October, 1999 and by Government Notice No. R.1077 of 3 November, 2000, repealed by s. 27 of Act No. 90 of 1997, inserted by Government Notice No. R509 in *Government Gazette* 24727 of 20 April, 2003, amended by Government Notice No. R.491 in *Government Gazette* 31010 of 25 April, 2008, substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008, Government Notice No. R.1230 in *Government Gazette* 32838 of 31 December, 2009, amended by Government Notice No. R.227 in *Government Gazette* 35149 of 15 March, 2012, amended by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013, amended by Government Notice No. R.690 in *Government Gazette* 36850 of 20 September, 2013, amended by Government Notice No. R.104 in *Government Gazette* 37318 of 11 February, 2014, amended by Government Notice No. R.352 in *Government Gazette* 37622 of 8 May, 2014, amended by Government Notice No. R.234 in *Government Gazette* 38586 of 20 March, 2015, amended by Government Notice No. 254 in *Government Gazette* 39815 of 15 March, 2016 and amended by Government Notice No. 620 in *Government Gazette* 40041 of 3 June, 2016.]

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.

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.

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 or practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 2 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

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

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

(iii)
Annexure 2:
Dental Therapist;

(iv)
Annexure 3:
Optometrist.

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

Aconite alkaloids, preparations containing 0,02 percent or more. (S0)

Acrivastine.

Adrenaline (epinephrine), except—

ophthalmic preparations when intended for glaucoma, and

preparations for injection. (S3, S4)

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—

astemizole and terfenadine; (S4)

when listed separately in these Schedules. (S5)

Antimicrobial substances, namely

griseofulvin, mupirocin, natamycin when intended for application to the skin, nares and external ear; (S4)

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; preparations containing the equivalent of 0,01 percent or more of arsenic trioxide. (S1)

Aspirin (acetyl salicylic acid), when intended for:

the treatment of children or adolescents; and

the prophylaxis of cardiovascular disease in adults (S0)

Atropine, except

when intended for use in ophthalmic preparations; (S3)

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 maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms per nostril and

a maximum pack size of 200 doses. (S3, S4)

Belladonna alkaloids, except when intended for topical application. (S1)

Benproperine.

Bevonium methylsulphate.

Bismuth, when intended for oral use.

Bromhexine.

Bromides, preparations containing less than 80 milligrams of bromine per recommended daily dose. (S5)

Brompheniramine.

Buclizine.

Butinoline.

Calabar bean alkaloids.

Camphorated Opium Tincture.

Camylofin.

Cantharidin.

Canthaxanthin

Carbinoxamine.

Carbocisteine.

Carbuterol, except

when contained in respirator solutions; (S3) and

when intended for injection. (S4)

Carisoprodol.

Cetirizine.

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)

Chloroguine, when used in combination with proguanil and when intended specifically for malaria prophylaxis. (S4)

Chlorpheniramine.

Chlorprenaline.

Cholestyramine.

Chlorzoxazone.

Clonidine when intended for the treatment 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),

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;

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;

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)

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)

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)

Desloratidine.

Dexchlorpheniramine.

Dextromethorphan.

Diclofenac, for a maximum period of 5 days when intended for

the emergency treatment of acute gout attacks, or

the treatment of post traumatic conditions. (S1, 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,

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;

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;

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)

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)

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, for periods not

exceeding 4 months of continuous use. (S4)

except in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), excluding when intended for administration in animal feed.

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:

oral preparations and mixtures containing not more than 30 milligrams of ephedra alkaloids per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S6)

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,

oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S6)

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.

Estradiol,

when intended for human vaginal use;

except when intended for oral contraception; (S3)

except when intended for hormone replacement therapy. (S4)

Ethylmorphine:

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

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 maximum dose of 10 milligrams;

a maximum daily dose (per 24 hours) of 20 milligrams;

a maximum treatment period of 2 weeks. (S4)

Fedrilate.

Fenoprofen,

when intended for the emergency treatment of acute gout attacks, and

when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S3)

Fenoterol, except—

when contained in respirator solutions; (S3) and

when intended for injection or for the prevention or delay of labour. (S4)

Fexofenadine.

Flavoxate.

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 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;

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;

a maximum pack size of 240 doses. (S3, S4)

Flurbiprofen,

when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S3)

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)

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. (S1)

except when intended for ophthalmic use; (S4)

Fluticasone furoate,

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)

except when intended for administration other than by inhalation or nasal administration. (S4)

Fluticasone propionate,

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)

except when intended for administration other than by inhalation or nasal administration. (S4)

Fusafungine.

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—

except when contained in respirator solutions; (S3) and

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,

when intended for human vaginal use, and

when specifically intended for emergency postcoital contraception. (S3, S4, S5)

Human papillomavirus vaccine.

Hyaluronic acid and its salts,

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

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

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

except when intended for parenteral use; (S4)

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, when used in

maximum concentration of 1 percent in preparations intended for application to the skin, and

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; substances, preparations and mixtures thereof, including transdermal preparations when intended for the prevention of the symptoms of motion sickness.

Ibuprofen when contained in oral medicinal preparations—

containing ibuprofen 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)

containing ibuprofen as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 ml 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)

for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S3)

except when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S4).

Indometacin,

when intended for the emergency treatment of acute gout attacks; (S3)

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

Influenza vaccine.

Influenza virus vaccine.

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

Isoaminile.

Isoprenaline (isoproterenol), except

when contained in respirator solutions; (S3) and

when intended for injection. (S4)

Isopropamide.

Isothipendyl.

Ketoprofen,

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;

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;

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)

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—

maximum daily dose of 15 milligrams;

maximum treatment period of 14 days. (S4)

Levocabastine.

Levocetirizine.

Levonorgestrel,

when intended for emergency post coital contraception;

except when intended for oral contraception; (S3)

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.

Loratadine.

Measles vaccine.

Mebeverine.

Mebhydrolin.

Meclozine.

Mefenamic acid,

when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days; and

preparations containing mefenamic acid as the only therapeutically active substance, when intended for 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)

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

substances, preparations and mixtures in the form of aerosols, intended for application to the skin and mucous membranes and substances,

preparations and mixtures containing the equivalent of 0,6 percent or more of elemental mercury, intended for application to the skin and mucous membranes,

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

when contained in respirator solutions; (S3) and

when intended for injection; (S4)

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 maximum dose of 200 micrograms per nostril in adults and 50 micrograms per nostril in children; and

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

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)

except when contained in preparations intended for application to the skin; (S1) and

except when contained in oral medicinal preparations 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)

Natamycin, when intended for application to the skin, nares and external ear. (S4)

Nedocromil.

Nicergoline.

Nicotine,

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;

when registered as metered sprays containing 1mg per dose or less;

when registered as oral solid dosage forms containing 2mg or less;

when registered as inhalers containing 10mg or less per cartridge;

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;

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)

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)

(Editorial Note: Wording as per original *Government Gazette*. It is suggested that the phrase “up to an including” is intended to be “up to and including”.)

