

MEDICINES AND RELATED SUBSTANCES ACT NO 101 OF 1965, AS AMENDED

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.]

1. Definitions.—

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

“**advertisement**”, in relation to any medicine or Scheduled substance, means any written, pictorial, visual or other descriptive matter or verbal statement or reference—

- (a) appearing in any newspaper, magazine, pamphlet or other publication; or [Para. (a) substituted by s. 1 (a) of Act No. 20 of 1981.] Wording of Sections
- (b) distributed to members of the public; or
- (c) brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that medicine or Scheduled substance; and “advertise” has a corresponding meaning;

“**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.] Wording of Sections

“**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.] Wording of Sections

“**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.]

“**council**” means the Medicines Control Council established by section 2;

“**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.]Wording of Sections

“**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.]Wording of Sections

“**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.]

“**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.]

“**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.] Wording of Sections

“medical device” means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent—

- (a) used or purporting to be suitable for use or manufactured or sold for use in—
 - (i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or
 - (ii) restoring, correcting or modifying any somatic or psychic or organic function; or
 - (iii) the diagnosis or prevention of pregnancy, and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or
- (b) declared by the Minister by notice in the Gazette to be a medical device, and includes any part or an accessory of a medical device;

[Definition of “medical device” inserted by s. 1 (c) of Act No. 94 of 1991.]

“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.] Wording of Sections

“medicinal purpose”

[Definition of “medicinal purpose” deleted by s. 1 (e) of Act No. 94 of 1991.] Wording of Sections

“medicine” means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

- (a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or
- (b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine;

[Definition of “medicine” substituted by s. 1 (d) of Act No. 17 of 1979.] Wording of Sections

“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.] Wording of Sections

“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.] Wording of Sections

“**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.] Wording of Sections

“**pharmacy Board**”

[Definition of “pharmacy Board” deleted by s. 1 (k) of Act No. 94 of 1991.] Wording of Sections

“**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.] Wording of Sections

“**prescribed**” means prescribed by or under this Act;

“**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**” means the Registrar of Medicines appointed under section 12; “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.]

Wording of Sections

“**Schedule 1 substance**”

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

Wording of Sections

“**Schedule 2 substance**”

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

Wording of Sections

“**Schedule 3 substance**”

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

Wording of Sections

“**Schedule 4 substance**”

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

Wording of Sections

“**Schedule 5 substance**”

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

“Schedule 6 substance”

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

“Schedule 7 substance”

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

“Schedule 8 substance”

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

“Schedule 9 substance”

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

“Secretary”

[Definition of “Secretary” deleted by s. 1 (f) of Act No. 20 of 1981.] Wording of
Sections

“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.] Wording of Sections

“**trainee pharmacist**”

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

“**unqualified assistant**”

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

“**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.] Wording of Sections

“**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.]

- (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.] Wording of Sections

- (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.] Wording of Sections

- (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.] Wording of Sections

2. Establishment, powers and functions of Medicines Control Council.—

- (1) There is hereby established a council to be known as the Medicines Control Council, which may exercise the powers and shall perform the functions conferred upon or assigned to the council by this Act.

- (2) The Council may advise the Minister or furnish a report to the Minister on any matter referred to the council by the Minister for consideration and arising from the application of this Act.

[Sub-s. (2) added by s. 2 of Act No. 94 of 1991.]

- (3) The council shall be a juristic person.

[S. 2 substituted by s. 2 (1) of Act No. 65 of 1974. Sub-s. (3) added by s. 2 of Act No. 90 of 1997.] Wording of Sections

3. Constitution of council.—The council shall consist of so many members, but not more than 24, as the Minister may from time to time determine and appoint.

[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 and substituted by s. 3 of Act No. 90 of 1997.] Wording of Sections

4. Period of office and remuneration of members of the council.—

(1) A member of the council shall, subject to the provisions of section 6 (3), be appointed for a period of five years but a new council shall be appointed within six months after the date of commencement of the Medicines and Related Substances Control Amendment Act, 1997.

[Sub-s. (1) substituted by s. 4 of Act No. 90 of 1997.] Wording of Sections

(2) Any person whose period of office as a member of the council has expired, shall be eligible for reappointment: Provided that no person who has served two periods of five years as a member shall be so eligible.

[Sub-s. (2) substituted by s. 4 of Act No. 90 of 1997.] Wording of Sections

(3) The Minister shall give notice in the Gazette of the appointment of any member of the council and the date from which his membership commences and, in the case of a member appointed to fill a casual vacancy on the council, the period for which he is appointed.

(4) A member of the council (other than a person who is in the full-time employment of the State) shall receive such remuneration and such allowances in respect of his services as a member of the council or of any committee thereof, as the Minister in consultation with the Minister of Finance may determine.

[Sub-s. (4) substituted by s. 4 (1) of Act No. 65 of 1974.] Wording of Sections

5. Chairman and vice-chairman.—

- (1) One of the members of the council shall be designated by the Minister as chairman of the council and another member shall be designated by the Minister as vice-chairman to act as chairman during the absence of the chairman.

[Sub-s. (1) amended by s. 46 of Act No. 97 of 1986.] Wording of Sections

- (2) The vice-chairman, when acting as chairman as provided in subsection (1), shall have all the powers and discharge all the duties of the chairman.

6. Disqualifications, vacation of office, filling of vacancies and declaration of interest.—

- (1) No person shall be appointed as a member of the council—
- (a) who is an unrehabilitated insolvent;
 - (b) who is disqualified under the Veterinary and Para-Veterinary Professions Act, 1982, the Chiropractors, Homeopaths and Allied Health Service Professions Act, 1982, the Health Professions Act, 1974, or the Pharmacy Act, 1974, from carrying on his or her profession, while so disqualified;
 - (c) who is not a South African citizen permanently resident in the Republic; or
 - (d) who is employed in the pharmaceutical industry.

- (2) A member of the council shall vacate his or her office—
- (a) if he or she is or becomes subject to any disqualification referred to in subsection (1);
 - (b)

[Para. (b) deleted by s. 2 (a) of Act No. 59 of 2002.] Wording of Sections

- (c) if he or she becomes mentally ill, as defined in the Mental Health Act, 1973 (Act No. 18 of 1973);
- (d) if he or she is convicted of an offence and is sentenced to imprisonment without

the option of a fine;

- (e) if he or she has been absent from more than two consecutive meetings of the council without the council's leave; or
- (f) if the Minister is satisfied that the member has violated the internal rules of conduct as determined by the council and published by notice in the Gazette.

- (3) If the office of any member of the council becomes vacant before the expiration of the period for which he or she was appointed, the Minister may, appoint another person to hold office for the unexpired portion of the period for which his or her predecessor was appointed.

[Sub-s. (3) substituted by s. 2 (b) of Act No. 59 of 2002.] Wording of Sections

- (4) A member of the council or of a committee appointed in terms of section 9 shall declare his or her commercial interests related to the pharmaceutical or health care industry, which interests shall include, but shall not be limited to, any consultancy, paid or unpaid, any research grant from which the member directly or indirectly benefits, or any equity holding or any executive or non-executive directorship or any other payment or benefit in kind, and shall recuse himself or herself from any discussion or decision-making to which the said interests relate or may relate.

[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 and substituted by s. 5 of Act No. 90 of 1997.] Wording of Sections

7. Meetings of the council.—

- (1) The first meeting of the council shall be held at a time and place to be fixed by the Minister, and all subsequent meetings shall, subject to the provisions of subsection (2), be held at such times and places as may be fixed by the council: Provided that the council shall hold at least one meeting in any period of three months and, if at the close of any meeting the council has not fixed the time and place for its next meeting, such

time and place shall be fixed by the chairman.

- (2) The chairman of the council may at any time call a special meeting of the council to be held at such time and place as he may determine, and shall, upon a written request by the Minister or a written request signed by not less than three members of the council, call a special meeting thereof to be held within thirty days after the date of receipt of such request, at such time and place as he may determine.

[Sub-s. (2) substituted by s. 6 of Act No. 65 of 1974.] Wording of Sections

8. Quorum, majority decision and chairman's casting vote.—

- (1) A majority of all the members of the council shall form a quorum for any meeting of the council.
- (2) At all meetings of the council the chairman, or in his absence the vice-chairman, or in the absence of both the chairman and the vice-chairman, some other member of the council chosen by the members present, shall preside.
- (3) Save as provided in section thirty-six, the decision of a majority of the members of the council present at any meeting thereof shall constitute a decision of the council, and in the event of an equality of votes in regard to any matter, the person presiding at the meeting in question shall have a casting vote in addition to his deliberative vote.
- (4) No decision or act done under the authority of the council shall be invalid by reason only of an interim vacancy on the council or of the fact that a person who is disqualified from being a member of the council, or with respect to whose appointment the provisions of this Act have not been observed, sat or acted as a member at the time when the decision was taken or the act was performed or authorized, if the decision was taken or the act was performed or authorized by the requisite majority of the members of the council present at the time who were entitled to sit and act as members.

9. Appointment of executive committee and other committees.—

(1) The council may appoint—

(a) subject to the approval of the Minister, from among its members an executive committee; and

[Para. (a) substituted by s. 6 of Act No. 90 of 1997.] Wording of Sections

(b) subject to the approval of the Minister, such other committees as it may deem necessary, to investigate and report to it on any matter within the purview of the council in terms of this Act.

(2) The executive committee may, subject to the directions of the council, exercise all the powers and perform all the functions of the council during periods between meetings of the council, but shall not have the power, save in so far as the council otherwise directs, to set aside or vary any decision of the council, and any action taken or decision made by the executive committee shall be subject to review at the first ensuing meeting of the council.

(3) The council may appoint such persons, including persons other than members of the council, as it may deem fit, to be members of any committee appointed in terms of paragraph (b) of subsection (1).

(4) There shall be payable to a member of a committee of the council (other than a member of the council or a person who is in the full-time employment of the State) such remuneration and such allowances, while he is engaged in the carrying out of his duties as a member of such committee, as the Minister may, in consultation with the Minister of Finance, determine.

[Sub-s. (4) substituted by s. 7 of Act No. 65 of 1974.] Wording of Sections

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.]

Wording of Sections

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.]

Wording of Sections

12. Appointment of Registrar and Deputy Registrar of Medicines.—

(1) The Minister may, after consultation with the council, appoint a Registrar and one or more Deputy Registrars or revoke such an appointment.

(2) The Registrar shall exercise the powers and perform the duties assigned to, or imposed upon him or her in terms of this Act and such other powers and duties as may from time to time be assigned to or imposed upon him or her by the council, Minister or Director-General.

(3) A Deputy Registrar shall assist the Registrar in the exercise of his or her powers and the performance of his or her duties and may, subject to the approval of the Registrar, exercise any power conferred upon the Registrar.

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

13. Medicines register.—The registrar shall keep in the prescribed form a register, to be known as the medicines register, in which he shall register all medicines the registration of

which has been approved by the council, and in which he shall enter all such particulars in regard to such medicines and the holder of the certificate of registration in respect of such medicines as are required by this Act to be entered therein.

[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.] Wording of Sections

14. Prohibition on the sale of medicines 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 which is subject to registration by virtue of a resolution published in terms of subsection (2) unless it is registered.

(2) (a) The council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines mentioned in the resolution shall be subject to registration in terms of this Act.

(b) Any such resolution may also relate only to medicines 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 which were not then so available.

[Para. (b) substituted by s. 7 (a) of Act No. 94 of 1991.] Wording of Sections

(c) Any such resolution shall be published in the Gazette by the registrar and shall come into operation on the date on which it is so published.

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

- (a) if no application for the registration of such medicine is made within the period of six months immediately succeeding that date, on the expiration of that period; or
- (b) if application for the registration of such medicine is made within the said period, on the date one month after the date on which a notice in respect of such medicine is published in the Gazette in terms of section 15 (10) or section 17 (a).

[Sub-s. (3) amended by s. 7 (b) of Act No. 94 of 1991.] Wording of Sections

- (4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine—
 - (a) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a licence contemplated in section 22C (1) (a), for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or
 - (b) compounded by a pharmacist in a quantity not greater than that prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Health Professions Act, 1974, 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.

[Sub-s. (4) substituted by s. 6 of Act No. 17 of 1979, by s. 7 (c) of Act No. 94 of 1991 and by s. 8 (a) of Act No. 90 of 1997.] Wording of Sections

(5).....

[S. 14 substituted by s. 1 (1) of Act No. 29 of 1968 and by s. 12 (1) of Act No. 65 of 1974. Sub-s. (5) deleted by s. 8 (b) of Act No. 90 of 1997.] Wording of Sections

15. Registration of medicines.—

- (1) Every application for the registration of a medicine shall be submitted to the registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant medicine and by the prescribed registration fee.
- (2) The registrar shall—
 - (a) as soon as possible after receipt by him or her of any such application submit the application together with any particulars and samples which accompanied the application to the council for consideration and shall simultaneously inform the applicant in writing that the application has been so submitted;
 - (b) ensure that such an application in respect of medicine which appears on the latest Essential Drug List or medicine which does not appear thereon but which, in the opinion of the Minister, is essential for national health is subject to such procedures as may be prescribed in order to expedite the registration.

[Sub-s. (2) substituted by s. 9 (a) of Act No. 90 of 1997.] Wording of Sections

- (3)
 - (a) If after consideration of any such application and after any investigation or enquiry which it may consider necessary the council is satisfied that the medicine in question is suitable for the purpose for which it is intended and complies with the prescribed requirements and that registration of that medicine is in the public interest, it shall approve of the registration thereof.
 - (b) If the council is not so satisfied 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 one month after the date of the notification furnish the registrar with his or her comments on the council's reasons for not being so satisfied.

