UNITED NATIONS

E/NL.1992/59
3 March 1993

ENGLISH ONLY*

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

SOUTH AFRICA

Communicated by the Government of South Africa

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

MEDICINES AND RELATED SUBSTANCES CONTROL ACT

NO. 101 OF 1965

AS AMENDED UNTIL 1991

V.93-82487

*Note by the Secretariat: This document is a direct reproduction of the text communicated to the Secretariat.

MEDICINES AND RELATED SUBSTANCES CONTROL ACT NO. 101 OF 1965

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

(Afrikaans text signed by the State President)

as amended by

Drugs Control Amendment Act, No. 29 of 1968
Drugs Control Amendment Act, No. 88 of 1970
Drugs Laws Amendment Act, No. 95 of 1971
Drugs Control Amendment Act, No. 65 of 1974
Medicines and Related Substances Control Amendment Act, No. 19 of 1976
Health Laws Amendment Act, No. 36 of 1977
Medicines and Related Substances Control Amendment Act, No. 17 of 1979
Medicines and Related Substances Control Amendment Act, No. 20 of 1981
Transfer of Powers and Duties of the State President Act, No. 97 of 1986
[with effect from 3 October, 1986—see title CONSTITUTIONAL LAW]
Businesses Act, No. 71 of 1991
[with effect from 24 May, 1991—see title TRADE AND INDUSTRY]
Medicines and Related Substances Control Amendment Act, No. 94 of 1991

GENERAL NOTE

Act No. 94 of 1991 was brought into operation by Proc. R.66 of 1991, with certain reservations. The affected sections in the English and Afrikaans texts of Proc. R.66 of 1991 do not correspond and, at the time of printing, the error had not yet been corrected. The amendments to this Act, brought about by Act No. 94 of 1991, have been made in accordance with the Afrikaans text of Proc. R.66 of 1991.

ACT

To provide for the registration of medicines intended for human and for animal use, for the registration of medical devices, for the establishment of a Medicines Control Council, for the control of medicines, Scheduled substances and medical devices for matters incidental thereto.

[Long title substituted by s. 37 of Act No. 65 of 1974, by s. 15 of Act No. 17 of 1979 and by s. 22 of Act No. 94 of 1991.]

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.]

(*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.]

"**approved name**", in relation to a medicine, means the internationally recognized name of such medicine or such other name as the council may determine, not being a brand name or trade name registered in terms of the Trade Marks Act, 1963 (Act No. 62 of 1963);

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

"**Director-General**" means the Director-General: National Health and Population Development;

[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.]

"**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;

"**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;

"**Medical Act**" means the Medical, Dental and Supplementary Health Service Professions Act, 1974;

"**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 Medical Act, and includes an intern registered under that Act;

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

"**medicinal purpose**", in relation to a Scheduled substance, means 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 Administration or the Administration of the territory, or approved for this purpose by the Minister;

"**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.]

"**Minister**" means the Minister of National Health;

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

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

[Definition of "nurse" inserted by s. 1 (*g*) of Act No. 94 of 1991.]

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

"**pathologist**" means a pathologist to whom authority has been granted under section 27;

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

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

"**pharmacist'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.]

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

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

"**pharmacy Board**" means the South African Pharmacy Board referred to in section 2 of the Pharmacy Act, 1974;

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

[Definition of "practitioner" inserted by s. 1 (*l*) of Act No. 94 of 1991.]

"**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 included in any Schedule to this Act;

"**Schedule 1 substance**" means any medicine or other substance included in Schedule 1 to this Act;

"**Schedule 2 substance**" means any medicine or other substance included in Schedule 2 to this Act;

"**Schedule 3 substance**" means any medicine or other substance included in Schedule 3 to this Act;

"**Schedule 4 substance**" means any medicine or other substance included in Schedule 4 to this Act;

"**Schedule 5 substance**" means any medicine or other substance included in Schedule 5 to this Act;

"**Schedule 6 substance**" means any medicine or other substance included in Schedule 6 to this Act;

"**Schedule 7 substance**" means any medicine or other substance included in Schedule 7 to this Act;

"**Schedule 8 substance**" means any medicine or other substance included in Schedule 8 to this Act;

"**Schedule 9 substance**" means any medicine or other substance included in Schedule 9 to this Act;

"**Secretary**" . . . . . .