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 maximum dose of 150 milligrams;

a maximum daily dose of 300 milligrams;

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,

when presented as oral drops containing not more than 100 000 I.U. per ml, and

except when intended for application to the skin, (S1) and

except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, (S1) and

except when intended for systemic use or the initial treatment of vaginal candidiasis. (S4)

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.

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

a maximum daily dose of 20 mg;

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.

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:

maximum daily dose of 20 milligrams;

maximum treatment period of 14 days. (S4)

Paracetamol,

when contained in rectal suppositories, or

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), 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 intended for the symptomatic relief of nasal and sinus congestion.

Phenyltoloxamine.

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

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,

when intended for the emergency treatment of acute gout attacks, and

when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (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,

in oral preperations or mixture containing more than 20 millimoles (1500 mg) of potassium per 24 hours; (S0)

except when intended for intravenous infusion or for injection; (S3) and

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.

Promethazine,

when intended for use as an antihistamine, and

when intended for application to the skin, and

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,

oral preparations and mixtures containing not more than 60 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)

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 maximum dose of 75 milligrams;

a maximum daily dose of 300 milligrams;

a maximum treatment period of two weeks. (S3)

Rabeprazole, when intended for the temporary short term relief of heartburn and hyperacidity, subject to—

maximum daily dose of 10 milligrams;

maximum treatment period of 14 days. (S4)

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

Rimiterol, except

when contained in respirator solutions (S3) and

when intended for injection. (S4)

Rotavirus, live attenuated.

Rubella vaccine.

Rupatidine.

Sabadilla alkaloids; substances, preparations and mixtures containing 1 percent or more thereof.

Salbutamol, except

when contained in respirator solutions; (S3) and

when intended for injection. (S4)

Salmefamol, except

when contained in respirator solutions; (S3) and

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)

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

Tetanus vaccine.

Tetracaine,

when contained in eye drops intended for the emergency treatment of "arc eyes"

except when intended for topical use; (S1)

(*c*) except in oral preparations containing 2 % or less of tetracaine, per dosage unit; (S1)

except when intended for ophthalmic or parenteral use. (S4)

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)

Tetrahydrozoline, except when intended for nasal use. (S1)

Thenalidine.

Thenyldiamine.

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.

Xylometazoline, except when intended for nasal use. (S1)

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Annex. 1A added by GNR. 674 in *Government Gazette* 36827 of 13 September, 2013.]

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

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Annex. 1B added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

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

ANNEXURE 2: DENTAL THERAPIST

[Annex. 2 added by Government Regulation No. 674 in *Government Gazette* 36827 of 13 September, 2013 and amended by Government Notice 620 in *Government Gazette* 40041 of 3 June, 2016.]

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

DENTAL THERAPIST (Bachelors degree in Dental Therapy)	
ANALGESIC, ANTIPYRETIC, ANTI INFLAMMATORY	
Substance	: Ibuprofen
Indication	: Dental pain
Schedule	: 2
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
Schedule	: 2
Route of Administration	: Oral

ANNEXURE 3: OPTOMETRIST

[Annex. 3 added by Government Notice 620 in *Government Gazette* 40041 of 3 June, 2016.]

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

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

SCHEDULE 3

[Schedule 3 added by s. 36 of Act No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975, No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by

Government Notices No. R.278 of 25 February, 1977, No. R.437 of 1 April, 1977, No. R.1674 of 18 August, 1978 (as amended by Government Notice No. R.2410 of 8 December, 1978), No. R.1926 of 31 August, 1979, No. R.2507 of 9 November, 1979, No. R.658 of 27 March, 1981, No. R.1289 of 14 June, 1985 and No. 154 of 31 January, 1986, substituted by Government Notice No. 225 of 17 February, 1989, amended by Government Notices No. R.2841 of 7 December, 1990, No. R.2169 of 6 September, 1991, and No. R.775 of 7 May, 1993, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991, amended by Government Notice No. R.1556 of 16 September, 1994, by Government Notice No. R.673 of 12 May, 1995, by Government Notice No. R.42 of 19 January, 1996, by Government Notice No. R.1496 of 13 September, 1996, by Government Notice No. R.1203 of 15 October, 1999 and by Government Notice No. R.1077 of 3 November, 2000, repealed by s. 27 of Act No. 90 of 1997, inserted by Government Notice No. R.509 in *Government Gazette* 24727 of 10 April, 2003, substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008, amended by Government Notice No. R. 1230 in *Government Gazette* 32838 of 31 December, 2009, amended by Government Notice No. R.227 in *Government Gazette* 35149 of 15 March, 2012, amended by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013, amended by Government Notice No. R.690 in *Government Gazette* 36850 of 20 September, 2013, amended by Government Notice No. R.104 in *Government Gazette* 37318 of 11 February, 2014, amended by Government Notice No. R.352 in *Government Gazette* 37622 of 8 May, 2014, amended by Government Notice No. R.234 in *Governemnt Gazette* 38586 of 20 March, 2015, amended by Government Notice No. 254 in *Government Gazette* 39815 of 15 March, 2016 and amended by Government Notice No. 620 in *Government Gazette* 40041 of 3 June, 2016.]

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.

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.

In terms/of section 22A (5) (f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 3 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act:

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

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

(iii)
Annexure 2:
Dental Therapist;

(Editorial Note: Government Notice No. 620 of 2016 makes reference to Annexure 2, however Annexure 2 was not published in this Notice.)

(iv)

Annexure 3:

Optometrist.

Acamprosate.

Acebutolol.

Aceclofenac.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use.

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

Acipimox.

Adapalene.

Adrenaline (epinephrine); ophthalmic preparations thereof, when intended for glaucoma. (S2, S4)

Alclofenac.

Alendronic acid.

Aliskiren.

Allopurinol.

Alprenolol.

Amiloride.

Amlodipine.

Ancrod.

Anthiolimine, when intended for injection.

Arsanilic acid.

Ascorbic Acid—see Vitamin C.

Atenolol.

Atropine,

when intended for use in ophthalmic preparations; (S2)

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 maximum dose of 100 micrograms per nostril and a maximum daily dose of 200 micrograms per nostril; and

a maximum pack size of 200 doses. (S2, S4)

Benazepril.

Bendazac.

Benfluorex.

Benoxaprofen.

Benzbromarone.

Benzydamine, except preparations and mixtures containing—

3 percent or less of benzydamine when intended for application to the skin; (S1)

0,15 percent or less of benzydamine when intended for use as a mouthrinse 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)

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, when intended for inhalation or nasal administration. (S4)

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,

in preparations thereof for injection; (S0)

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)

except when indicated for the treatment of hyperphosphataemia; (S4)

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 treatment of migraine. (S2)

Clopidogrel.