[Para. (b) substituted by s. 9 (b) of Act No. 90 of 1997.] Wording of Sections

- (c) If no such comments are submitted by the applicant within the said period, or if after consideration of any comments so submitted the council is still not satisfied

as aforesaid, it shall reject the application.

- (4) When the council has approved of the registration of any medicine the registrar shall register that medicine and shall enter in the register such particulars in regard to the medicine as are required by this Act to be so entered and shall issue to the applicant a certificate of registration in the prescribed form in respect of that medicine.
- (5) Every medicine shall be registered under such name as the council may approve.
- (6) The registrar shall allocate to every medicine registered under this Act a registration number which shall be recorded in the register opposite the name of such medicine and which shall be stated in the certificate of registration issued in respect of such medicine.
- (7) Any registration under this section, including the registration of medicines already registered, shall be valid for a period of five years and may be made subject to such conditions as may with regard to the succeeding provisions of this section be determined by the council.

[Sub-s. (7) substituted by s. 9 (c) of Act No. 90 of 1997.] Wording of Sections

- (8) No condition shall be imposed under subsection (7) 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 registrar that the imposition of such condition is contemplated and invited to submit written representations to the council in regard to the matter.
- (9) If no such representations are lodged with the registrar by the applicant concerned within a period of one month after the receipt by him or her of any notification referred to in subsection (8), or if after consideration of any such representations the council is still of the opinion that the condition in question should be imposed, the council shall direct the registrar to register the medicine concerned subject to the said condition.

[Sub-s. (9) substituted by s. 9 (d) of Act No. 90 of 1997.] Wording of Sections

- (10) Notice of the rejection of an application under this section in respect of a medicine referred to in subsection (3) of section 14 shall be given in the Gazette by the registrar—
- (a) if no appeal is lodged against the rejection within the period referred to in section 24, as soon as possible after the expiration of that period; or
- [Para. (a) substituted by s. 8 of Act No. 94 of 1991.] Wording of Sections
- (b) if any appeal so lodged is dismissed, as soon as possible after the decision dismissing the appeal has been given.

- (11) The registrar 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.

[Sub-s. (11) substituted by s. 9 (e) of Act No. 90 of 1997.] Wording of Sections

- (12) For the purposes of this section, “Essential Drug List” means the list of essential drugs included in the latest edition of the official publication relating to guidelines for standard treatment which is compiled by the Department of Health.

[S. 15 amended by s. 2 of Act No. 29 of 1968 and substituted by s. 13 of Act No. 65 of 1974. Sub-s. (12) added by s. 9 (f) of Act No. 90 of 1997.] Wording of Sections

15A. Amendment of entries in register.—

- (1) The entry made in the register with respect to any medicine may on application by the holder of the certificate of registration issued in respect of such medicine be amended by the registrar with the approval of the council.
- (2) Application for the amendment of an entry in the register shall be made to the registrar

on the prescribed form and shall be accompanied by the prescribed application fees.

- (3) The registrar shall as soon as possible after the receipt of any such application submit the application to the council for consideration.
- (4) If the council grants its approval in respect of any application submitted to it in terms of subsection (6) the registrar shall make the required amendments in the register and, if necessary, cancel the existing certificate of registration in respect of such medicine and issue a new certificate of registration on the prescribed form to the applicant in respect of such medicine.

[S. 15A inserted by s. 3 of Act No. 20 of 1981.]

15B. Transfer of certificates of registration.—

- (1) certificate of registration may with the approval of the council be transferred by the holder thereof to any other person.
- (2) Application for approval of the transfer of a certificate of registration shall be made to the registrar on the prescribed form and shall be accompanied by the certificate of registration in question and the prescribed application fees.
- (3) The registrar shall as soon as practicable after the receipt of any such application submit the application to the council for consideration.
- (4) If the council grants any application submitted to it in terms of subsection (3) the registrar 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 certificate of registration on the prescribed form to such person in respect of the relevant medicine.

[S. 15B inserted by s. 3 of Act No. 20 of 1981.]

15C. Measures to ensure supply of more affordable medicines.—

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

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 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;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

[S. 15C inserted by s. 10 of Act No. 90 of 1997.]

16. Cancellation of registration.—

- (1) If the council—
 - (a) is of the opinion that any person has failed to comply with any condition subject to which any medicine has been registered; or
 - (b) is of the opinion that any medicine does not comply with any prescribed requirement; or
 - (c) is of the opinion that it is not in the public interest that any medicine shall be available to the public, the council shall cause notice in writing to be given accordingly by the registrar to the holder of the certificate of registration issued in

respect of that medicine.

[Sub-s. (1) amended by s. 14 of Act No. 65 of 1974 (English only) and substituted by s. 4 (a) of Act No. 20 of 1981.] Wording of Sections

- (2) Any such notice shall specify the grounds on which the council'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 registrar any comments he 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 council is of the opinion that the registration of the medicine in question should be cancelled, the council may direct the registrar to cancel the registration thereof.

[Sub-s. (3) amended by s. 14 of Act No. 65 of 1974 (English only).] Wording of Sections

- (4) If the person who is the holder of the certificate of registration issued in respect of any medicine fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine before or on the prescribed date or such later date as the registrar may with the approval of the council determine on application by that person, the registrar shall cancel the registration of that medicine.

[Sub-s. (4) added by s. 3 of Act No. 29 of 1968, amended by s. 14 of Act No. 65 of 1974 and substituted by s. 4 (b) of Act No. 20 of 1981 (English only).] Wording of Sections

17. Notification of registration or cancellation of registration in Gazette.—The registrar shall give notice in the Gazette of the registration or cancellation of the registration of any medicine in terms of this Act, and shall in such notice specify—

- (a) in the case of a registration of any medicine, the name under which such medicine is registered, the active components of such medicine, the name of the person who

applied for the registration of such medicine, the number allocated to it in terms of section 15 and the conditions (if any) subject to which it is registered;

- (b) in the case of a cancellation of the registration of any medicine, the name under which such medicine was registered, the name of the holder of the certificate of registration issued in respect of such medicine 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 and substituted by s. 15 of Act No. 65 of 1974. Para. (b) substituted by s. 5 of Act No. 20 of 1981.] Wording of Sections

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.
- (2) No person shall advertise any medicine or Scheduled substance for sale unless such advertisement complies with the prescribed requirements.
- (3) The label referred to in subsection (1) shall be approved by the council. [Sub-s. (3) added by s. 11 of Act No. 90 of 1997.]
- (4) The council may authorise a deviation from the prescribed format and contents of any label. [Sub-s. (4) added by s. 11 of Act No. 90 of 1997.]

- (5) The Minister may prescribe additional requirements for the labelling of medicines.

[S. 18 substituted by s. 16 of Act No. 65 of 1974 and by s. 7 of Act No. 17 of 1979. Sub-s. (5) added by s. 11 of Act No. 90 of 1997.] Wording of Sections

18A. Bonusing.—No person shall supply any medicine according to a bonus system, rebate

system or any other incentive scheme.

[S. 18A inserted by s. 12 of Act No. 90 of 1997.] (Date of commencement: 2 May, 2004.)

18B. Sampling of medicines.—

- (1) No person shall sample any medicine.
- (2) For the purposes of this section “sample” means the free supply of medicines by a 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, but does not include the free supply of medicines for the purposes of clinical trials, donations of medicines to the State, tendering to the State and quality control by inspectors.
- (3) The use of medicines or Scheduled substances for exhibition purposes shall be as prescribed.

[S. 18B inserted by s. 12 of Act No. 90 of 1997.]

18C. Marketing of medicines.—The Minister shall, after consultation with the pharmaceutical industry and other stakeholders, make regulations relating to the marketing of medicines, and such regulations shall also provide for an enforceable Code of Practice.

[S. 18C inserted by s. 12 of Act No. 90 of 1997 and substituted by s. 4 of Act No. 59 of 2002.]

Wording of Sections

19. Prohibition on sale of medicines which do not comply with prescribed requirements and furnishing of information regarding medicines to the council.—

- (1) No person shall sell any medicine unless it complies with the prescribed requirements.

[Sub-s. (1) amended by s. 17 of Act No. 65 of 1974 (English only).] Wording of Sections

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

[Sub-s. (2) amended by s. 17 of Act No. 65 of 1974 (English only).] Wording of Sections

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

20. Publication or distribution of false advertisements concerning medicines.—

- (1) No person shall—

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

[Para. (a) amended by s. 18 of Act No. 65 of 1974 (English only).] Wording of Sections

- (b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine is other than that stated by the council in terms of subparagraph (ii) of paragraph (a) of section twenty-two or state or suggest that any medicine should be used for a purpose or under circumstances or in a manner other than that stated by the council in terms of subparagraph (iii) or paragraph (a) of that section.

[Para. (b) amended by s. 18 of Act No. 65 of 1974 (English only).] Wording of

Sections

- (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 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, unless it is proved that the accused failed on demand by the registrar or an inspector or a member of the South African Police to furnish the name and address of the person at whose instance the advertisement was published, distributed or so brought to the notice of the public.

[Sub-s. 2 amended by s. 18 of Act No. 65 of 1974 (English only).]

21. Council may authorize sale of unregistered medicine for certain purposes.—

- (1) The council 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 which is not registered.

[Sub-s. (1) amended by s. 19 of Act No. 65 of 1974 (English only).] Wording of Sections

- (2) Any medicine sold in pursuance of any authority under subsection (1) may be used for such purposes and in such manner and during such period as the council may in writing determine.

[Sub-s. (2) amended by s. 19 of Act No. 65 of 1974 (English only).] Wording of Sections

- (3) The council 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).

22. Director-General to cause certain information to be furnished.—

- (1) The Director-General shall after consultation with the council, cause, in such manner as the Director-General considers most suitable—
 - (a) as soon as practicable after any medicine, other than a veterinary medicine, has been registered, medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine to be informed—
 - (i) of the name and number under which such medicine is registered and the conditions, if any, subject to which such medicine 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 should be used; and
 - (iv) regarding any other matter concerning such medicine which, in the opinion of the council, may be of value to them;
 - (b) as soon as practicable after the registration of any medicine, other than a veterinary medicine, has been cancelled in terms of section 16, medical practitioners, dentists, pharmacists and the holder of the certificate of registration issued in respect of such medicine to be informed of the cancellation of such registration.

[Para (b) substituted by s. 6 of Act No. 20 of 1981.] Wording of Sections

- (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 and by s. 8 of Act No. 17 of 1979.] Wording of Sections

22A. Control of medicines and Scheduled substances.—

- (1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine or Scheduled substance, except in accordance with the prescribed conditions.
- (2) The Minister may, on the recommendation of the council, prescribe the Scheduled substances referred to in this section.
- (3) Any Schedule 0 substance may be sold in an open shop.
- (4) Any Schedule 1 substance shall not be sold—
 - (a) by any person other than—
 - (i) a pharmacist, or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist;
 - (ii) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
 - (iii) a medical practitioner or dentist, who may—
 - (aa) prescribe such substance;
 - (bb) compound and dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
 - (iv) a veterinarian who may prescribe, compound or dispense such substance;
 - (v) a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may—
 - (aa) prescribe only the Scheduled substances identified in the Schedule for that purpose;
 - (bb) compound and dispense the Scheduled substances referred to in item (aa) only if he or she is the holder of a licence contemplated in section 22C (1) (a);
 - (b) to any person apparently under the age of 14 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 14 years;
- (c) unless the seller, other than a manufacturer or wholesale dealer in pharmaceutical products, enters in a prescription book required to be kept in the prescribed manner, the prescribed particulars of such sale.
- (5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than—
- (a) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;
 - (b) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;
 - (c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
 - (d) a medical practitioner or dentist, who may—
 - (i) prescribe such substance;
 - (ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
 - (e) a veterinarian who may prescribe, compound or dispense such substance;
 - (f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may—
 - (i) prescribe only the Scheduled substances identified in the Schedule for that purpose;

- (ii) compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C (1) (a).
- (6) Any sale under subsection (5) shall only take place on condition that—
- (a) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner;
 - (b) the authorised prescriber who has given verbal instructions to a pharmacist to dispense a prescription shall within seven days after giving such instructions furnish such pharmacist with a prescription confirming such instructions;
 - (c) in the case of verbal instructions the treatment period shall not exceed seven days;
 - (d) if a prescription is not presented for dispensing within 30 days of issue it shall not be dispensed;
 - (e) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of 14 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 14 years;
 - (f) in the case of a Schedule 2, Schedule 3 or Schedule 4 substance, such sale may be repeated if the person who issued the prescription has indicated thereon the number of times it may be dispensed, but not for longer than six months;
 - (g) in the case of a Schedule 5 substance, such sale shall not be repeated for longer than six months, and then only if the authorised prescriber has indicated on the prescription the number of times and the intervals at which it may be dispensed;
 - (h) where a Schedule 5 substance is used for—
 - (i) its anxiolytic, 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;
- (i) in the case of a Schedule 6 substance, it shall not be repeated without a new prescription being issued;
- (j) in an emergency in which the health or life of a patient is at stake, a pharmacist engaged in wholesale practice may, on receipt of a telephonic or telefaxed or other electronic request, supply a Schedule 6 substance to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, without a written order: Provided that—
- (i) it shall be the responsibility of such pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person to ensure that such pharmacist receives a written order within seven days;
- (ii) the Schedule 6 substance shall be supplied in the smallest unit sales pack available;
- (iii) a permanent record is made and kept of such supply;
- (k) in an emergency a pharmacist may sell any Schedule 5 or Schedule 6 substance in a quantity not greater than that required for continuous use for a period of 48 hours, on the verbal instructions of a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, who is known to such pharmacist, but the prescriber who has given such verbal instructions shall within 72 hours after giving such instructions furnish to such pharmacist a written prescription confirming the instructions;
- (l) in an emergency a pharmacist may sell a Schedule 2, Schedule 3 or Schedule 4 substance on a non-recurring basis for a period not exceeding 30 days in accordance with the original prescription in order to ensure that therapy is not disrupted if he or she is satisfied that an authorised prescriber initiated the therapy,

with the intention that the therapy be continued, and that the particulars of such sale are recorded in a prescription book or other prescribed permanent record;

- (m) a pharmacist may sell a greater or a lesser quantity of a Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance than the quantity prescribed or ordered, according to the therapeutic pack in the original container of such substance as supplied to him or her, but the quantity so sold shall not exceed or be less than, 25 per cent of the quantity specified in the prescription or order in question;
- (n) any seller referred to in this subsection shall retain the prescription or order concerned for a period of not less than five years as from the date of such sale;
- (o) a Schedule 6 substance may only be sold if the course of treatment does not exceed 30 consecutive days;
- (p) the sale of 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.] Wording of Sections

- (q) a pharmacist shall endorse on the prescription the date of sale and the quantity of the substance sold, and when it is repeated, the date of sale and the quantity of the said substance sold, and the last seller shall retain the prescription for a period of not less than five years as from the date of the last sale;
 - (r) any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal may be supplied by any person practising a para-veterinary profession within the meaning of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 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.] Wording of Sections

- (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.] Wording of Sections

- (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.] Wording of Sections

 - (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.] Wording of Sections
 - (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.] Wording of Sections
- (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.] Wording of Sections

- (13) Any permit issued under subsection (11) shall be subject—
- (a) to the applicant's furnishing the registrar annually with the prescribed information;
 - (b) to the requirement that there shall be no deviation from the particulars reflected on the permit: Provided that if the quantity of such substance or medicine to be imported is less than that provided for in the permit, the Director-General shall be informed in writing thereof within 10 days after the importation of such substance or medicine; and
 - (c) to the conditions, as detailed on the permit, having been complied with, the triplicate copy of the 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) 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.] Wording of Sections
 - (b) no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional council concerned.
- (15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the Interim Pharmacy Council of South Africa 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.