[Definition of "Secretary" deleted by s. 1 (*f*) of Act No. 20 of 1981.]

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

"**this Act**" includes any regulation;

"**the territory**" means the territory of South-West Africa;

"**trainee pharmacist**" . . . . . .

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

"unqualified assistant" .....

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

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

[Definition of "veterinarian" substituted by s. 1 (*p*) of Act No. 94 of 1991.]

"veterinary medicine" means any substance or mixture of substances, other than a stock remedy or farm feed to be registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), used or purporting to be suitable for use or manufactured or sold for use in connection with vertebrates, for the treatment, diagnosis, prevention or cure of any disease, infection or other unhealthy condition, or for the maintenance or improvement of health, growth, production or working capacity, or for curing, correcting or modifying any somatic or organic function, or for correcting or modifying behaviour.

[Definition of "veterinary medicine" added by s. 1 (*h*) of Act No. 17 of 1979.]

(2) 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 and by s. 1 (*g*) of Act No. 20 of 1981.]

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

[S. 1 substituted by s. 1 (1) of Act No. 65 of 1974. Sub-s. (3) substituted by s. 1 (*j*) of Act No. 17 of 1979.]

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.

[S. 2 substituted by s. 2 (1) of Act No. 65 of 1974. Sub-s. (2) added by s. 2 of Act No. 94 of 1991.]

3. Constitution of council.—(1) The council shall consist of so many members, but not more than 24, as the Minister may from time to time determine.

[Sub-s. (1) substituted by s. 3 (*a*) of Act No. 65 of 1974, by s. 1 of Act No. 36 of 1977 and by s. 2 (*a*) of Act No. 17 of 1979, amended by s. 46 of Act No. 97 of 1986 and substituted by s. 3 (*a*) of Act No. 94 of 1991.]

(2) The following persons shall be appointed by the Minister as members of the council, namely—

(*a*) at least two persons who shall be medical practitioners who have a speciality in medicine entered in the appropriate register contemplated in section 19 of the Medical Act;

[Para. (*a*) substituted by s. 3 (*b*) of Act No. 65 of 1974.]

(*b*) at least one person who shall be a medical practitioner engaged in general medical practice;

(*c*) at least one person who shall have a special knowledge of the action and application of medicines for human use;

[Para. (*c*) amended by s. 3 (*c*) of Act No. 65 of 1974.]

(*d*) at least one person who shall be a pharmacist in private pharmaceutical practice;

[Para. (*d*) substituted by s. 3 (*d*) of Act No. 65 of 1974 and substituted by s. 3 (*b*) of Act No. 94 of 1991.]

(*dA*) .....

[Para. (*d* A) inserted by s. 2 (*b*) of Act No. 17 of 1979 and deleted by s. 3 (*b*) of Act No. 94 of 1991.]

(*e*) at least one person who shall be a veterinarian;

[Para. (*e*) substituted by s. 3 (*b*) of Act No. 94 of 1991.]

(*f*) one person who shall be an officer of the Department of National Health and Population Development;

[Para. (*f*) substituted by s. 3 (*b*) of Act No. 94 of 1991.]

(*g*) one person who shall be an officer of the Department of Agriculture and be designated by the Minister of Agriculture;

[Para. (*g*) added by s. 3 (*b*) of Act No. 94 of 1991.]

(*h*) at least one person who shall be a pharmacist who has a special knowledge of pharmacology or pharmaceutical chemistry;

[Para. (*h*) added by s. 3 (*b*) of Act No. 94 of 1991.]

(*i*) at least one person who shall have a special knowledge of pharmaceutics; and

[Para. (*i*) added by s. 3 (*b*) of Act No. 94 of 1991.]

(*j*) not more than four other persons.

[Sub-s. (2) amended by s. 46 of Act No. 97 of 1986. Para (*j*) added by s. 3 (*b*) of Act No. 94 of 1991.]

(3) If two or more persons are appointed in terms of paragraph (*c*) of sub-section (2) at least one of them shall also be a medical practitioner.