Codeine (methylmorphine),

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;

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;

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)

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)

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,

in preparations thereof for injection; (S0)

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.

Dialysate preparations.

Dichlorphenamide.

Diclofenac,

except when intended for application to the skin; (S1) and

except when intended for the emergency treatment of acute gout attacks; (S2) and

except when intended for the treatment of post traumatic conditions, 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.

Dihydrocodeine—

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;

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;

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)

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)

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,

when intended for oral contraception;

except when intended for hormone replacement therapy. (S4)

Eltenac.

Enalapril.

Endralazine.

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.

when intended for oral contraception;

except when intended for human vaginal use; (S2)

except when intended for hormone replacement therapy. (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,

except when intended for the emergency treatment of acute gout attacks, (S2) and

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 strenghth 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 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;

a maximum dose of 25 micrograms per nostril and a maximum dose of 75 micrograms in children 12 to 16 years of age;

a maximum pack size of 2400 doses. (S2, S4)

Flunixin.

Flurbiprofen, 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)

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. (S1)

when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; (S2)

when intended for ophthalmic use; (S4)

Fluticasone furoate,

when intended for inhalation or nasal administration;

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)

except when intended for administration other than by inhalation or nasal administration. (S4)

Fluticasone propionate,

when intended for inhalation or nasal administration;

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—

(Editorial Note: Wording as per the original *Government Gazette*. It is suggested that the phrase "in the short-term (less than 6 months prophylaxis" is intended to be "in the short-term (less than 6 months) prophylaxis".)

(i)
a maximum daily dose of 100 micrograms per nostril; and

(ii)
a maximum pack size of 120 doses. (S2)

except when intended for administration other than by inhalation or nasal administration. (S4)

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).

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;

when intended for oral contraception;

except when intended for human vaginal use (S2), and

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)

Ibuprofen, except when used in oral medicinal preparations—

containing ibuprofen 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)

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, S2, S3)

containing ibuprofen as the only active therapeutic substance in oral liquid preparations in packs not exceeding 100 ml 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, S2)

for the emergency treatment of acute gout attacks for a maximum treatment period of 5 days; (S2)

when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S4)

Imepitoin, when intended for veterinary use.

Imidapril.

Indacaterol.

Indapamide.

Indometacin, except

for application to the skin (S1), and

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

Indoprofen.

Indoramin.

Injections, unless listed in another Schedule.

Insulin.

Insulin aspart.

Insulin degludec.

Ipratropium, when contained in respirator solutions. (S2)

Irbesartan.

Iron,

in preparations thereof for injection; (S0)

except in oral preparations or mixtures containing more than 24 mg of Iron per recommended daily dose alone or in combination with other active pharmaceutical ingredients; (S1)

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).

Isoniazid and its derivatives, unless listed in another Schedule.

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,

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

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)

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)

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)

Ketorolac when intended for ophthalmic use. (S4)

Labetalol.

Lacidipine.

Lacosamide.

Lumiracoxib.

Lamotrigine.

Lercanidipine.

Levothyroxine.

Levetiracetam.

Levobunolol.

Levonorgestrel,

when intended for oral contraception

except when intended for emergency post coital contraception; (S2)

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—

when intended for the treatment of post-traumatic conditions, for a maximum period of 5 days; and

preparations containing mefenamic acid as the only therapeutic active substance, when intended for the treatment of

primary dysmenorrhoea subject to a maximum daily dose of 500 millligrams mefenamic acid 3 times a day and a maximum treatment period of 3 days. (S2)

Meloxicam.

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 maximum dose of 200 microgtams per nostril in adults and 50 micrograms per nostril in children; and

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

when contained in preparations intended for application to the skin; (S1, S2)

when contained in oral medicinal preparations 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 peroid. (S1, S2)

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,

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);

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)

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)

(Editorial Note: Wording as per original *Government Gazette*. It is suggested that the phrase "up to an including" is intended to be "up to and including".)

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)

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)

except when registered as metered sprays containing not more than 1 mg per dose; (S2)

except when registered as oral solid dosage forms containing not more than 2 mg; (S2)

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,

when intended for oral contraception;

except when intended for parenteral use as a contraceptive; (S4)

except when intended for hormone replacement therapy. (S4)

Norgestrel,

when intended for oral contraception;

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 when intended for the emergency treatment of acute gout attacks, (S2) or

when intended for the treatment of post-traumatic conditions, for a maximum treatment period of 5 days. (S2)

Pirprofen.

Potassium canrenoate.

Potassium chloride, where the recommended dose is more than 20 millimol of potassium (1 500 milligrams of potassium chloride) per 24 hours (S2) or when intended for intravenous infusion or for injection, but except when contained in oral rehydration preparations. (S0)

Practolol.

Prazosin.

Primidone.

Probenecid.

Probucol.

Procaterol, when contained in respirator solutions. (S2)

Proctofene.

Propacetamol.

Propiverine.

Propranolol.

Proquazone.

Proscillaridine.

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.

Salbutamol, when contained in respirator solutions. (S2, S4)

Salmefamol, when contained in respirator solutions. (S2, S4)

Saxagliptin.

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

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.

Trimethadione.

Tropicamide.

Tulobuterol, when contained in respirator solutions. (S2)

Ursodeoxycholic acid.

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,

in preparations thereof for injection; (S0)

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,

in preparations thereof for injection; (S0)

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,

in preparations thereof for injection; (S0)

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,

in preparations thereof for injection; (S0)

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,

in preparations thereof for injection; (S0)

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),

in preparations thereof for injection; (S0)

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,

in injection preparations; (S0)

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)

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,

for oral ingestion, where the daily dose is more than 50 milligrams of elemental zinc; (S0),

except preparations thereof for injection, when intended for veterinary use; (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).

Zomepirac.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Annex. 1A added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

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
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 contral of seizures and hypertension in toxaemia of pregnancy
Schedule	: 3
Route of Administration	: Parenteral

CARBOHYDRATES	
Substance	: Dextrose
Indication	: Nutrition / Acute Symptomatic Hypoglycaemic Treatment
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

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Annex. 1B added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

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
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 Treatment
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

(Editorial Note: Government Notice No. 620 of 2016 makes reference to Annexure 2, however Annexure 2 was not published in this Notice.)

ANNEXURE 3: OPTOMETRIST

[Annex. 3 added by Government Notice 620 in *Government Gazette* 40041 of 3 June, 2016.]