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

- (a) any person may possess a Schedule 0, Schedule 1 or Schedule 2 substance for medicinal purposes;
- (b) any person may possess a Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance if he or she is in possession of a prescription issued by an authorised prescriber;

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

- (c) any medicine or scheduled substance may be possessed by a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, or under the Veterinary and Para-Veterinary Professions Act, 1982, for the purposes of administering it in accordance with his or her scope of practice;
- (d) any medicine or scheduled substance may be possessed for sale by a pharmacist, a person licenced to own a pharmacy in terms of the Pharmacy Act, 1974, or a person who is the holder of a licence as contemplated in section 22C.

(17) For the purposes of this section—

- (a) “authorised prescriber” means a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974; and
- (b) “medicinal purpose” means for the purposes of the treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or craving for the substance used or for any other such substance, except where the substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a provincial government or approved for such purpose by the Minister.

[S. 22A inserted by s. 21 of Act 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.] Wording of Sections

22B. Publication of information relating to medicine, Scheduled substance or medical device.—

- (1) Notwithstanding the provisions of section 34 the council 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 or medical device.
- (2) The Director-General may publish the information referred to in subsection (1) or release it to the public in a manner which he thinks fit.

[S. 22B inserted by s. 10 of Act No. 94 of 1991.]

22C. Licensing.—

- (1) Subject to the provisions of this section—
 - (a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions;
 - (b) the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine.

[Para. (b) substituted by s. 6 (a) of Act No. 59 of 2002.] Wording of Sections

- (2) A licence referred to in subsection shall (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, the Allied 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.] Wording of Sections

- (3) The Director-General or the council, 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 council may deem necessary.
- (4) When the Director-General or the council, as the case may be, grants or refuses an application for a licence—
 - (a) written notice shall be given of that fact to the applicant; and
 - (b) in the event of the refusal of an application, the applicant shall be furnished with the reasons for such refusal.
- (5) No person shall compound or dispense a medicine unless he or she is authorised thereto in terms of the Pharmacy Act, 1974, is a veterinarian or is the holder of a licence as contemplated in subsection (1) (a).

[Sub-s. (5) substituted by s. 6 (c) of Act No. 59 of 2002.] Wording of Sections

- (6) No manufacturer, wholesaler or distributor referred to in subsection (1) (b) shall manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any medicine 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.] Wording of Sections

- (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.] Wording of Sections

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 council, 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.]

22E. Suspension and cancellation of licence.—

- (1) If the holder of a licence under section 22C—
 - (a) has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the council, as the case may be, with any information which to the knowledge of such holder is untrue or misleading in any material respect;
 - (b) has contravened or failed to comply with a condition upon which the licence was issued;
 - (c) has contravened or failed to comply with a provision of this Act;
 - (d) has, in the case of a licence issued in terms of section 22C (1) (a), at any time been convicted of an offence which is of such a nature that, in the opinion of the Director-General, it renders him or her unsuitable to compound or dispense medicines, the Director-General or the council, 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.

- (2) The Director-General or the council, as the case may be, may after considering the reasons furnished to him or her in terms of subsection (1)—
 - (a) suspend the licence in question for such period as he or she or the council may determine; or
 - (b) revoke the licence in question.

- (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 licensd in terms of section 22C (1) (a) shall—

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

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

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

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

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

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

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

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

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

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

[S. 22F inserted by s. 14 of Act No. 90 of 1997.]

22G. Pricing committee.—

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

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

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

- (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
- (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C (1) (a);
- (c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule O medicines.

[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.] Wording of Sections

- (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 by wholesalers.—

- (1) (a) No wholesaler shall purchase medicines from any source other than from the original manufacturer or from the primary importer of the finished product.
(b) A wholesaler shall sell medicines only into the retail sector.
- (2) Subsection (1) shall not be construed as preventing the return of medicines for credit purposes only, to the manufacturer or wholesaler from which that medicine was initially obtained.
- (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.]

23. Disposal of undesirable medicines.—

- (1) If the council is of the opinion that it is not in the public interest that any medicine shall be made available to the public, it may—
- (a) by notice in writing transmitted by registered post to any person direct that person; or
- (b) by notice in the Gazette direct any person, to return any quantity of such medicine which he has in his possession to the manufacturer thereof or (in the case of any imported medicine) to the importer concerned or to deliver or send it to any other person designated by the council.

[Sub-s. (1) amended by s. 22 of Act No. 65 of 1974 (English only).] Wording of Sections

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

[Sub-s. (2) amended by s. 22 of Act No. 65 of 1974 (English only).] Wording of Sections

- (3) No person shall sell any medicine 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).] Wording of Sections

24. Appeal against decision of council or Director- General.—

- (1) Any person aggrieved by a decision of the council may, within the prescribed period, in the prescribed manner and upon payment of the prescribed fee, appeal against such decision to an appeal committee appointed by the Minister for the purposes of the appeal concerned.

[Sub-s. (1) substituted by s. 9 (b) of Act No. 59 of 2002.] Wording of Sections

- (2) An appeal committee contemplated in subsection (1) shall consist of no fewer than three persons: Provided that—

(a) the chairperson shall be appointed on account of his or her knowledge of the law;

[Para. (a) substituted by s. 9 (c) of Act No. 59 of 2002.] Wording of Sections

(b) the skills of the other two members shall be relevant to the case concerned;

(c) no member shall have a direct or indirect interest in the affairs of the appellant or respondent.

- (3) The appeal committee may after hearing the appeal—
- (a) confirm, set aside or vary the relevant decision of the council; and
 - (b) direct the council to execute the decision of the appeal committee.

[Sub-s. (3) substituted by s. 9 (d) of Act No. 59 of 2002.] Wording of Sections

- (4) The decision of the appeal committee shall be in writing and a copy thereof shall be furnished to the appellant as well as to the council.

[Sub-s. (4) substituted by s. 9 (e) of Act No. 59 of 2002.] Wording of Sections

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

- (6) 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. [Sub-s. (6) substituted by s. 9 (f) of Act No. 59 of 2002.]
Wording of Sections

- (7) The Minister shall, after considering representations made in terms of subsection (6), 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 and amended by s. 9 (a) of Act No. 59 of 2002.

Sub-s. (7) added by s. 9 (g) of Act No. 59 of 2002.] Wording of Sections

25. Privileges of council and committees.—The council or a committee appointed under section 9 (1), 22G (1) or 24 (1) or any member of the council or of any such committee shall not be liable in respect of anything done in good faith under this Act.

[S. 25 substituted by s. 32 of Act No. 88 of 1996 and by s. 10 of Act No. 59 of 2002.] Wording of Sections

26. Inspectors.—

- (1) The Director-General may authorize such persons as inspectors, as he may consider necessary for the proper enforcement of this Act.

[Sub-s. (1) substituted by s. 10 of Act No. 17 of 1979.] Wording of Sections

- (2) Every inspector shall be furnished with a certificate signed by the Director-General and stating that he has been authorized as an inspector under this Act.

[Sub-s. (2) substituted by s. 1 of Act No. 19 of 1976.] Wording of Sections

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

[S. 26 substituted by s. 24 (1) of Act No. 65 of 1974.] Wording of Sections

27. Analysts, pharmacologists and pathologists.—The Director-General may grant such authority to such analysts, pharmacologists and pathologists as he may consider necessary for the proper enforcement of this Act.

[S. 27 substituted by s. 25 (1) of Act No. 65 of 1974 and by s. 11 of Act No. 17 of 1979.]
Wording of Sections

28. Powers of inspectors.—

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

(a) enter upon—

(i) any place or premises from which—

(aa) a person authorized under this Act to compound or dispense medicines or scheduled substances;

(bb) the holder of a licence as contemplated in section 22C (1) (b);

(cc) the holder of a certificate of registration of a medicine, conducts

business;

- (ii) any place, premises, vessel or aircraft if he or she suspects on reasonable grounds that an offence in terms of this Act has been or is being committed thereon or therein or that an attempt has been made or is being made to commit such an offence thereon or therein; or
- (iii) any private dwelling, with the consent of the occupier or under the authority of a warrant issued in terms of subsection (5) or without a warrant in terms of subsection (6);
- (b) inspect any medicine or scheduled substance, any book, record or documents that the inspector believes on reasonable grounds contains any information relevant to the administration or enforcement of this Act;
- (c) seize any book record, documents or medicine or scheduled substance or take so many samples of any such medicine or scheduled substance as he or she may consider necessary for the purpose of testing, examination or analysis in terms 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.] Wording of Sections

- (2) Any sample taken in terms of paragraph (d) of subsection (1) shall be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such medicine or Scheduled substance, or if there is no such person or if he is absent for any reason, in the presence of any other witness, shall forthwith be packed and sealed and suitably labelled or marked in such manner as its nature may permit and shall then be transmitted to an analyst, pharmacologist or pathologist together with a certificate in the prescribed forms signed by such inspector and a copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such medicine or Scheduled substance or his agent.

[Sub-s. (2) amended by s. 26 (a) of Act No. 65 of 1974 and substituted by s. 12 (a) of Act No. 17 of 1979.] Wording of Sections

- (3) The analyst, pharmacologist or pathologist 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, 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.] Wording of Sections

- (4) The owner of the medicine or Scheduled substance from which the sample was taken may claim from the Director-General an amount equal to the market value thereof.

[Sub-s. (4) substituted by s. 26 (b) of Act No. 65 of 1974.] Wording of Sections

- (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—

- (a) the conditions for entry described in subsection (1) (a) exist in relation to a private dwelling;
- (b) entry to that private dwelling is necessary for any purpose relating to the administration or enforcement of this Act; and
- (c) entry to the private dwelling has been refused or that entry thereto will be refused, a magistrate may issue a warrant 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) a warrant would be issued to him or her under subsection (5) if he or she applies for such a warrant; and
- (b) a delay in obtaining such warrant would defeat the object of the entry, search and seizure, he or she may without a warrant enter and search any premises for any medicines, scheduled substance, book, record or document relevant to the administration or enforcement of this Act and seize or take samples as contemplated in subsection (1) (c).

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

29. Offences.—Any person who—

- (a) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties under this Act; or
[Para. (a) substituted by s. 17 (a) of Act No. 90 of 1997.] Wording of Sections
- (b) 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.] Wording of Sections
- (c) 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.] Wording of Sections
- (d) contravenes the provisions of section 20 (1); or
[Para. (d) substituted by s. 17 (a) of Act No. 90 of 1997.] Wording of Sections
- (e) contravenes or fails to comply with any condition imposed under section 15 (7); or
[Para. (e) substituted by s. 17 (a) of Act No. 90 of 1997.] Wording of Sections
- (f) 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.] Wording of Sections
- (g) with fraudulent intent tampers with any sample taken in terms of this Act; or
- (h) makes any false or misleading statement in connection with any medicine or Scheduled substance—
 - (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.] Wording of Sections
- (i) sells any medicine or Scheduled substance 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.] Wording of Sections
- (j) for purposes of business or trade makes use of any report or certificate made or issued by an inspector, analyst, pharmacologist or pathologist under this Act; or
- (k) contravenes any provision of section 22A, 22C (5) and (6), 22F, 22G or 22H or

contravenes or fails to comply with any condition imposed thereunder;

[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.] Wording of Sections

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

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

(m) manufactures, sells or uses a veterinary medicine in contravention of a prohibition referred to in section 36A, or contravenes, or fails to comply with, a condition 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.] Wording of Sections

(2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any medicine or Scheduled substance 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.] Wording of Sections

(3) Any medicine or Scheduled substance forfeited under this Act shall be destroyed or otherwise dealt with as the Director-General may direct.

[Sub-s. (3) substituted by s. 28 (b) of Act No. 65 of 1974.] Wording of Sections

(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—

(a) any quantity of a medicine or Scheduled substance 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.] Wording of Sections

(b)

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

(c) 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;

(d) any statement or entry contained in any book, record or document kept by any owner of a medicine or Scheduled substance, 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 as an admission of the facts set forth in that statement or entry, unless it is proved 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 work as manager, or in the course of his agency or employment.

[Para. (d) amended by s. 29 of Act No. 65 of 1974.] Wording of Sections

(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.] Wording of Sections

(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.]Wording of Sections

33. Act or omission by manager, agent or employee.—

- (1) Whenever any manager, agent or employee of any person (hereinafter called the employer) does or omits to do any act which it would be an offence under this Act for the employer to do or omit to do, then unless it is proved that—
 - (a) in doing or omitting to do that act the manager, agent or employee was acting without the connivance or the permission of the employer; and
 - (b) all reasonable steps were taken by the employer to prevent any act or omission of the kind in question; and
 - (c) it was not under any condition or in any circumstances within the scope of the authority or in the course of the employment of the manager, agent or employee to do or to omit to do acts, whether lawful or unlawful, of the character of the act or omission charged, the employer shall be presumed himself to have done or omitted to do that act and shall be liable to be convicted and sentenced in respect thereof; and the fact that he issued instructions forbidding any act or omission of the kind in question shall not, of itself, be accepted as sufficient proof that he took all reasonable steps to prevent the act or omission.
- (2) Whenever any manager, agent or employee of any such employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, he shall be liable to be convicted and sentenced in respect thereof as if he were the employer.
- (3) Any such manager, agent or employee may be so convicted and sentenced in addition to

the employer.

33A. Funds of council.—

- (1) The funds of the council shall consist of—
 - (a) State funds received through the Department of Health;
 - (b) fees raised and interest on overdue fees;
 - (c) money accruing to the council from any other source.
- (2)
 - (a) The council may accept money or other goods donated or bequeathed to the council, 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 council.
- (3) The council shall utilise its funds for the defrayal of expenses incurred by the council in the performance of its functions under this Act.
- (4) The council 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 council 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 council 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 council's financial year stands to the credit of the council 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 council.

[S. 33A inserted by s. 21 of Act No. 90 of 1997.]

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.] Wording of Sections

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.] Wording of Sections

- (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.

[S. 34A inserted by s. 2 of Act No. 19 of 1976, substituted by s. 15 of Act No. 94 of 1991. Sub-s. (2) amended by s. 22 (b) of Act No. 90 of 1997.] Wording of Sections

35. Regulations.—

- (1) The Minister may, in consultation with the council, make regulations—
 - (i) prescribing the categories of persons by whom application may be made for the registration of any medicine or to whom a certificate of registration may be transferred;

- (ii) prescribing the forms which shall be used for any application for the registration of any medicine and the particulars which shall be furnished with any such application (including particulars regarding the method by which the medicine in question or any component of such medicine is manufactured and the premises at which such medicine or any such component is manufactured);
- (iii) providing for the classification of medicines into classes or categories for the purposes of this Act;
- (iv) prescribing the samples of any medicine and the quantity thereof which shall accompany any application for the registration of a medicine;
- (v) prescribing the form in which the medicines register shall be kept and the particulars which shall be entered therein in respect of any registered medicine;
- (vi) prescribing the form of any certificate of registration of any medicine;
- (vii) prescribing the circumstances in which, the conditions on which and the persons or categories of persons to whom any medicine or Scheduled substance may be sold;
- (viii) prescribing the manner in which any package containing any medicine or Scheduled substance shall be labelled, packed or sealed;
- (ix) prescribing the particulars in regard to the use thereof which shall be furnished with any medicine or Scheduled substance sold, and the manner in which such particulars shall be furnished;
- (x) prescribing the particulars which shall appear in any advertisement relating to any medicine or Scheduled substance, 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;
- (xi) prescribing the requirements with which any medicine or any component thereof shall comply in regard to composition, therapeutic suitability and effect, purity or any other property;
- (xii) prescribing the particulars which shall be published in the Gazette in respect of any application for registration referred to in section 15 (11);

- (xiii) prescribing the procedure at meetings of the council and of any committee appointed under section 9 (including the quorum in the case of committees) and the manner in which meetings of any such committee shall be called;
- (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 Scheduled substances, 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;
- (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 transshipment or the exportation from or importation into the Republic of any Scheduled substance, specifying the ports or places at which such substance may be brought into the Republic;
- (xviii) authorising and regulating or restricting the transmission through the Republic of Scheduled substances;
- (xix) prescribing the manner in which packages containing Scheduled substances 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;
- (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 Scheduled substances for personal medicinal use;
- (xxiii) as to the disposal or destruction of a medicine or a Scheduled substance, and the records which shall be kept in respect thereof;
- (xxiv) as to the importation, exportation, conveyance, keeping, storage, processing and packing of medicines and Scheduled substances, and the manner in which medicines and Scheduled substances shall be kept and controlled in different categories of hospitals;
[Para. (xxiv) substituted by s. 12 (a) of Act No. 59 of 2002.] Wording of Sections
- (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 or class of medical devices or medicines in respect of its safety, quality and efficacy;
[Para. (xxvii) substituted by s. 12 (b) of Act No. 59 of 2002.] Wording of Sections
- (xxviii) with regard to any matter to ensure the safety, quality and efficacy of medicines and medical devices;
- (xxix) as to the summary seizure and disposal of any Scheduled substance found in the possession or custody of any person not entitled under this Act to keep or use it;
- (xxx) as to the disposal or destruction of a Scheduled substance which has become unfit for use, and the report to be furnished in respect thereof;
- (xxxi) prescribing the fee to be paid to the registrar in respect of an application for the

- registration, and in respect of the registration of a medicine, Scheduled substance or medical device, the fee to be paid annually to the registrar in respect of the retention of the registration of a medicine, Scheduled substance or medical device and the date on which such annual fee shall be paid;
- (xxxii) prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, 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 quality of medicines, Scheduled substances or medical devices for the purpose of registration and the evaluation of changes to the particulars contained in registers;
- (xxxiii) relating to appeals against decisions of the Director-General or the council;
- (xxxiv) relating to the conditions under which medicines or Scheduled substances may be sold;
- (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 and other skills required by a member of the council or by a member of the executive committee of the council to evaluate the quality, efficacy and safety of medicines;
- (xxxviii) relating to the safety, quality and efficacy of imported medicines;
- (xxxix) relating to the control and conduct of clinical trials;
- (xl) with regard to any matter which in terms of this Act shall or may be prescribed; and
- (xli) 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.
- (2) The Minister shall, not less than three months before any regulation is made under subsection (1), cause the text of such regulation to be published in the Gazette, together

with a notice declaring his or her intention to make that regulation and inviting interested persons to furnish him or her with any comments thereon or any representations they may wish to make in regard thereto.

- (3) The provisions of subsection (2) shall not apply in respect of—
 - (a) any regulation which, after the provisions of that subsection have been complied with, has been amended by the Minister in consequence of comments or representations received by him or her in pursuance of the notice issued thereunder; or
 - (b) any regulation in respect of which the Minister is, after consultation with the council, of the opinion that the public interest requires it to be made without delay.
- (4) A regulation under subsection (1) (xxxix) and (xxxix) shall be made only in consultation with the Minister of Finance.
- (5) Regulations made under subsection (1) (xi) may prescribe that any medicine or any component thereof shall comply with the requirements set out in any publication which in the opinion of the council is generally recognised as authoritative.
- (6) Regulations may be made under this section in respect of particular medicines or Scheduled substances or classes or categories of medicines or Scheduled substances or in respect of medicines or Scheduled substances other than particular classes or categories of medicines or Scheduled substances, and different regulations may be so made in respect of different medicines or Scheduled substances or different classes or categories of medicines or Scheduled substances.
- (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 executive committee appointed under section 9, 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.] Wording of Sections

36. Exclusion of any drug from operation of Act.—The Minister may, on the unanimous recommendation of the members present at any meeting of the council, by notice in the Gazette exclude, subject to such conditions as he may determine, any medicine from the operation of any or all the provisions of this Act, and may in like manner amend or withdraw any such notice.

[S. 36 amended by s. 32 of Act No. 65 of 1974 (English only).] Wording of Sections

36A. Minister may prohibit the manufacture, sale or use of certain veterinary medicines.— Notwithstanding anything to the contrary in this Act or in any other law contained, the Minister may by notice in the Gazette for any reason other than the safety, quality or therapeutic efficacy of a veterinary medicine—

- (a) prohibit the manufacture, sale or use of any veterinary medicine containing a substance mentioned in the notice; or
- (b) prohibit such manufacture, sale or use, except in accordance with such conditions as may be specified in the notice, and may in like manner repeal or amend such notice. [S. 36A inserted by s. 17 of Act 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.]Wording of Sections

37A. Amendment of Schedules.—Notwithstanding the provisions of section 35 (2), the Minister may, on the recommendation of the council, 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 and substituted by s. 25 of Act No. 90 of 1997.]Wording of Sections

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.] Wording of Sections

(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.] Wording of Sections

Schedule 0

[Schedule 0 inserted by Government Notice No. R.509 in Government Gazette 24727 of 10 April, 2003 with effect from 2 May, 2003.]

- (a) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for—
 - (i) 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 No. 54 of 1972) or registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947); and
 - (ii) analytical laboratory purposes.
- (b) All substances 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.

This Schedule includes all 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 and inserted by Government Notice No. R.509 in Government Gazette 24727 of 10 April, 2003 with effect from 2 May, 2003.]Wording of Sections

- (a) All substances referred to in this Schedule are excluded when specifically packed, labeled and used for—
 - (i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and
 - (ii) analytical laboratory purposes.
- (b) All substances 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.
- (c) In terms of section 22A (4) (a) (v) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974 (Act No. 56 of 1974) other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 1 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the Gazette.

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)

Anethole trithione.

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

Antimalarials; chloroquine in combination with proguanil when intended specifically for malaria prophylaxis. (S4)

Antimicrobial substances, namely bacitracin, gramicidin, polymyxin B and tyrothricin, when intended for application to the skin, nares and external ear, as excluded from the conditions of Schedule 4. (S2, S4) Antimony potassium tartrate and antimony sodium tartrate; substances, preparations and mixtures containing 1,0 percent or more thereof.

Arsenic; substances, preparations and mixtures containing the equivalent of less than 0,01 percent of arsenic trioxide. (S2)

Azelaic acid.

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

Benzethonium chloride, when intended for human vaginal use. Benzydamine; preparations and mixtures containing—

- (a) 3 per cent or less of benzydamine when intended for application to the skin;
- (b) 0,15 per cent 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 daily dose does not exceed 36 mg of benzydamine. (S3)

Beta-aminopropylbenzene and beta-aminoisopropylbenzene as excluded from the conditions of Schedule 5. (S5)

Bifonazole, when intended for application to the skin. Bioallethrin.

Bitolterol.

Bufexamac, when intended for application to the skin. Bunamidine.

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. Chlorhexidine, when intended for human vaginal use.

Chloroform, preparations and mixtures containing less than 20 percent of chloroform.

(S5)

Clotrimazole, when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S4)

Dialysate preparations.

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

Dithiazanine.

Econazole, when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S4)

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

Ephedra alkaloids (natural or synthetic) except ephedrine preparations and mixtures intended for application to skin, eyes, ears and nares containing 1,0 per cent or less of ephedra alkaloids, and other preparations and mixtures containing not more than 30 milligrams of ephedrine or ephedra alkaloids per dose. (S2, S5)

Ephedrine contained in products registered in terms of the Act, preparations and mixtures intended for application to the skin, eyes, ears and nares containing 1,0 per cent or less of ephedrine, and other oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose. (S2, S5)

Escin (aescin); medicinal preparations and mixtures thereof intended for application to the skin and containing 1,0 per cent or less of escin. (S3)

Ether (diethyl ether); all substances, preparations and mixtures containing less than 20 per cent of ether. (S5)

Ethylphenylephrine.

Etofenamate, when intended for application to the skin. Felbinac, when intended for application to the skin.

Fenbendazole, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Fenticonazole, when intended for application to the skin.

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.

Flufenamic acid, when intended for application to the skin. (S3)

Flurbiprofen, when intended for application to the skin, including by transdermal patch, provided that in the case of application by transdermal patch indications are for use by adults and children 12 years and older and the treatment period is limited to 4 weeks. (S2, S3, S4)

Fluorescein, when intended for ophthalmic use.

Fluorides; oral medicinal preparations and mixtures thereof containing 0,25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another Schedule. (S4)

Gamma benzene hexachloride human medicinal preparations and mixtures when intended for application to the skin.

Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester) when intended for application to the skin. (S4)

O-b-hydroxyethyl) rutosides.

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

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

Indanazoline.

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

Injections, unless listed in another Schedule, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Irrigation fluids.

Isoconazole, when intended for application to the skin and when intended for human vaginal use specifically for the treatment of recurrent vaginal candidiasis. (S4)

Ketoconazole, when intended for application to the skin, except preparations and mixtures containing not more than 1,0 percent of ketaconazole, when intended for the

prevention and treatment of dandruff. (S0, S4)

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

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.

Local anaesthetics, except when intended for ophthalmic and for parenteral use. (S2, S4)

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. 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.

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

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.

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

Mebendazole, except intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Methenamine (hexamine), except when intended for application to the skin and except when intended and registered as an urinary tract antiseptic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Methionine, when intended for medicinal purposes.

Miconazole when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S2, S4)

Microfibrillar collagen hydrochloride.

Morantel citrate, 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. N-acetyl-aspartyl-glutamic acid.

Naphazoline, when intended for nasal use.

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

Nicotine; when used as nicotine transdermal patches for continuous application to the skin in strengths up to and including 15mg/16 hours when these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only. (S2), except nicotine gum containing 4mg or less nicotine per piece where the pack size does not exceed 30 pieces per pack when these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only (S0).