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

OPTOMETRIST	
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)

SCHEDULE 4

[Schedule 4 added by s. 36 of Act No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975, No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by Government Notices No. R.279 of 25 February, 1977, No. R.437 of 1 April, 1977, No. R.1194 of 1 July, 1977, No. R.1674 of 18 August, 1978 (as amended by Government Notice No. R.2410 of 8 December, 1978), No. R.1926 of 31 August, 1979, No. R.658 of 27 March, 1981, No. R.2416 of 12 November, 1982, No. R.1289 of 14 June, 1985 and No. 154 of 31 January, 1986, substituted by Government Notice No. 225 of 17 February, 1989, amended by Government Notices No. R.2841 of 7 December, 1990, No. R.2169 of 6 September, 1991, No. R.580 of 21 February, 1992, No. R.141 of 5 February, 1993 and No. R.775 of 7 May, 1993, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991, amended by Government Notice No. R.1556 of 16 September, 1994, by Government Notice No. R.673 of 12 May, 1995, by Government Notice No. R.42 of 19 January, 1996, by Government Notice No. R.1496 of 13 September 1996, by Government Notice No. R.1203 of 15 October, 1999 and by Government Notice No. R.1077 of 3 November, 2000, repealed by s. 27 of Act No. 90 of 1997, inserted by Government Notice No. R.509 in *Government Gazette* 24727 of 10 April, 2003, substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008, Government Notice No. R.1230 in *Government Gazette* 32838 of 31 December, 2009, amended by Government Notice No. R.227 in *Government Gazette* 35149 of 15 March, 2012, amended by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013, amended by Government Notice No. R.690 in *Government Gazette* 36850 of 20 September, 2013, amended by Government Notice No. R.104 in *Government Gazette* 37318 of 11 February, 2014, amended by Government Notice No. R.352 in *Government Gazette* 37622 of 8 May, 2014, amended by Government Notice No. R.234 in *Government Gazette* 38586 of 20 March, 2015, amended by Government Notice No. 254 in *Government Gazette* 39815 of 15 March, 2016 and amended by Government Notice No. 620 in *Government Gazette* 40041 of 3 June, 2016.]

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.

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.

(Editorial Note: Numbering as per original *Government Gazette*.)

In terms of section 22A (5) (f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act 56 of 1974) other than a medical practitioner or dentist may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the

Medicines Control Council, to patients under his/her care, the Schedule 4 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act—

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

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

(iii) Annexure 2: Dental Therapist;

(iv) Annexure 3: Optometrist.

Abacavir.

Abatacept.

Abciximab.

Abiraterone.

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, 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).

Alclometasone.

Alcuronium.

Aldesleukin.

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)

Alizapride.

Almitrine.

Alosetron.

Alfacalcidol.

Alphachymotrypsin (α-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.

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—

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)

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).

Apixaban.

Apomorphine, when indicated for the treatment of erectile dysfunction. (S2)

Apraclonidine.

Apramycin.

Aprotinin.

Aprepitant.

A-β 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.

Artemether and its derivatives.

Artemisinin.

Artemotil.

Artesunate.

L-Asparaginase.

Astemizole.

Atazanavir.

Atipamizole.

Atorvastatin.

Atosiban.

Atovaquine.

Atracurium besilate.

Atropine,

when intended for use in injections. (S2)

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).

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).

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).

Barium sulfate.

Basiliximab.

Bacampicillin.

Beclomethasone dipropionate, except when intended for inhalation or nasal administration. (S3)

Bedaquiline.

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

Belatacep.

Bemegride.

Bemiparin.

Bendamustine.

Benethamine penicillin.

Benzathine benzylpenicillin.

Benzathine phenoxymethylpenicillin.

Benzocaine,

when intended for ophthalmic or parenteral use;

except in lozenges containing 30 mg or less of benzocaine, per dosage unit; (S1)

except when intended for topical use; (S1)

except in preparations containing 2 % or less of benzocaine. (S1)

Benzylpenicillin.

Betamethasone.

Bethanechol.

Betiatide.

Bevacizumab.

Bicalutamide.

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,

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).

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.

Boceprevir.

Bortezomib.

Botulinum toxin.

Brentuximab.

Bretylium tosilate.

Bromocriptine.

Budesonide, except when intended for inhalation or nasal administration. (S3)

Bufenoide.

Bumadizone.

Bupivicaine.

Buserelin.

Busulfan.

Butoconazole, 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)

Cabazitaxel.

Cabergoline.

Calcitonin.

Calcitriol.

Calcium,

when indicated for the treatment of hyperphosphataemia; (S0)

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)

except in preparations thereof for injection; (S3)

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.

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.

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)

Carmustine.

Capreomycin.

Caspofungin.

Casopitant.

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.

Ceftriaxone.

Cefuroxime.

Cefalotin.

Cerivastatin.

Certoparin.

Ceruletide.

Cetrorelix.

Cetuximab.

Chlorambucil.

Clodantoin.

Chlormadinone.

Chloroquine.

Choriogonadotropin alfa.

Chorionic gonadotrophin.

Chloramphenicol.

Chlorguinaldol.

Chlortetracycline except when listed elsewhere in the Schedules and except injections thereof intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle and capsules thereof intended for the use in pigeons and derivatives when intended for topical use in the management of wounds in 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).

Colfosceril.

Colistin.

Contrast media, unless listed elsewhere in the Schedules.

Copper,

in preparations thereof for injection; (S0)

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—

hydrocortisone and hydrocortisone acetate when used as a single active ingredient in a maximum concentration of 1,0 per cent in preparations intended for application to the skin; (S2)

triamcinolone when intended for application to oral lesions; (S2) and

when contained in preparations intended for nasal administration. (S2, S3)

Co-tetroxazine.

Co-trifamole.

Co-trimoxazole.

Crizotinib.

Cyclofenil.

Cyclophosphamide and its derivatives, unless listed in another Schedule.

Cycloserine.

Cyprenorphine.

Cyproterone acetate.

Cytarabine.

Dabigatran.

Dacarbazine.

Dacliximab.

Daclizumab.

Dactinomycin.

Dalteparin.

Danaparoid.

Danofloxacin.

Dantrolene.

Dapagliflozin.

Dapsone and its derivatives, unless listed elsewhere in the Schedules.

Daptomycin.

Darbepoetin Alfa.

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.

Deferoxamine.

Degarelix.

Demecarium.

Demeclocycline.

Denosumab.

Desirudin.

Desmopressin.

Desonide.

Desoximetasone.

Dexamethasone.

Diatrizoic acid.

Diazoxide.

Dichlorophen, except—

preparations and mixtures when intended for application to the skin; (S0) and

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 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.

Dolutegravir.

Domperidone.

Dopa.

Dopamine.

Doripenem.

Doxapram.

Doxepin, when intended for application to the skin. (S5)

Doxorubicin.

Doxycycline, except

when intended and labelled for the chemoprophylaxis of malaria in those aged 8 years and older, for periods not exceeding 4 months of continuous use; (S2)

in preparations thereof for the treatment of animals and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947), excluding when intended for administration in animal feed.

Dronedarone.

Drospirenone,

when intended for hormone replacement therapy;

except when intended for oral contraception. (S3)

Drotrecognin.

Dutasteride.

Dydrogesterone.

Econazole, 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)

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).

Edoxudine.

Edrophonium.