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

Nystatin, when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S4)

Omidazole, when intended for application to the skin. (S4) Orthodichlorobenzene, when intended for topical human medicinal use.

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.

Oxymetazoline, when intended for nasal use. Paracetamol—

- (1) substances, preparations and mixtures, except—
 - (a) in tablets or capsules each containing 500 milligrams or less of paracetamol, when—
 - (i) packed in a primary pack containing not more than an aggregate of 12,5 grams of paracetamol in such tablets or capsules;
 - (ii) packed in blister strip packaging or in containers with child-resistant closures;
 - (iii) the primary pack is labeled 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;
 - (b) in individually wrapped powders or in sachets containing 1 000 milligrams or

less of paracetamol, when—

- (i) packed in a primary pack containing not more than an aggregate of 12,5 grams of paracetamol in such powders or sachets;
 - (ii) the primary pack is 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;**
- (c) in liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres or in paediatric dosage form (drops) containing 120 milligrams or less of paracetamol per 1,2 millilitres, when—
- (i) packed in a primary pack containing not more than 100 millilitres in the case of the liquid or syrup dosage form containing 120 milligrams or less of paracetamol per 5 millilitres;
 - (ii) packed in a primary pack containing not more than 20 millilitres in the case of the paediatric dosage form (drops) containing 120 milligrams or less of paracetamol per 1,2 millilitres;
 - (iii) the primary pack is 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;**
- (2) when contained in rectal suppositories. (S2) 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 per cent or less of phenylephrine. Phospholipids, when applied for therapeutic purposes.
- Procaine hydrochloride, when intended for oral administration.
- Proguanil when used in combination with chloroquine when intended specifically for malaria prophylaxis. (S4)

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, unless listed in another Schedule, and except when intended for soft contact lens cleaners and except when intended for injection (S0, 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.

Pyridoxilate.

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

Sodium fluoride; preparations and mixtures thereof containing 40 milligrams or more per daily dose. (S4) Terbinafine, when intended for application to the skin. (S4)

Tetrahydrozoline, when intended for nasal use. Thiabendazole, when intended for application to the skin. (S4)

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.

Ticlatone, when intended for application to the skin.

Tioconazole, when intended for application to the skin and when intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S4)

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

L-tryptophan when intended for medicinal use as supplementation for nutritional purposes. (S5) Xylometazoline, when intended for nasal use.

Zinc salts, preparations thereof for injection, when intended for veterinary use. (S3)

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 and inserted by Government Notice No. R509 in Government Gazette 24727 of 20 April, 2003 with effect from 2 May, 2003.] Wording of Sections

- (a) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for—
 - (i) Industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose; and
 - (ii) Analytical laboratory purposes.
- (b) All substances 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.
- (c) 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 to patients under their care, the

Schedule 2 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the Government Gazette.

Acetylcysteine.

Acetyldihydrocodeine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 millilitre dosage unit. (S6)

Aconite alkaloids; substances, preparations and mixtures containing 0,02 percent or more thereof.

Acrivastine.

Adrenaline (epinephrine), except ophthalmic preparations when intended for glaucoma and except preparations for injection. (S3, S4)

Alkaloids and glycosides; all poisonous alkaloids and glycosides, and the salts of such poisonous alkaloids and glycosides not specifically named in any other Schedule.

Alverin. Aminopentamide. Amorolfine. Amyl nitrite

Antihistamines, irrespective of indication or dosage form, except—

- (a) astemizole and terfenadine; (S4)
- (b) when listed separately in these Schedules; (S2, S5) and
- (c) except when registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Antimicrobial substances, namely griseofulvin, mupirocin, natamycin, when intended for application to the skin, nares and external ear, as well as nystatin preparations intended for application to the oral cavity, nares and external ear and excluding nystatin when intended for application to the skin and for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis, as excluded from the conditions of Schedule 4. (S1, S4)

Apomorphine; preparations and mixtures thereof, except when indicated for the treatment of erectile dysfunction. (S4)

Aptocaine.

Arecoline.

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

Atropine; substances, preparations and mixtures thereof, except ophthalmic preparations. (S3) Azelastin.

Bambuterol.

Beclomethasone dipropionate, when intended for nasal administration (other than by aerosol), in the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to—

- (a) a maximum dose of 100 micrograms per nostril;
- (b) a maximum daily dose of 200 micrograms per nostril;
- (c) a pack size limit of 200 doses. (S3, S4).

Belladonna alkaloids; substances and preparations thereof, except when intended for topical application (S1)

Benproperine.

Bevonium methylsulphate.

Biologicals, when intended for human medicinal use, including polyvalent snake antivenom, and except other injectable preparations thereof (S4).

Bismuth, when intended for oral use. Bromhexine.

Bromides; preparations and mixtures thereof containing less than 80 milligrams of bromine as bromide per recommended daily dose. (S5)

Butinoline.

Calabar bean alkaloids; substances, preparations and mixtures thereof. Camphorated Opium Tincture BP.

Camylofin.

Cantharidin.

Canthaxanthin; when intended for medicinal purposes. Carbocisteine.

Carbuterol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Carisoprodol.

Cathine ((+)-norpseudoephedrine); preparations and mixtures containing 50 milligrams or less of cathine per dosage unit. (S6)

Cetirizine.

Chlormezanone; mixtures thereof where the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (S5)

Chlorodyne (Chloroform and Morphine Tincture BP 1980); or any preparation or mixture thereof described as chlorodyne: preparations and mixtures containing 5,0 percent or less of chlorodyne in combination with other active medicinal ingredients. (S6)

Chlorprenaline.

Cholestyramine.

Chlorzoxazone.

Clonidine when intended for treatment of migraine. (S3)

Cimetidine, when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, subject to—

- (a) a maximum dose of 200 milligrams;
- (b) a maximum daily dose (per 24 hours) of 800 milligrams;
- (c) a maximum treatment period of 2 weeks. (S3) Clidinium bromide.

Codeine (methylnorphine); preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S6)

Colchicine, in cases of emergency. (S3) Contrast media.

Cydandelate.

Cydopentolate, except ophthalmic preparations thereof. (S3) Desloratidine.

Dextromethorphan.

Diclofenac, when intended for the emergency treatment of acute gout attacks, and when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for maximum period of 5 days. (S1, S3)

Dicyclomine.

Difenoxin (or diphenoxylate); 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 5,0 per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S6)

Dihydrocodeine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 millilitre dosage unit. (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) {D-norpseudoephedrine – see cathine.}

Domperidone.

Emedastine.

Emepronium.

Ephedra alkaloids (natural or synthetic), other than ephedrine preparations and mixtures intended for application to the skin, eyes, ears and nares containing 1,0 per cent or less of ephedra alkaloids, and other preparations and mixtures containing not more than 30 milligrams of ephedrine or ephedra alkaloids per dose. (S1, S5)

Ephedrine contained in products registered in terms of the Act, except preparations and mixtures intended for application to the skin, eyes, ears and nares containing 1,0 per cent or less of ephedrine, and other oral preparations and mixtures containing not more than 30 milligrams of ephedrine per dose. (S1, S5)

Ergot alkaloids (natural or synthetic), when intended for the treatment of migraine. (S4)

Ethylmorphine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine

(calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S6)

Etilefrine.

Exalamide.

Famotidine, when intended for the short-term symptomatic relief of heartburn caused by excess acid, subject to—

- (a) a maximum dose of 10 milligrams;
- (b) a maximum daily dose (per 24 hours) of 20 milligrams;
- (c) a maximum treatment period of 2 weeks. (S4)

Fedrilate.

Fenoprofen, when intended for the emergency treatment of acute gout attacks and when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Fenoterol, except when contained in respirator solutions (S3) and except when intended for injection or for the prevention or delay of labour. (S4)

Flavoxate.

Flunisolide, when intended for nasal administration, other than by aerosol in a strength not exceeding 0,025 per cent (w/v), indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, subject to—

- (a) a maximum dose of 50 micrograms per nostril and a maximum daily dose of 100 micrograms per nostril in the case of adults and children over the age of 16 years;
- (b) a maximum dose of 25 micrograms per nostril and a maximum daily dose of 75 micrograms per nostril in the case of children 12 to 16 years of age; and
- (c) a pack size containing not more than 240 doses. (S3, S4)

Flurbiprofen, when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3, S4)

Fluticasone propionate, when intended for nasal administration (other than by aerosol), in the short-term (less than 6 months) prophylaxis and treatment of symptoms of

allergic rhinitis (hay fever) in adults and children over 12, subject to—

- (a) a maximum daily dose of 100 micrograms per nostril;
- (b) a pack size limit of 120 doses. (S3). Formoterol.

Fusafungine. Gadopentetic acid.

Gelsemium alkaloids; substances, preparations and mixtures thereof. Glycopyrronium.

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

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 or anti-hormonal action, when intended for human vaginal use and oral contraceptives containing only progestogen and hormones when specifically intended for emergency postcoital contraception. (S3, S4, S5)

Hydrocortisone and hydrocortisone acetate, when used in a maximum concentration of 1,0 percent in preparations intended for application to the skin and hydrocortisone in a maximum concentration of 1,0 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 used in oral medicinal preparations—

- (a) where the recommended daily dose for adults does not exceed 1,2 grams and that for children up to and including the age of 12 years does not exceed 20 milligrams per kilogram of body weight;
- (b) the emergency treatment of acute gout attacks;
- (c) when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days; except when intended for treatment of inflammatory joint disease. (S3)

Indomethacin, when intended for the emergency treatment of acute gout attacks. (S1, S3) Iopromide.

Ipratropium bromide. Isoaminile.

Isoprenaline (isoproterenol), except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Isopropamide.

Ketoprofen,

- (a) when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours;
- (b) when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, at a maximum dose of 100mg of ketoprofen per day, for a maximum period of 5 days. (S1, S3)

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

- (a) a maximum daily dose of 15 mg
- (b) a maximum treatment period of 14 days. (S4)

Levocetirizine.

Lithium salts, when intended for application to the skin. (S5) Lobelia alkaloids; substances, preparations and mixtures thereof. Lodoxamide.

Loperamide

Loratadine.

Mebeverine.

Mefenamic acid, when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, 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 where the maximum daily dose is 500 milligrams 3 times a day and the maximum treatment period is 3 days. (S3) Mepenzolate bromide.

Mephenesin.

Mercuric ammonium chloride. Mercuric chloride.

Mercuric iodide.

Mercuric oxides; substances, preparations and mixtures thereof, except those containing less than 3 per cent of mercury.

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 per cent 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 No. 36 of 1947).

Mesna, except preparations intended for injection. (S4)

Metaproterenol (orciprenaline) except when contained in respirator solutions (S3) and except when intended for injection or for the prevention or delay of labour. (S4)

Methixene

Methocarbamol, when intended for medicinal purposes. Methoxyphenamine.

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. (S4)

Morphine; mixtures containing 0,2 percent or less of morphine, calculated as anhydrous morphine. (S6) Nabumetone, when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Naproxen,

(a) as the sodium salt, 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 600 milligrams naproxen (660 milligrams naproxen sodium) in 24 hours;

- (b) and when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S1, S3)

Nedocromil.

Nicergoline.

Nicotine when intended for human medicinal use, except—

- (a) nicotine gum containing 4mg or less nicotine per piece where the pack size does not exceed 30 pieces per pack when these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only (S0).
- (b) nicotine transdermal patches for continuous application to the skin in strengths up to and including 15mg/16 hours when these medicines are used for the relief of nicotine withdrawal symptoms as an aid to smoking cessation only. (S1)

Nizatidine, when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to—

- (a) a maximum dose of 150 milligrams;
- (b) a daily dose of 300 milligrams;
- (c) a maximum treatment period of two weeks. (S4)

Norcodeine; preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (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. Octatropine methylbromide.

Oleoresin of aspidium (Filix Mas). Olopatadine.

Opium; mixtures containing not more than 0,2 percent of morphine, calculated as anhydrous morphine. (S6)

Orphenadrine. Otilonium bromide.

Oxybuprocaine, when contained in eye drops intended for emergency treatment of arc eyes. (S4) Oxyphencyclimine.

Oxyphenonium.

Papaverine; substances, preparations and mixtures thereof.

Paracetamol, when contained in rectal suppositories. (S0, S1) Pentoxifylline

Phenazone (antipyrone). Phenazopyridine.

Phenylpropanolamine, 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.

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

Pholedrine.

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 such as pain, swelling and inflammation, for a maximum period of 5 days. (S3)

Pizotifen; preparations and mixtures, when intended for prophylaxis of migraine. (S5)

Podophyllum resin; preparations and mixtures containing 20 percent or less thereof. (S4) Poldine methylsulphate.

Polyvalent snake antivenom.

Potassium chloride, where the recommended dose is more than 20 millimol of potassium (1500 milligrams of potassium chloride) per 24 hours or when intended for intravenous infusion or for injection, but except when contained in oral rehydration preparations. (S0)

Prifinium bromide.

Procaterol, except when contained in respirator solutions. (S3) Procyclidine.

Proglumide.

Promethazine; preparations and mixtures when intended for use as an antihistamine, 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 emergency treatment of arc eyes. (S4) Quinine; preparations and mixtures containing more than 1,0 percent thereof.

Ranitidine, when administered orally for short-term symptomatic relief of heartburn and hyperacidity, subject to—

- (a) a maximum dose of 75 milligrams;
- (b) a daily dose of 300 milligrams;
- (c) a maximum treatment period of two weeks. (S3) Reproterol, except when contained in respirator solutions. (S3)

Rimiterol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Sabadilla alkaloids; substances, preparations and mixtures containing 1,0 percent or more thereof. Salbutamol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Salmefamol, except when contained in respirator solutions (S3) and except when intended for injection. (S4)

Salmeterol.

Siccanin, when intended for application to the skin.

Silver sulphadiazine, 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)

Sodium cromoglycate, except when intended for veterinary use. (S4)

Strychnine; preparations and mixtures containing 0,2 percent or less thereof, except the substance. (S4) Sulphonamides, when intended for application to the eyes, nares and vagina, (S4), except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

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

Tetracaine, when contained in eye drops intended for emergency treatment of arc eyes.

(S4) Theophylline and its derivatives, unless listed in another Schedule, except preparations for injection. (S4)

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.

Tiotropium.

Triamcinolone, when intended for application to oral lesions. (S4)

Trimebutine.

Trospium.

Tuberculin, when intended for human use. (S4)

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

Vaccines, when intended for human use.

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 and inserted by Government Notice No. R.509 in Government Gazette 24727 of 10 April, 2003 with effect from 2 May, 2003.]

Wording of Sections

- (a) All substances referred to in this Schedule are excluded when specifically packed, labelled and used for—
 - (i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose; and
 - (ii) analytical laboratory purposes.
- (b) All substances 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.
- (c) 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 to patients under their care, the Schedule 3 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the Gazette.

Acamprosate.

Acebutolol.

Aceclofenac.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use. Acipimox.

Adapalene.

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

Alendronic acid. Allopurinol. Alprenolol. Amiloride. Amodipine. Ancrod.

Anthiolimine, when intended for injection. Arsanilic acid.

Atenolol.

Atropine; ophthalmic preparations thereof. (S2) Azapropazone.

Balsalazide.

Bamidipine.

Beclamide.

Benazepril.

Bendazac.

Benfluorex.

Benoxaprofen.

Benzbromarone.

Benzydamine, except preparations and mixtures containing—

- (a) 3 per cent or less of benzydamine when intended for application to the skin;
- (b) 0,15 per cent 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 does not exceed 36 mg of benzydamine per day. (S1)

Bepriidil. Beta-benzalbutyramide.

Beta-galactosidase, when intended for therapeutic purposes. Betahistine.

Betaxolol.

Bethanidine.

Bevantolol.

Bezafibrate.

Bisoprolol.
Bopindolol.
Brimonidine.
Brinzolamide.
Buflomedil.
Buformin.
Bumetanide.
Cadralazine.
Calcipotriol. Calcium carbimide.
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. Carbuterol, when contained in respirator solutions. (S2, S4)
Carprofen.
Carteolol.
Carvedilol.
Celecoxib.
Celiprolol. Chenodeoxycholic acid. Chlorazaniol. 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.
Chromonar.
Cilazapril.

Cimetidine, except when intended for the short-term symptomatic relief of heartburn, dyspepsia and hyperacidity, where the maximum dose is 200 milligrams, the maximum daily dose (per 24 hours) is 800 milligrams and the maximum treatment period is 2 weeks. (S2)

Clofibrate.

Clonidine, except when intended for the treatment of migraine. (S2) Clopidogrel.

Colchicine, except in cases of emergency. (S2) Colestipol.

Copper salts, when intended for injection.

Corticosteroids (natural or synthetic), when contained in preparations intended for inhalation, except—

- (a) beclomethasone dipropionate, when intended for nasal administration, other than by aerosol, indicated for the treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, where the maximum dose per nostril is 100 micrograms, the maximum daily dose per nostril is 200 micrograms and the pack size is limited to 200 doses; and
- (b) flunisolide, when intended for nasal administration, other than by aerosol, in a strength not exceeding 0,025 per cent (w/v), indicated for treatment of the symptoms of seasonal allergic rhinitis (hay fever) in adults and children over 12, where in the case of adults and children over the age of 16 years, the maximum dose per nostril is 50 micrograms and the maximum daily dose per nostril is 100 micrograms and in the case of children 12 to 16 years, the maximum dose per nostril is 25 micrograms and the maximum daily dose per nostril is 75 micrograms and the pack size is limited to 240 doses; and
- (c) fluticasone propionate, when intended for nasal administration, other than by aerosol, in the short-term (less than 6 months) prophylaxis and treatment of symptoms of allergic rhinitis (hay fever) in adults and children over 12, where the maximum daily dose per nostril is 100 micrograms and the pack size is limited to 120 doses. (S2, S4)

Cyclandelate.

Cyclopentolate; ophthalmic preparations thereof. (S2) Debrisoquine.

Delapril.

Dichlorphenamide.

Diclofenac, except when intended for application to the skin, (S1) and except when intended for the emergency treatment of acute gout attacks and except when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Diflunisal.

Diflalone.

Digitalis; its glycosides and other active principles thereof, unless diluted below one unit (BP) in each 2,0 grams.

Dihydroergocristine.

Dilevalol.

Diltiazem.

Dimercaprol, when intended for injection. Dipivefrin.

Dipyridamole.

Dipyrocetyl.

Disulfiram.

Dithranol.

Domase alfa (rh DNase). Dorzolamide. Doxazosin.

Eltenac.

Enalapril.

Endralazine.

Eprosartan.

Escin (aescin), except preparations and mixtures thereof intended for application to the skin and containing 1,0 percent or less of escin. (S1)

Esculin, when intended for oral use. Esmolol.

Ethacrynic acid. Ethambutol.

Ethionamide, when intended for oral use. Ethosuximide.

Etisazol.

Etodolac. Etodolic acid. Felbamate. Felodipine. Fenbufen. Fenclofenac. Fendiline.

Fenofibrate.

Fenoprofen, except when intended for the emergency treatment of acute gout attacks and when intended for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Fenoterol, when contained in respirator solutions. (S2, S4) Fentiazac.

Floctafenine.

Flufenamic acid, except preparations and mixtures intended for application to the skin.

(S1) Flunixin.

Flurbiprofen, except—

- (a) when intended for ophthalmic use; (S4)
- (b) when intended for application to the skin, including application by transdermal patch, the indications are for use by adults and children 12 years and older and the treatment period is limited to 4 weeks; (S1)
- (c) when supplied by a pharmacist to a patient and intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2) Fosinopril.

Furosemide.

Gabapentin.

Gemfibrozil.

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.

Guanabenz.

Guanethidine.

Guanfacine.

Guanoxan.

Hexoprenaline, when contained in respirator solutions. (S2, S4) Homatropine; ophthalmic preparations thereof. (S2)

Hormones (natural or synthetic, including recombinant forms), when intended for oral contraception, except oral contraceptives containing only progestogen and except hormones when specifically intended for emergency postcoital contraception. (S2, S4, S5)

Hydralazine.

Hydroquinone; preparations and mixtures thereof containing more than 2,0 percent hydroquinone. (S2) Ibuprofen, when specifically intended for the treatment of inflammatory joint diseases. (S1, S2) Indapamide.

Indomethacin, except when intended for application to the skin, and except when intended for the emergency treatment of acute gout attacks. (S1, S2)

Indoprofen.

Indoramin. Insulin Irbesartan.

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.

Isoniazid and its derivatives, unless listed in another Schedule.

Isoprenaline (isoproterenol), when contained in respirator solutions. (S2, S4) Isosorbide.

Isoxicam.

Isradipine.

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. Ketanserin.

Ketoprofen, except—

- (a) when intended for application to the skin; (S1)
- (b) when intended for the short term management of headache, toothache, muscular ache, backache, minor pain associated with arthritis, pain associated with

menstrual cramps (dysmenorrhoea), minor aches and pains associated with the common cold and fever, at a maximum dose of 75 milligrams of ketoprofen in 24 hours; (S2)

- (c) when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post-traumatic conditions such as pain, swelling and inflammation, at a maximum dose of 75mg of ketoprofen per day, for a maximum period of 5 days. (S2)

Ketorolac trometamol, when intended for ophthalmic use. (S4) Labetalol.

Lacidipine.

Lamotrigine.

Lercanidipine.

Levetiracetam.

Levobunolol.

Levosemindan.

Lidoflazine.

Lisinopril.

Lonazolac.

Lomoxicam.

Losartan. Meclofenamic acid.

Mefenamic acid, except when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days; and except preparations containing mefenamic acid as the only therapeutic active substance, when intended for the treatment of primary dysmenorrhoea where the maximum daily dose is 500 milligrams mefenamic acid 3 times a day and the maximum treatment period is 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.

Moexipril.

Montelukast.

Moxonidine.

Nabumetone, except when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Nadolol.

Naftidrofuryl. Naproxen, except—

- (a) when intended for application to the skin; (S1)
- (b) the sodium salt, 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 600 milligrams naproxen (660 milligrams naproxen sodium) in 24 hours; (S2)
- (c) when supplied by a pharmacist to a patient and intended for the emergency treatment of acute gout attacks or for the treatment of post traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Nateglinide.

Nebivolol.

Nicardipine.

Nifedipine. Niflumic acid. Nimesulide. Nimodipine. Nisoldipine. Nitrendipine.

Nitroglycerine, when intended for medicinal use. Olsalazine.

Orlistat.

Oxaprozin.

Oxcarbazepine.

Oxtracetam.

Oxovinca.

Oxyprenolol.

Oxybutynin.

Parecoxib.

Para-aminosalicylic acid and its esters. 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 and when intended for the treatment of post-traumatic conditions such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Pirprofen.

Potassium canrenoate. 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. Pyrimethamine.

Pyrithioxin.

Quinapril.

Racecadotril.

Raloxifene.

Ramipril.

Ranitidine, except where administered orally for short-term symptomatic relief of heartburn and hyperacidity, where the maximum dose is 75 milligrams, the maximum daily dose is 300 milligrams and the maximum treatment period is two weeks. (S2)

Raubasine. Rauwolfia alkaloids. Repaglinide.

Reproterol, when contained in respirator solutions. (S2) Reserpine (natural or synthetic).

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) Solcoseryl; ophthalmic preparations thereof. (S0, S4) Sotalol.

Spirapril.

Spironolactone.

Strophanthus; its glycosides and their hydrolysis products, and their derivatives, unless listed in another Schedule.

Sulindac.

Suloctidil.

Sulphinpyrazone.

Sulthiame.

Suprofen.

Sylimarin.

Tasosartan.

Tazarotene.

Telmisartan.

Tenidap.

Tenoxicam.

Terazosin.

Terbutaline, when contained in respirator solutions. (S2) Terizidone.

Terodiline.

Thiacetazone.

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 such as pain, swelling and inflammation, for a maximum period of 5 days. (S2)

Ticlopidine.

Timolol.

Tolamolol.

Tolazamide.

Tolbutamide. Tolfenamic acid.

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

Topiramate.

Torasemide.

Trandolapril.

Tretinoin.

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.

Vincamine.

Vinpocetine.

Vitamin A; preparations thereof for injection and oral preparations and mixtures thereof containing more than 10 000 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.

Vitamin D; preparations thereof for injection and oral preparations and mixtures thereof containing more than 500 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.

Xamoterol.

Xipamide.

Zafirlukast.

Zinc salts for oral ingestion where the daily dose is more than 50 milligrams of elemental zinc (S1), except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

Zomepirac.

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 and inserted by Government Notice No. R.509 in Government Gazette 24727 of 10 April, 2003 with effect from 2 May, 2003.]

Wording of Sections

- (a) All substances referred to in this Schedule are excluded where specifically packed, labelled and used for—
 - (i) industrial purposes including the manufacture or compounding of consumer items or products, which have no pharmacological action or medicinal purpose; and
 - (ii) analytical laboratory purposes.
- (b) All substances 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.
- (c) 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 to patients under their care, the Schedule 4 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the Gazette.

Abacavir.

Acarbose.

Acetarsona diethylamine salt, where intended for injection.

Acyclovir, except where intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S1)

Adenosine.

Adrenaline, where intended for injection. (S2, S3)

Albendazole, except where intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Alcuronium.

Aldesleukin.

Alfuzosin.

Alisapride.

Almitrine.

Alosetron.

Alphacalcidol, except when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Alphachymotrypsin, when intended for ophthalmic use. Alprostadil.

Amantadine.

Amifostine.

Aminoglutethimide. Aminopyrine (amidopyrine). Amiodarone. Amiphenazole.
Amprenavir.

Amrinone.

Amsacrine.

Anagrelide.

Anastrozole.

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

Antihemophilic factor.

Antimalarials, excluding chloroquine in combination with proguanil when intended specifically for malaria prophylaxis. (S1)

Antimicrobial substances synthesised in nature or the laboratory, being substances used in the specific treatment of infections, except the following when intended for topical application to the epidermis, nares and external ear:

Bacitracin; (S1) gramicidin; (S1) griseofulvin; (S2) mupirocin; (S2) natamycin; (S2) nystatin; (S1, S2) polymyxin B; (S1) tyrothricin; (S1)

and except where intended for use as germicides and antiseptics, and except nystatin oral drops (S1) and except nystatin where intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1), and except phenoxymethylpenicillin where intended for the prophylaxis of rheumatic fever (S3) and except where intended for use as indicated below and registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947:

Ampicillin, cloxacillin, dihydrostreptomycin, penethamate hydriodide and procaine benzylpenicillin; intra-mammary preparations thereof, containing tracer dye(s) and intended for the treatment of mastitis in cattle;

amprolium, decoquinate, dinitolmide, ethopabate, lasalocid, maduramicin, monensin and narasin where intended as anti-coccidial preparations;

avilomycin, avoparcin, carbadox, flavophospholipol, monensin, nitrovin, olaquinox, virginiamycin and zinc bacitracin where intended to promote growth as a feed additive;

camidazole, where intended for trichomonas in pigeons;
chlortetracycline, rolitetracycline and tetracycline; injections thereof, intended for the treatment of anaplasmosis, footrot, heartwater, navel ill and pneumonia in sheep and cattle; chlortetracycline; capsules thereof, for use in pigeons; chlortetracycline and tetracycline derivatives where intended for topical use in the management of wounds in animals; dimetridazole, where intended for trichomonas in pigeons, as an anti-bacterial preparation for pigs and to promote growth; doxycycline and oxytetracycline; preparations thereof, except preparations intended to be used as an additive to feed; furaltadone, where intended as a single oral dosage for gastro-intestinal infections; hygromycin, where intended as an anthelmintic for pigs; salinomycin, when intended as an anti-coccidial preparation and to promote growth; tylosin, when intended for addition to drinking water and feedstuff for administration to poultry and pigs. Antisera, 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.