Efalizumab.

Efavirenz.

Eicosapent (EPA) 460, when indicated for the treatment of hypertriglyceridaemia.

Eletriptan.

Eltrombopag.

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.

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.

Estradiol,

when intended for hormone replacement therapy;

except when intended for human vaginal use; (S2)

except when intended for oral contraception; (S3)

Estramustine.

Etamiyan.

Etanercept.

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.

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.

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.

Filgrastim.

Finasteride.

Fingolimod.

Flecainide.

Florfenicol.

Flosequinan.

Flucloxacillin.

Fluconazole.

Flucytosine.

Fludarabine.

Fludrocortisone acetate.

Flugestone.

Flumethasone.

Flunisolide, except when intended for inhalation or nasal administration. (S2, S3).

Fluocinolone.

Fluocinonide.

Fluocortolone.

Fluorides,

except in oral medicinal preparations and mixtures intended for ingestion containing 0,25 milligrams or less of fluorine per dosage unit; (S0, S1)

except in toothpaste containing less than 0.15 percent fluoride; (S0) and

except in mouth rinses containing less than 0.15 percent fluoride. (S0)

Fluorometholone.

5-Fluorouracil.

Fluprednidene.

Flurbiprofen,

when intended for ophthalmic use; (S3)

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)

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. (S1)

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**—

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)

when intended for inhalation or nasal administration. (S3)

Fluticasone propionate, **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—

(Editorial Note: Wording as per the original *Government Gazette*. It is suggested that the phrase "in the short-term (less than 6 months prophylaxis" is intended to be "in the short-term (less than 6 months) prophylaxis".)

(i)
a maximum daily dose of 100 micrograms per nostril; and

(ii)

a maximum pack size limit of 120 doses. (S2)

when intended for inhalation or nasal administration. (S3)

(Editorial Note: Numbering as per original *Government Gazette*.)

Fluvastatin.

Follitropin alfa.

Fondaparinux.

Formoterol.

Fosamprenavir.

Fosaprepitant.

Fosfomycin.

Fosphenytoin sodium.

Fotemustine.

Framycetin.

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.

Gadobutrol.

Gadodiamide.

Gadofosveset.

Gadoversetamide.

Galactose, when used as a contrast agent.

Galantamine.

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.

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).

Griseofulvin except when intended for topical application to the epidermis, nares and external ear. (S2)

Grepafloxacin.

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—

when specifically intended for emergency postcoital contraception; (S2)

when intended for oral contraception; (S3)

insulin; (S3)

epinephrine; (S2, S3, S4)

corticotrophin (adrenocorticotrophic hormone; ACTH); (S5)

human growth hormone (human somatotropin) – all forms; (S5)

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).

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 fibrinogen, when indicated for use as a haemostatic.

Human thrombin, when indicated for use as a haemostatic.

Human Plasma.

Hyaluronidase.

Hyaluronic acid and its salts—

when intended for parenteral use;

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

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

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

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.

Hydroxycarbamide. (Hydroxyurea)

Hydroxychloroquine.

Ibandronic acid.

Ibuprofen, when intended for the treatment of haemodynamically significant patent ductus arteriosus in infants less than 34 weeks of gestational age. (S1, S2, S3)

Ibutilide.

Ibritumomab.

Idarubicin.

Idoxuridine, except when intended for application to the skin. (S1)

Idursulfase.

Ifosfamide.

Iloprost.

Imatinib.

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.

Indacaterol.

Indinavir.

Indium chloride pentetreotide.

Infliximab.

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)

Isoniazid.

Isopirin.

Isoprenaline (isoproterenol), when intended for injection. (S2, S3)

Isoxsuprine.

Itraconazole.

Ixabepilone.

Josamycin.

Kanamycin.

Ketoconazole, except—

preparations and mixtures containing not more than 1,0 percent of ketoconazole when intended for the prevention and treatment of dandruff; (S0) or

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 maximum daily dose of 15 milligrams (S2); and

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.

Leflunomide.

Lenalidomide.

Lenograstim.

Lepirudin.

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,

when administered via an Intra Uterine System;

except when intended for oral contraception; (S3)

except when intended for emergency post coital contraception. (S2)

Levosimendan.

Liarozole.

Lidocaine,

when intended for ophthalmic or parenteral use;

when intended for the treatment of neuropathic pain associated with previous herpes zoster infection;

except when intended for topical use; (S1)

except in oral preparations containing 2 % or less of lidocaine per dosage form. (S1)

Lignocaine, *see* Lidocaine.

Lincomycin.

Linezolid.

Liraglutide.

Lixisenatide.

Local anaesthetics, when intended for ophthalmic or parenteral use except–

when intended for topical use; (S1)

oxybuprocaine, proxymetacaine and tetracaine when contained in eye drops intended for emergency treatment of "arc eyes"; (S2).

Lomefloxacin.

Lomustine.

Lopinavir.

Loracarbef.

Loteprednol.

Lovastatin.

Lumefantrine.

Luprositol, when intended for veterinary use.

Lutropin alfa.

Lymecycline.

Lysozyme, except preparations and mixtures when intended for application to the skin. (S1)

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.

Menotrophin.

Mepacrine.

Mephentermine.

Mepirizole.

Mepivicaine.

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)

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:

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

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

Mexiletine.

Mezlocillin.

Micafungin.

Miconazole,

except when intended for application to the skin; (S1) and

except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis; (S1) and

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)

Mifepristone.

Miglitol.

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.

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.

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.

Netilmicin.

Netobimin.

Nevirapine.

Niacin (Nicotinic Acid, Vitamin B3) and derivatives thereof,

when intended for hypercholesterolaemia and for the management of dyslipidaemias; (S0)

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.

Niridazole.

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).

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.

Norethisterone,

when intended for parenteral use as a contraceptive;

when intended for hormone replacement therapy;

except when intended for oral contraception. (S3)

Norfloxacin.

Norgestrel,

when intended for hormone replacement therapy;

except when intended for oral contraception. (S3)

Novobiocin.

Nystatin,

when intended for systemic use or the initial treatment of vaginal candidiasis;

except when presented as oral drops containing not more than100 000 I.U. per ml. (S2)

except when intended for application to the skin, (S1) and

except when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)

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.

Ocriplasmin.

Octocog alfa.

Octreotide.

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).

Oleandomycin.

Omalizumab.

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

a maximum daily dose of 20mg

a maximum treatment period of 14 days. (S2)

Ondansetron.

Oprelvekin.

Ornidazole, except when intended for application to the skin. (S1)

Ornipressin.

Osaterone, when intended for veterinary use.

Oseltamivir.

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),

when intended for ophthalmic or parenteral use;

except in oral preparations containing an antacid. (S1)

Oxolinic acid.

Oxybuprocaine,

when intended for ophthalmic or parenteral use;

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) excluding when intended for administration in animal feed.

Oxytocin.

Paclitaxel.