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

Aprotinin.

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. Arsenamide, when intended for injection.

Artemether and its derivatives. Artemotil.

L-asparaginase. Astemizole. Atipamezole. Atorvastatin. Atosiban. Atovaquone.

Atracurium besilate. Auranofin. Azathioprine. Baclofen. Basiliximab.

Bee venom, except preparations intended for application to the skin. Bemegride.

Bethanechol.

Bimatoprost.

Biologicals, injectable preparations thereof, when intended for human use, except tuberculin when intended for human use and except vaccines when intended for human use, and except polyvalent snake antivenom. (S2)

Biperiden.

Bleomycin. Bretylium tosylate. Bromocriptine. Bufenoide. Bumadizone. Buserelin.
Busulphan. Cabergoline. Calcitonin. Calcitriol.

Calcium polystyrene sulphonate, when intended for therapeutic purposes.
Cambendazole.

Capecitabine.

Carbachol, except ophthalmic preparations thereof, when intended for glaucoma. (S3)

Carbidopa.

Carboplatin.

Carbuterol, when intended for injection. (S2, S3) Carmustine.

Cerivastatin.

Ceruletide.

Chlorambucil.

Chlordantoin, when intended for human vaginal use. Chloroquine, when intended for
antirheumatic use. (S1) Chymopapain, when intended for injection.

Cisapride.

Cisatracurium.

Cisplatin.

Cladribine.

Clanobutin.

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.

Clenbuterol.

Clofazimine.

Clomiphene.

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.

Clotrimazole, except when intended for application to the skin and when intended for

human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)
Colfosceril.

Corticosteroids (natural or synthetic), unless listed in another Schedule, except—

- (a) 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)
- (b) triamcinolone when intended for application to oral lesions; (S2) and
- (c) when contained in preparations intended for inhalation. (S2, S3)

Cotetroxazine.

Co-trimoxazole. Cyclofenil.

Cyclophosphamide and its derivatives, unless listed in another Schedule. Cyclosporin.

Cyprenorphine. Cyproterone acetate. Cytarabine. Dacarbazine. Dacliximab.

Dactinomycin (actinomycin D). Dantrolene.

Dapsone and its derivatives, unless listed in another Schedule. Daunomycin (daunorubicin).

Deferoxamine.

Demecarium.

Desirudin.

Diazoxide.

Dichlorophen, except preparations and mixtures when intended for application to the skin 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.

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.

Diclodronic acid. Didanosine. Diethylcarbamazine. Dihydralazine. Dihydrotachysterol.

Di-isopropyl fluorophosphate. Dilazep.

Diloxanide furoate. Dimethyl sulphoxide.

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.

Dinitrophenol.

Dinoprostone.

Diphemethoxidine.

Diphenidol.

Diprenorphine. Disodium pamidronate.

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.

Disopyramide.

Distigmine.

Ditazole.

Dobutamine.

Docetaxol.

Dolasetron.

Dopa.

Dopamine.

Doxapram.

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

Drotecognin.

Econazole, except when intended for application to the skin 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) Edoxudine.

Edrophonium.

Efavirenz.

Eletriptan.

Emetine, except substances, preparations and mixtures containing less than 0,2 percent of alkaloids, calculated as emetine.

Encainide.

Enoxacin.

Enrofloxacin.

Entacapone.

Epirubicin. (4-epidoxorubicin)

Ergot alkaloids (natural or synthetic); except preparations and mixtures thereof when intended for the treatment of migraine. (S2)

Esomeprazole.

Estramustine.

Etidronate.

Etiproston.

Ethoglucid.

Etofamide.

Etoposide.

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)

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.

Fenclorphos.

Fenoterol, when intended for the prevention or delay of labour and preparations thereof for injection. (S2, S3)

Fenticonazole.

Fertirelin.

Filgrastim.

Finasteride.

Flecainide.

Flosequinan.

Fluconazole.

Flucytosine.

Fludarabine.

Flugestone.

Flunisolide.

Fluorides; except oral medicinal preparations and mixtures thereof containing 0,25 milligrams or more of fluorine as fluoride per recommended daily dose, unless listed in another Schedule. (S1) 5-fluorouracil.

Flurbiprofen, when intended for ophthalmic use. (S1, S2, S3) Flutamide.

Fluvastatin.

Fondaparinux.

Fotemustine.

Ftorafur.

Furazolidone.

Galatamine.

Gallamine.

Ganciclovir.

Ganirelix.

Gemcitabine.

Gemtuzumab

Gestrinone.

Glatiramer.

Glycosaminoglycan polysulphate (previously mucopolysaccharide poly-sulphuric acid ester), except when intended for application to the skin. (S1)

Goserelin.

Granisetron.

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. Halogenated hydroxyquinolines, except when intended for application to the skin (S2), and except di-iodohydroxyquinoline 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 No. 36 of 1947).

Hemin.

Heptaminol.

Hexoprenaline, when intended for the prevention or delay of labour and preparations thereof for injection. (S2, S3)

Hormones (natural or synthetic, including recombinant forms), with either hormonal or anti-hormonal action, unless listed in another Schedule, except—

- (a) when specifically intended for emergency postcoital contraception (S2);
- (b) when intended for oral contraception (S2, S3);
- (c) insulin (S3);
- (d) adrenaline (epinephrine) (S2, S3, S4);
- (e) corticotrophin (adrenocorticotrophichormone; ACTH) (S5);
- (f) Human growth hormone (human somatotropin) -all forms (S5);
- (g) 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;
- (h) BST (Bovine somatotropin), 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. Hyaluronidase.

Hyaluronic acid and its derivatives. Hycanthon.

Hydroxyurea.

Hylan. Ibandronic Acid. Ibutilide. Idarubicin.

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

Imatinib.

Imidocarb, except where 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.

Imiglucerase.

Imiquimod.

Indinavir.

Infliximab.

Inosiplex (inosine pranobex). Interferon alpha.

Interferon beta. Interferon gamma. Intra-uterine devices. Intrifiban.

Irinotecan.

Isepamicin.

Isoconazole, except where intended for application to the skin and where intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis. (S1)

Isopirin.

Isoprenaline (isoproterenol), where intended for injection. (S2, S3) Isoxsuprine.

Itraconazole.

Ketoconazole, except preparations and mixtures containing not more than 1,0 percent of ketaconazole, when intended for the prevention and treatment of dandruff and except when intended for application to the skin. (S0, S1)

Ketorolac trometamol, except when intended for ophthalmic use. (S3) Lamivudine.

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

- (a) a maximum daily dose of 15mg
- (b) a maximum treatment period of 14 days. (S2).

Latanoprost.

Leflunomide.

Letrozole.

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. Levobupivacaine.

Liarozole.

Local anaesthetics, when intended for ophthalmic and parenteral use, except oxybuprocaine, proxymetacaine and tetracaine, when contained in eye drops intended for emergency treatment of arc eyes, and except lignocaine when contained in antimicrobial preparations for injection as well as in ophthalmic preparations registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Lomustine.

Lopinavir.

Lovastatin.

Lumefantrine.

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

(S1) Mecamylamine.

Mefloquine.

Melarsoprol, when intended for injection.

Melphalan and its derivatives, unless listed in another Schedule. Mephentermine.

Mepirizole. 2-mercaptopropionyl glycine.

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. Mesna, where intended for injection. (S2)

Metaproterenol (orciprenaline), where intended for the prevention or delay of labour, and preparations thereof for injection. (S2, S3)

Metergoline.

Methacholine.

Methampyrone.

Methotrexate.

Methoxsalen.

Methysergide.

Metoclopramide.

Metomidate.

Metronidazole.

Mexiletine.

Miconazole, except where intended for application to the skin and except where intended for human vaginal use, specifically for the treatment of recurrent vaginal candidiasis (S1), and except where intended for human use in preparations containing 2 per cent or less of miconazole, where intended for the topical treatment of fungal infections of the mouth (oral candidiasis) (S2).

Mifepristone.

Miglitol.

Milrinone.

Miltefosine.

Minoxidil, except when intended for application to the scalp. (S2) Misoprostol.

Mitomycin C. Mitoxantrone. Mivacurium.

Mizolastine.

Mofebutazone.

Malgramostim.

Mometasone.

Moracizine.

Morazone.

Morphazinamide.

Morphethylbutyne.

Mucoglucuronan.

Muromonab. Mycophenolic acid. Nalidixic acid. Nalorphine. Naloxone. Naltrexone.

Naratriptan. Nefopam. Nelfinavir. Neostigmine. Netobimin. Nevirapine.

Nicarbazin, 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. Nifuratel.

Nikethamide.

Nilutamide.

Nimorazole.

Nimustine.

Niridazole.

Nitrofurantoin, except preparations thereof intended for application to the skin. (S1)

Nitrofurazone, except preparations thereof intended for application to the skin. (S1)

Nitrous oxide gas, alone or in combination with other gasses.

Nitroxoline.

Nitroxynil, except where intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Nizatidine, except where 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)

Obidoxime.

Octreotide.

Omeprazole.

Ondansetron.

Oprelvekin.

Omidazole, except where intended for application to the skin. (S1) Oseltamivir.

Oxamniquine.

Oxfendazole, except where intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Oxolinic acid.

Oxybuprocaine, except where contained in eye drops intended for emergency treatment of arc eyes. (S2)

Oxyclosanide, except where intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Paclitaxel.

Palivizumab.

Paltitrexid. Pamidronic acid. Pancuronium. Pantoprazole. Paricalcitol.

Penciclovir, except where intended for application to the lips in the early treatment of recurrent Herpes simplex virus infections. (S1)

Penicillamine. Pentamidine isethionate. Pentostatin.

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.

Phenopyrazone.

Phenoxybenzamine.

Phenylbutazone and its derivatives, unless listed in another Schedule.

Physostigmine, except ophthalmic preparations thereof when intended for glaucoma. (S3) Picrotoxin.

Pilocarpine, except ophthalmic preparations thereof intended for glaucoma. (S3)

Pimecrolimus.

Pipemidic acid. Pirenzepine. Piribedil. Piromidic acid.

Podophyllum resin; preparations and mixtures containing more than 20 per cent of podophyllum resin. (S1)

Polyglycerylene-dextran. Poractant alpha.

Potassium dichromate, except preparations and mixtures containing not more than 15 micrograms of potassium dichromate per dosage unit.

Pralidoxime.

Pramipexole.

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.

Procainamide.

Procarbazine.

Propafenone.

Propentofylline, except when intended for veterinary use. (S1)

Propylhexedrine, except when used as a vasoconstrictor and decongestant in nose preparations and inhalants. (S1)

Proteolytic (fibrinolytic) enzymes, where intended for injection. (S1)

Proxymetacaine, except when contained in eye drops intended for emergency treatment of arc eyes. (S2)

Pyridinolcarbamate.

Pyridostigmine.

Quinoronium sulphate, 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. Rabeprazole.

Ractopamine, where used as a veterinary production improver. Radio-active compounds, where used for diagnostic purposes.

Rafoxanide, except where intended and registered as an anthelmintic in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Rapacuronium.

Rasburicase.

Recombinant human tissue-type plasminogen activator (rt-PA).

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.

Riluzole.

Rimiterol, where intended for injection. (S2, S3) Ritodrine.

Ritonavir.

Rituximab.

Rizatriptan. Rocuronium bromide. Ropinirole. Rosoxacin. Rosuvastatin. Roxatidine.

Salbutamol, when intended for injection. (S2, S3) Salmefamol, when intended for injection. (S2, S3) Saquinavir.

Selegiline.

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

Sermorelin.

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

Sildenafil.

Simvastatin.

Sirolimus.

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.

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).

Stavudine.

Streptokinase.

Strychnine, subject thereto that for the control of problem predatory mammals—

- (a) it shall only be supplied on a written prescription issued by a State Veterinarian, for use in the particular State Veterinarians' area of jurisdiction, in a quantity not exceeding 5 grams; and
- (b) the State Veterinarian shall obtain 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 which shall be attached to the written prescription; and except preparations and mixtures containing 0,2 per cent or less of strychnine

when included in Schedule 2.

Styramate. Sulphonamides, except—

- (a) substances, preparations and mixtures intended for application to the eyes, nares and vagina; (S2)
- (b) silver sulphadiazine, 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)
- (c) when registered in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Sumatriptan.

Suramin.

Suxamethonium.

Suxethonium.

Tacrine.

Tacrolimus.

Tadalafil.

Tamoxifen.

Tamsulosin.

Tasonermin.

Tegafur.

Tegaserod.

Temozolomide.

Tenecteplase.

Teniposide.

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

Terfenadine.

Teriparatide.

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.

Theophylline and its derivatives, unless listed in another Schedule; preparations intended for injection. (S2)

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

Thioguanine.

Thymopentin.

Tibolone. Tiludronic Acid.

Tin fluoride, when intended for injection. Tinidazole.

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)

Tirilazad.

Tocainide.

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. Topotecan.

Toremifene. 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.

Triethylene thiophosphoramidate. Trifluorothymidine. Trimetaphane.

Trimethoprim, except when specifically intended and registered 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.

Trimetrexate.

Trioxsalen.

Triptorelin.

Tromantadine.

Trometamol.

Tropisetron.

Tuberculin, when intended for veterinary use. (S2) Tubocurarine.

Unoprostone.

Urapidil.

Urethane.

Urokinase.

Vaccines for veterinary use except vaccines registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947.