Palivizumab.

Palonosetron.

Pamidronate disodium.

Pamidronic acid.

Pancuronium.

Panituzumab.

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

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

a maximum treatment period of 14 days. (S2)

Paricalcitol.

Pazopanib.

Pegfilgrastim.

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.

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)

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.

Piribedil.

Pirlimycin.

Piromidic acid.

Pivampicillin.

Pivmecillinam.

Plerixafor.

Podophyllum resin, preparations and mixtures containing more than 20 percent of podophyllum resin. (S1)

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.

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.

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.

Prilocaine,

when intended for ophthalmic or parenteral use; (S4)

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.

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—

maximum daily dose of 10 milligrams;

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)
^{18}F – Fludeoxyglucose (2 – deoxy – 2 – [^{18}F] fluoro – D – glucose

(iv)

Gallium-67;

(v)
Indium-111;

(vi)
Iodine-123;

(vii)
Iodine-125;

(viii)
Iodine-131;

(ix)
Phosphorous-32;

(x)
Strontium-89;

(xi)
Technetium-99;

(xii)
Thallium-201;

(xiii)
Xenon-133;

(xiv)
Yttrium-90;

(xv)
Gold-198.

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.

Ranibizumab.

Rapacuronium.

Rasagiline.

Rasburicase.

Regorafenib.

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).

Retapamulin.

Ribavirin.

Rifabutin.

Rifampicin.

Rifaximin.

Rilpivirine.

Riluzole.

Rimiterol, when intended for injection. (S2, S3)

Riociguat.

Ritodrine.

Ritonavir.

Rotigotine.

Rituximab.

Rivaroxaban.

Rizatriptan.

Robenacoxib.

Rocuronium.

Roflumilast.

Rolitetracycline except when listed elsewhere in the Schedules and except injections thereof intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle 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.

Roxithromycin.

Roxatidine.

Ruxolitinib.

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.

Selegiline.

Selenium salts, preparations thereof for injection, when intended for veterinary use.

Serelaxin.

Sermorelin.

Sertaconazole, except when intended for application to the skin. (S1)

Sertindole.

Sevelamer.

Sildenafil.

Silicone oil (polydimethylsiloxane) when intended for intraocular use.

Silodosin.

Simvastatin.

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)

Sorafenib.

Sparfloxacin.

Spectinomycin.

Stavudine.

Stents, Drug Eluting, unless listed elsewhere in the Schedules.

Streptokinase.

Strychnine, except—

preparations and mixtures containing 0,2 percent or less of strychnine; (S2) and

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—

substances, preparations and mixtures intended for application to the eyes, nares and vagina; (S2) and

when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Sumatriptan.

Sunitinib.

Suramin.

Surfactant associated proteins.

Suxamethonium.

Suxethonium.

Streptokinase.

Streptomycin.

Tacrine.

Tacrolimus.

Tadalafil.

Tafluprost.

Talampicillin.

Tamoxifen.

Tamsulosin.

Taurolidine.

Tasonermin.

Tazobactam.

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.

Tetrabenazine.

Tetracaine,

when intended for ophthalmic or parenteral use;

except when intended for topical use; (S1)

except in oral preparations containing 2 % or less of Tetracaine; (S1)

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 anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle and derivatives when intended for topical use in the management of wounds in 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—

when intended for application to the skin; (S1) and

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.

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.

Tipranavir.

Tirilazad.

Tobramycin.

Tocainide.

Tocilizumab.

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.

Trabectedin.

Tranexamic acid.

Trastuzumab.

Travoprost.

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.

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.

Urapidil.

Urethane.

Urokinase.

Urofollitropin.

Ustekinumab.

{Vaccines, see—Biologicals}

Valaciclovir.

Valganciclovir.

Valnemulin.

Vancomycin.

Vardenafil.

Vasoactive intestinal polypeptide.

Vecuronium.

Vemurafenib.

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.

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.

Zolmitriptan.

Zoledronic acid.

Zotarolimus.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Annex. 1A added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

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
Indication	: Competitive Anti-Cholinergic, Bradycardia, Anti-arrhythmic
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	: Oral
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

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Annex. 1B added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

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	: Oral
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

ANNEXURE 2: DENTAL THERAPIST

[Annex. 2 added by Government Regulation No. 674 in *Government Gazette* 36827 of 13 September, 2013.]

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

DENTAL THERAPIST (Bachelors degree in Dental Therapy)	
LOCAL ANAESTHETIC	
Substance	: Lignocaine/Lidocaine Hydrochloride 2 % with Vasoconstrictor (Adrenaline)
Indication	: Dental local anaesthesia
Schedule	: 4
Route of Administration	: Parenteral
LOCAL ANAESTHETIC	
Substance	: Lignocaine/Lidocaine Hydrochloride 3 % without a Vasoconstrictor (Adrenaline)
Indication	: Dental local anaesthesia
Schedule	: 4
Route of Administration	: Parenteral

DENTAL THERAPIST (Bachelors degree in Dental Therapy)	
LOCAL ANAESTHETIC	
Substance	: Mepivacaine Hydrochloride 2 % with a Vasoconstrictor (Adrenaline)
Indication	: Dental local anaesthesia
Schedule	: 4
Route of Administration	: Parenteral
LOCAL ANAESTHETIC	
Substance	: Mepivacaine Hydrochloride 3 % without a Vasoconstrictor (Adrenaline)
Indication	: Dental local anaesthesia
Schedule	: 4
Route of Administration	: Parenteral
ANTI-MICROBIALS (Beta-Lactams)	
Substance	: Penicillins
Indication	: Dental orofacial and odontogenic infections (Non prophylactic)
Schedule	: 4
Route of Administration	: Oral
ANTI-PROTOZOAL	
Substance	: Metronidazole

Indication	: Dental orofacial and odontogenic infections (Non prophylactic)
Schedule	: 4
Route of Administration	: Oral
AUTONOMIC SYMPATHOMIMETICS	
Substance	: Adrenaline
Indication	: Emergency medicine for drug related anaphylactic shock
Schedule	: 4
Route of Administration	: Parenteral

ANNEXURE 3: OPTOMETRIST

[Annex. 3 added by Government Notice 620 in *Government Gazette* 40041 of 3 June, 2016.]