Valaciclovir.

Vanillic acid diethylamide. Vardenafil.

Vasoactive intestinal polypeptide. Vecuronium bromide. Verteporfin.

Vidarabine.

Vinblastin.

Vincristin.

Vindesine.

Vinorelbine.

Voriconazole.

Vorozole.

Zalcitabine.

Zanamivir. Zidovudine (AZT). Zolmitriptan. Vecuronium bromide. Verteporfin.

Vidarabine. Vinblastin.

Vincristin.

Vindesine.

Vinorelbine.

Voriconazole.

Vorozole.

Zalcitabine.

Zanamivir. Zidovudine (AZT). Zolmitriptan. Zoledronic acid.

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, by 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 and inserted by Government Notice No. R.509 in Government Gazette 24727 of 10 April, 2003 with effect from 2 May, 2003.]

Wording of Sections

- (a) All substances 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.
- (b) In terms of Section 22A (5) (f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 5 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the Government Gazette.

- (c) Specified Schedule 5 substances listed in this Schedule are subject to additional control in terms of section 22A of the Act as required under the provisions of the 1971 Convention on Psychotropic Substances and are denoted by “**”.

Acitretin.

Amisulpride.

Amitriptyline and its derivatives, unless listed in another Schedule. Amoxapine.

Anaesthetic preparations containing pregnanedione derivatives. Androstanolone.

Androstenediol.

Aponal.

Apronalide.

Azacyclonol.

Barbituric acid** and its derivatives**, unless listed in another Schedule, excluding—

- (a) amobarbital, cyclobarbital, pentobarbital and secobarbital (S6), and
- (b) preparations and mixtures containing not more than 90 milligrams of phenobarbital** per minimum recommended or prescribed dose where 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, except preparations and mixtures of the above where used as vasoconstrictors and decongestants in antihistamine nose and eye preparations and except where contained in appliances for inhalation in which the substance is absorbed in solid material and excluding cathine ((+)-norpseudoephedrine), ephedrine,

etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof except substances listed in Schedule 7. (S1, 82, S7) 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, Cosmetic and Disinfectants Act, 1972 and for analytical laboratory purposes. (S2)

Bromisovalum.

Brotizolam**.

Bupropion.

Buspirone.

Butriptyline.

Butyrophenones.

Carbromal.

Chloral derivatives, unless listed in another Schedule.

Chlormezanone, except mixtures thereof where the maximum recommended or prescribed dose does not exceed 100 milligrams of chlormezanone. (S2)

Chlorprothixene.

Citalopram.

Clomacran.

Clomethiazole (previously listed as "heminevrin"). Clomipramine.

Clopenthixol.

Clostebol.

Clothiapine.

Clozapine.

Corticotrophin (adrenocorticotrophic hormone; ACTH). Cyclobenzaprine.

Danazol.

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, Cosmetic and Disinfectants Act, 1972, and for analytical laboratory purposes. (S1)

Dehydrochloromethyltestosterone Desflurane.

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)

Diprenorphine.

Donepezil.

Dothiepin.

Doxepin, except when intended for application to the skin. (S4) Droperidol.

Drostanolone.

Ecothiopate.

Emylcamate.

Enflurane.

Ephedrine (natural or synthetic), except when contained in products registered in terms of the Act. (S1, S2)

Epitiostanol.

Escitalopram.

Ethchlorvynol**.

Ether (diethyl ether); except substances, preparations and mixtures containing more than 20 per cent of ether. (S1)

Ethinamate** and its derivatives**, unless listed in another Schedule. Ethylestrenol.
Etodroxizine, except preparations and mixtures thereof where used solely as an antihistamine. (S2) Etomidate.
Etretinate. Fencamfamine**. Fenfluramine. Flumazenil. Fluoxetine. Fluoxymesterone.
Flupenthixol. 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, Cosmetic and Disinfectants Act, 1972, and for analytical laboratory purposes.
Human growth hormone (human somatotropin) – all forms. Hydroxyzine.
Imipramine and its derivatives, unless listed in another Schedule. Iproniazid.
Isoflurane.
Isotretinoin.
Ketamine.
Lithium salts, when intended for medicinal use, except when intended for application to the skin. (S2) Lofepamine.
Loxapine.
Maprotiline.
Mazindol**.
Mebolazine
Mechlorethamine and its derivatives, unless listed in another Schedule. Meclofenoxate.
Medetomidine.
Melitracene.
Mephenoalone.
Meprobamate**. Mesterolone Metandienone Metenolone. Methandranone.
Methandriol. Methoxyflurane. Methyltestosterone. Metrifonate. Mianserin. Mibolerone.

Milnacipran. Mirtazapine. Moclobemide. Molindone. Nalbuphine. Nandrolone. Nefazodone. Nomifensine. Norclostebol. Norethandronlone. Olanzapine. Oxabolone. Oxandrolone. Oxymesterone. Oxymetholone. Oxypertine. Paraldehyde. Pargyline. Paroxetine.

Pemoline** and its complexes**. 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.

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). Prolintane.

Propofol.

Quetiapine.

Quinbolone.

Quinupramine.

Reboxetine.

Risperidone.

Rivastigmine.

Romifidine.

Sertraline.

Sevoflurane.

Sibutramine.

Stanozolol.

Stenbolone.

Sulphonmethane.

Sulpyride.

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.

Thioguanosine.

Thiothixene.

Tiapride.

Tiletamine.

Tizanidine.

Tramadol.

Tranlycypromine.

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.

Trihexyphenidyl.

L-tryptophan, when intended for medicinal use, except when intended for medicinal use as supplementation for nutritional purposes. (S1)

Venlafaxine.

Viloxazine.

Xylazine.

Zaleplon.

Zimelidine.

Ziprasidone.

Zolazepam.

Zolpidem**.

Zopiclone.
Zotepine.
Zuclopenthixol.

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 and inserted by Government Notice No. R.509 in Government Gazette 24727 of 10 April, 2003 with effect from 2 May, 2003.] Wording of Sections

- (a) All 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 esters, ethers and isomers 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.

- (b) In terms of Section 22A (5) (f) of the Act, a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe and supply to patients under their care, the Schedule 6 substances and medicines provided for in the Annexures, only within their scope of practice and subject to the conditions determined by the Medicines Control Council. The conditions and the Annexures will be published in the Gazette.

Acetorphine.

Acetyldihydrocodeine, except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine (calculated as base) per 5 milliliter dosage unit. (S2)

Acetylmethadol.

Alfentanil.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Amobarbital.

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Buprenorphine.

Butalbital.

Butorphanol

Cathine ((+)-norpseudoephedrine), except preparations and mixtures containing 50 milligrams or less of cathine per dosage unit. (S2)

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne; except preparations and mixtures containing 5,0 percent or less of chlorodyne in combination with other active medicinal substances. (S2)

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 (methymorphine); except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of codeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of codeine (calculated as base) per 5 millilitre dosage unit. (S2)

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)

Diampromide.

Diethylpropion (amfepramone). Diethylthiambutene.

Difenoxin (or diphenoxylate), 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 5,0 per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S2)

Dihydrocodeine, except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of dihydrocodeine (calculated as base) per dosage unit and except liquid oral preparations and mixtures containing 20 milligrams or less of dihydrocodeine (calculated as base) per 5 milliliter dosage unit. (S2)

Dihydroetorphine.

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene. Dioxaphethyl butyrate.

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. (S1)

Dipipanone.

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. Ethylmethylthiambutene.

Ethylmorphine; except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of ethylmorphine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of ethylmorphine (calculated as base) per 5 millilitre dosage unit. (S2)

Etonitazene.

Etorphine and analogues. Etoxadine. Fenproporex
Fentanyl, when intended for therapeutic purposes. (S7) Flunirazepam.
Furethidine.
Glutethimide.
Hydrocodone (dihydrocodeinone). Hydromorphenol (14-hydroxydihydromorphine).
Hydromorphone (dihydromorphinone). Hydroxypethidine.
Isomethadone.
Ketobemidone.
Levomoramide.
Levophenacymorphan.
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). Nicocodine.
Nicodicodine.
Nicomorphine.
Noracymethadol.

Norcodeine; except preparations and mixtures when compounded with one or more therapeutically active substances and containing 20 milligrams or less of norcodeine (calculated as base) per dosage unit and liquid oral preparations and mixtures containing 20 milligrams or less of norcodeine (calculated as base) per 5 millilitre dosage unit. (S2)
Norevorphanol.

Normethadone.

Normorphine (demethylmorphine or N-demethylated morphine). 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 per cent 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. (S8) Phenadoxone.

Phenampromide.

Phenazocine.

Phendimetrazine.

Phenomorphane.

Phenoperidine.

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

(S2)

Piminodine.

Piritramide.

Proheptazine.

Properidine.

Propiram.

Racemoramide.

Racemorphan.

Remifentanil.

Secobarbital.

Sufentanil.

Thebacon.

Thebaine.

Tilidine.

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

Zipeprol.

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 and inserted by Government Notice No. R.509 in Government Gazette 24727 of 10 April, 2003 with effect from 2 May, 2003.] Wording of Sections

All substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

- (a) The isomers of such substances, where the existence of such isomers is possible within the chemical designation;
- (b) The esters and ethers of such substances and of the isomers referred to in (a), as well as the isomers of such esters and ethers, where the existence of such esters, ethers and isomers is possible;
- (c) The salts of such substances and of the isomers referred to in (a), as well as the salts of the esters, ethers and isomers referred to in (b), where the existence of such salts is possible;
- (d) The isomers of any of the salts referred to in (c), where the existence of such isomers is possible;
- (e) All preparations and mixtures of any of the above. (Trivial or unofficial names are marked *.)

Aminorex. Amphetamine. (S8)

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:

- (a) when separately specified in the Schedules; (S6) or
- (b) processed hemp fibre containing 0.1 per cent 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
- (c) processed product made from cannabis seeds containing not more than 10mg/kg (0.001 per cent) 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.]

Cathinone ((-)-(S)-2-aminopropiophenone). Dexamphetamine. (S8)

Diethyltryptamine [3-(2-(diethylamino) ethyl) indole] *(DET). (±)-2,5-dimethoxy-*a*-methylphenethylamine *(DMA). 2,5-dimethoxy-*a*-4-dimethylphenethylamine *(DOM, STP) and its derivatives. 3-(1,2-dimethylheptyl)-7, 8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran-1-ol *(DMHP).

(±)-N,*a*-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: acetyl-*alpha*-methylfentanyl;

alpha-methylfentanyl; *alpha*-methylfentanyl-acetanilide; *alpha*-methylthiofentanyl; benzyl-fentanyl; beta-hydroxyfentanyl; beta-hydroxy-3-methylfentanyl; 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; 3-methylthiofentanyl; para-fluorofentanyl; and thiofentanyl. (S6)

Gamma-hydroxybutyrate (GHB). Harmaline (3,4-dihydroharmine).

Harmine [7-methoxy-1-methyl-9H-pyrindo (3,4-b)-indole]. Heroin (diacetylmorphine).

3-hexyl-7,8,9,10-tetrahydro-6,6,0-trimethyl-6H-dibenzo[b,d]-pyran-1-ol * (parahexyl).

Lefetamine *(SPA).

Lysergide (Lysergic acid diethylamide)*(LSD). Mescaline (3,4,5-trimethoxyphenethylamine). Mesocarb.

Methamphetamine and methamphetamine racemate. Methaqualone and any preparation containing methaqualone. Methcathinone. 2-methoxy-*a*-methyl-4,5-(methylenedioxy)phenethylamine *(MMDA).

(p)-methoxy- α -methylphenethylamine *(PMA). 4 methylaminorex.

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

Nabilone. (S8) Pethidine-analogues, including:

1-methyl-4-phenyl-4propionoxy-piperidine *(MPPP); 1-methyl-4 phenyl-1,2,5,6-tetrahydropiperidine *(MPTP); and 1-phenylethyl-4-phenyl-4-acetyloxy-piperidine *(PEPAP).

Phencyclidine *(PCP) and its congeners, including: eticyclidine (N-ethyl-1-phenylcyclohexylamine *(PCE));

rolycyclidine (1-(1-phenylcyclohexyl) pyrrolidine *(PHP or PCPY)); and 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). Tenamfetamine (methylenedioxyamphetamine *(MDA)) and its analogues:

(\pm)-N-ethyl- α -methyl-3,4 (methylenedioxy) phenethylamine *(N-ethyl MDA),

(\pm)-N-[α -methyl-3,4-(methylenedioxy) phenethyl] hydroxylamine *(N-hydroxy MDA);

Tetrahydrocannabinol and their alkyl homologues, except:

- (a) when separately specified in the Schedules;
- (b) dronabinol ((-)-transdelta-9-tetrahydrocannabinol), when intended for therapeutic purposes. (S6);
- (c) in hemp seed oil, containing 10mg/kg or less of tetrahydrocannabinols, when labelled “Not to be taken” (Not for internal human use – alternatively); or
- (d) in products for purposes other than internal human use containing 10mg/kg or less of tetrahydrocannabinols.

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

(\pm)-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 and inserted by Government Notice No. R.509 in Government Gazette 24727 of 10 April, 2003 with effect from 2 May, 2003.]

Wording of Sections

All substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

- (a) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;
- (b) the esters and ethers of such substances and of the isomers referred to in (a), as well as the isomers of such esters and ethers, where the existence of such esters, ethers and isomers is possible;
- (c) the salts of such substances and of the isomers referred to in (a), as well as the salts of the esters, ethers and isomers referred to in (b), where the existence of such salts is possible;
- (d) the isomers of any of the salts referred to in (c), where the existence of such isomers is possible;
- (e) all preparations and mixtures of any of the above.

Amphetamine and its salts; preparations thereof. (S7)

Dexamphetamine and its salts; preparations thereof. (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.]Wording of Sections