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

OPTOMETRIST	
ANTIBACTERIAL	
Substance	: 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)

SCHEDULE 5 AND SPECIFIED SCHEDULE 5

[Schedule 5 added by s. 36 of Act No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975, No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by Government Notices Nos. R.143 of 4 February, 1977, R.279 of 25 February, 1977, R.437 of 1 April, 1977, R.1674 of 18 August, 1978 (as amended by Government Notice No. R.2410 of 8 December, 1978), No. R.1926 of 31 August,

1979, (as amended by Government Notice No. 271 of 15 February, 1980), No. R.2416 of 12 November, 1982, No. R.1289 of 14 June, 1985 and No. 154 of 31 January, 1986, substituted by Government Notice No. 225 of 17 February, 1989, amended by Government Notices No. R.2841 of 7 December, 1990, No. R.580 of 21 February, 1992 and No. R.775 of 7 May, 1993, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991, amended by Government Notice No. R.1556 of 16 September, 1994, by Government Notice No. R.673 of 12 May, 1995, by Government Notice No. R.42 of 19 January, 1996, by Government Notice No. R.1203 of 15 October, 1999 and by Government Notice No. R.1077 of 3 November, 2000, repealed by s. 27 of Act No. 90 of 1997, inserted by Government Notice No. R.509 in *Government Gazette* 24727 of 10 April, 2003, substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008, Government Notice No. R.1230 in *Government Gazette* 32838 of 31 December, 2009, amended by Government Notice No. R.227 in *Government Gazette* 35149 of 15 March, 2012, amended by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013, amended by Government Notice No. R.690 in *Government Gazette* 36850 of 20 September, 2013, amended by Government Notice No. R.104 in *Government Gazette* 37318 of 11 February, 2014, amended by Government Notice No. R.234 in *Government Gazette* 38586 of 20 March, 2015 and amended by Government Notice No. 254 in *Government Gazette* 39815 of 15 March, 2016.]

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.

In terms of Section 22A (5) (f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and apply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 5 and Specified Schedule 5 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

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

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

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.

Alprazolam**.

Amisulpride.

Amitryptyline and its derivatives.

Amoxapine.

Anaesthetic preparations containing pregnanedione derivatives.

Androstanolone.

Androstenediol.

Aponal.

Apronalide.

Aripriprazole.

Atomoxetine.

Asenapine.

Azacyclonol.

Barbituric acid** and its derivatives**, unless listed in another Schedule, excluding— amobarbital, cyclobarbital, pentobarbital and secobarbital (S6), and 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:

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

any salt or substance falling under the above; and

except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and

except when contained in appliances for inhalation in which the substance is absorbed onto solid material; (S1, S7) and

excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof; and

except substances listed in Schedule 7. (S1, S2, S6)

Bolandiol.

Bolasterone.

Boldenone.

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.

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.

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**.

Fluocinolone.

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).

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**.

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.

Phenothiazine and its derivatives,

unless listed in another Schedule;

except preparations and mixtures containing promethazine or dimethothiazine or their salts when used solely as an antihistaminic; (S2) and

except preparations containing promethazine or its salts when intended specifically for the treatment of travel sickness or application to the skin; (S2) and

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, except when intended for medicinal use in dosages of less than 5 mg/kg/day or intended as supplementation for nutritional purposes. (S1)

Varenicline.

Venlafaxine.

Viloxazine.

Vortioxetine.

Xylazine.

Zaleplon.

Zimelidine.

Ziprasidone.

Zolazepam.

Zolpidem**.

Zopiclone.

Zotepine.

Zuclopenthixol.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Annex. 1A added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

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

ANNEXURE 1B: EMERGENCY CARE PROVIDER (EMERGENCY CARE PRACTITIONER)

[Annex. 1B added by Government Regulation No. 674 in *Government Gazette* 36827 of 13 September, 2013.]

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

SCHEDULE 6

[Schedule 6 added by s. 36 of Act No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975,

No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by Government Notices No. R.437 of 1 April, 1977, No. R.1674 of 18 August, 1978, No. R.1926 of 31 August, 1979, No. R.658 of 27 March, 1981, No. R.2416 of 12 November, 1982 and No. R.1289 of 14 June, 1985, substituted by Government Notice No. 225 of 17 February, 1989, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991, amended by Government Notice No. R.1557 of 16 September, 1994 and by Government Notice No. R.1203 of 15 October, 1999, repealed by s. 27 of Act No. 90 of 1997, inserted by Government Notice No. R.509 in *Government Gazette* 24727 of 10 April, 2003, amended by Government Notice No. R.491 in *Government Gazette* 31010 of 25 April, 2008, substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008, Government Notice No. R.1230 in *Government Gazette* 32838 of 31 December, 2009, amended by Government Notice No. R.227 in *Government Gazette* 35149 of 15 March, 2010, amended by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013, amended by Government Notice No. R.104 in *Government Gazette* 37318 of 11 February, 2014, amended by Government Notice No. R.352 in *Government Gazette* 37622 of 8 May, 2014, amended by Government Notice No. R.234 in *Government Gazette* 38586 of 20 March, 2015, amended by Government Notice No. 254 in *Government Gazette* 39815 of 15 March, 2016 and amended by Government Notice No. 620 in *Government Gazette* 40041 of 3 June, 2016.]

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.

In terms of section 22A (5) (f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply, only within his/her scope of practice and subject to the indication for use of such substances and medicines and to the conditions determined by the Medicines Control Council, to patients under his/her care, the Schedule 6 substances and medicines provided for in the Annexures to this Schedule published in the *Gazette* in terms of the Act.

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

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

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):

except preparations and mixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and

except when contained in appliances for inhalation in which the substance is absorbed in solid material: (S1) and

excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof; (S1, S2, S5) and

except substances listed in Schedule 7. (S1, S2, S5)

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Buprenorphine.

Butalbital.

Butorphanol.

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.

Codeine (methylmorphine),

single component codeine preparations;

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)

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.

Cyclobarbital.

Desomorphine.

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—

single component dihydrocodeine preparations;

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)

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}

Dronabinol ((-)-transdelta-9-tetrahydrocannabinol), when intended for therapeutic purposes. (S7)

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,

except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures containing not more than 30 milligrams of ephedra alkaloids per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S2)

except when intended for application to skin, eyes, ears and nares and containing 1 percent or less of ephedra alkaloids. (S1)

Ephedrine,

except products registered in terms of the Act, not intended for export, and being oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose, when in combination with another pharmacologically active substance and intended for the symptomatic relief of colds and flu, subject to a maximum pack size of 720 milligrams and limited to one pack per customer; (S2)

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

(Editorial Note: Numbering as per original *Government Gazette*.)

Ethylmethylthiambutene.

Ethylmorphine,

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

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.

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.

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

Tapentadol.

Thebacon.

Thebaine.

Thiafentanyl.

Tilidine.

{(-)-transdelta-9-tetrahydrocannabinol - see dronabinol.}

Trimeperidine.

Zipeprol.

ANNEXURE 1A: EMERGENCY CARE PROVIDER (PARAMEDIC)

[Annex. 1A added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

PARAMEDIC (National Diploma in Emergency Medical Care graduates ***only)*** registered with the Health Professions Council of South

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)

[Annex. 1B added by Government Notice R.674 in *Government Gazette* 36827 of 13 September, 2013.]

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)	
ANALGESICS	
Substance	: Morphine Sulphate
Indication	: Opioid/Narcotic
Schedule	: 6
Route of Administration	: Parenteral

SCHEDULE 7

[Schedule 7 added by s. 36 of Act No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975, No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by Government Notices No. R.437 of 1 April, 1977, No. R.1567 of 12 August, 1977, No. R.1674 of 18 August, 1978 (as amended by Government Notice No. R.2410 of 8 December, 1978), No. R.1926 of 31 August, 1979, No. R.658 of 27 March, 1981, No. R.2416 of 12 November, 1982 and No. R.1289 of 14 June, 1985, substituted by Government Notice No. 225 of 17 February, 1989, amended by Government Notices No. R.2841 of 7 December, 1990 and No. R.775 of 7 May, 1993, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991, amended by Government Notice No. R.1496 of 13 September, 1996, by Government Notice No. R.1203 of 15 October, 1999 and by Government Notice No. R.1077 of 3 November, 2000, repealed by s. 27 of Act No. 90 of 1997, inserted by Government Notice No. R.509 in *Government Gazette* 24727 of 10 April, 2003, amended by Government Notice No. R.491 in *Government Gazette* 31010 of 25 April, 2008, substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008, amended by Government Notice No. 227 in *Government Gazette* 35149 of 15 March, 2012, amended by Government Notice No. R.690 in *Government Gazette* 36850 of 20 September, 2013, amended by Government Notice No. R.352 in *Government Gazette* 37622 of 8 May, 2014, amended by Government Notice No. R.234 in *Government Gazette* 38586 of 20 March, 2015 and amended by Government Notice No. 254 in *Government Gazette* 39815 of 15 March, 2016.]

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 *)

AH-7921.

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:

preparations and mixtures when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations; (S1) and

appliances for inhalation in which the substance is absorbed onto solid material; (S1)

excluding cathine ((+)-norpseudoephedrine), ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine; (S1, S2, S5)

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).

Bufotenine (N,N-dimethylserotonin).

Cannabis (dagga), the whole plant or any portion or product thereof, except:

when separately specified in the Schedules; (S6) or

processed hemp fibre containing 0.1 percent or less of tetrahydrocannabinol and products manufactured from such fibre, provided that the product does not contain whole cannabis seeds and is in a form not suitable for ingestion, smoking or inhaling purposes; or

processed product made from cannabis seeds containing not more than 10 milligram per kilogram (0,001 percent) of tetrahydrocannabinol and does not contain whole cannabis seeds.

["Processed" means treated by mechanical, chemical or other artificial means but does not include—(*a*) harvesting; or (*b*) the natural process of decay.]

Catha edulis ("khat"), the whole plant or any portion or product thereof.

Cathinone((-)-(S)-2-aminopropiophenone).

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

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).

(+)-4-ethyl-2,5-dimethoxy-a-phenethylamine *(DOET).

Dronabinol [(-)-transdelta-9-tetrahydrocannabinol]. (S6)

Etilamfetamine(N-ethylamphetamine).

Etryptamine.

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)

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).

Lefetamine *(SPA).

Lisdexamfetamine (lisdexamphetamine). (S8)

Lysergide (Lysergic acid diethylamide) *(LSD).

Mephedrone.

Mescaline (3,4,5-trimethoxyphenethylamine).

Mesocarb.

Methamphetamine and methamphetamine racemate.

Methaqualone and any preparation containing methaqualone.

Methcathinone.

2-methoxy-α-methyl-4,5-(methylenedioxy)phenethylamine *(MMDA).

p-methoxy-α-methylphenethylamine *(PMA).

4 methylaminorex.

{(Methylenedioxyamphetamine *(MDA) and its analogues—see tenamphetamine.}

3.4-methylenedoxypyrovalerone (MDPV).

Methylone (beta-keto-MDMA).

Methyprylon.

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

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

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

Nabilone. (S8)

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.

Psilocin (4-hydroxy-NN-dimethyltryptamine).

Psilocybine(4-phosphoryloxy-NN-dimethyltryptamine).

Pyrovalerone (4'-methyl-2-(1-pyrrolidinyl) valerophenone).

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).

Tetrahydrocannabinol and their alkyl homologues, except:

when separately specified in the Schedules;

dronabinol ((-)-transdelta-9-tetrahydrocannabinol), when intended for therapeutic purposes; (S6)

in hemp seed oil, containing 10 milligram per kilogram or less of tetrahydrocannabinols, when labelled "Not to be taken"or "Not for internal human use"; or

in products for purposes other than internal human use containing 10 milligram per kilogram or less of tetrahydrocannabinols.

["Hemp seed oil" means the oil obtained by cold expression from the ripened fruits (seeds) of Cannabis sativa.]

1-(3-trifluoromethylphenyl) piperazine *(TFMPP).

(+)-3, 4, 5-trimethoxy-α-methylphenethylamine *(TMA).

SCHEDULE 8

[Schedule 8 added by s. 36 of Act No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975, No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by Government Notices No. R.437 of 1 April, 1977, No. R.1567 of 12 August, 1977, No. R.1674 of 18 August, 1978 (as amended by Government Notice No. 2410 of 8 December, 1978), No. R.1926 of 31 August, 1979, No. R.658 of 27 March, 1981, No. R.2416 of 12 November, 1982 and No. R.1289 of 14 June, 1985, substituted by Government Notice No. 225 of 17 February, 1989, amended by Government Notices No. R.1133 of 2 June, 1989, No. R.2841 of 7 December, 1990 and No. R.775 of 7 May, 1993, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991, amended by Government Notice No. R.1556 of 16 September, 1994, by Government Notice No. R.1203 of 15 October, 1999 and by Government Notice No. R.1077 of 3 November, 2000, repealed by s. 27 of Act No. 90 of 1997, inserted by Government Notice No. R.509 in *Government Gazette* 24727 of 10 April, 2003 and substituted by Government Notice No. 935 in *Government Gazette* 31387 of 5 September, 2008 and amended by Government Notice No. 254 in *Government Gazette* 39815 of 15 March, 2016.]

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

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

(ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and

ethers, where the existence of such isomers of esters and ethers is possible;

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

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

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

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

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

Lisdexamfetamine (lisdexamphetamine). (S7)

Nabilone. (S7)

SCHEDULE 9

[Schedule 9 added by s. 36 of Act No. 65 of 1974, substituted by Government Notices No. R.420 of 7 March, 1975, No. R.2244 of 28 November, 1975, No. R.575 of 2 April, 1976 and No. R.2082 of 5 November, 1976, amended by Government Notices No. R.437 of 1 April, 1977, No. R.2416 of 12 November, 1982 and No. R.1289 of 14 June, 1985, substituted by Government Notice No. 225 of 17 February, 1989, amended by Government Notice No. R.775 of 7 May, 1993, repealed, and subsequently re-inserted (after amendment), by s. 21 of Act No. 94 of 1991 and repealed by s. 27 of Act No. 90 of 1997.]