4. Period of office and remuneration of members of the council.—(1) A member of the council shall, subject to the provisions of sub-section (3) of section *six*, be appointed for a period of five years.

(2) Any person whose period of office as a member of the council has expired, shall be eligible for reappointment.

(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.]

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.]

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

6. Disqualifications, vacation of office and filling of vacancies.—(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 Medical Act or the Pharmacy Act, 1974, from carrying on his profession, while so disqualified; or

[Para. (*b*) substituted by s. 5 (*a*) of Act No. 65 of 1974, by s. 3 (*a*) of Act No. 17 of 1979 and by s. 4 (*a*) of Act No. 94 of 1991.]

(*c*) .....

[Para. (*c*) substituted by s. 5 (*b*) of Act No. 65 of 1974 and deleted by s. 4 (*b*) of Act No. 94 of 1991.]

(*d*) who is not a South African citizen permanently resident in the Republic or the territory.

(2) A member of the council shall vacate his office—

(*a*) if he becomes subject to any disqualification referred to in sub-section (1);

(*b*) if he ceases to hold any qualification necessary for his appointment;

(*c*) if he becomes mentally ill, as defined in the Mental Health Act, 1973 (Act No. 18 of 1973);

[Para. (*c*) substituted by s. 5 (*c*) of Act No. 65 of 1974.]

(*d*) if he is convicted of an offence and is sentenced to imprisonment without the option of a fine; or

(*e*) if he has been absent from more than two consecutive meetings of the council without the council's leave.

(3) If the office of any member of the council becomes vacant before the expiration of the period for which he was appointed, the Minister may, subject to the applicable provisions of section *three*, appoint another person to hold office for the unexpired portion of the period for which his predecessor was appointed.

[Sub-s. (3) amended by s. 46 of Act No. 97 of 1986.]

(4) .....

[Sub-s. (4) substituted by s. 5 (*d*) of Act No. 65 of 1974 and by s. 3 (*b*) of Act No. 17 of 1979 and deleted by s. 4 (*c*) of Act No. 94 of 1991.]

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 sub-section (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.]

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*) from among its members an executive committee the majority of the members of which shall be persons appointed in terms of paragraphs (*a*) and (*c*) of sub-section (2) of section *three*; and

(*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 sub-section (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.]

10. .....

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

11. .....

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

12. Appointment of Registrar of Medicines.—(1) The Minister may, subject to the laws governing the public service and after consultation with the council, appoint an officer to be styled the Registrar of Medicines who shall perform the functions and carry out the duties assigned to or imposed upon the registrar by or under this Act and such other functions and duties as may from time to time be assigned to or imposed upon him by the Minister or the Director-General.

(2) The registrar shall also act as secretary of the council.

[S. 12 substituted by s. 10 (1) of Act No. 65 of 1974.]

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 and substituted by s. 2 of Act No. 20 of 1981.]

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.]

(*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.]

(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 professional activities by a medical practitioner, pharmacist, practitioner or veterinarian 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, 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 and has not been advertised.

[Sub-s. (4) substituted by s. 6 of Act No. 17 of 1979 and by s. 7 (*c*) of Act No. 94 of 1991.]

(5) The provisions of subsection (4) shall, with effect from the date upon which all medicines become subject to registration by virtue of resolutions published in terms of subsection (2), not apply to any medicine unless the active components of such medicine have been registered under this Act.

[S. 14 substituted by s. 1 (1) of Act No. 29 of 1968 and by s. 12 (1) of Act No. 65 of 1974.]

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 as soon as possible after the receipt by him 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.

(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 may within a period of one month after the date of the notification furnish the registrar with his comments on the council's reasons for not being so satisfied.

(*c*) If no such comments are submitted by the applicant within the said period, or if after consideration of any comments so submitted the 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 may be made subject to such conditions as may with due regard to the succeeding provisions of this section be determined by the council.

(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 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 relevant medicine subject to the said condition.

(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.]

(*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 subsection (3) of section 14 publish in the *Gazette* the prescribed particulars in respect of all applications for registration received by him prior to such date.

[S. 15 amended by s. 2 of Act No. 29 of 1968 and substituted by s. 13 of Act No. 65 of 1974.]

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 (3) 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) A 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.]

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 and substituted by s. 4 (*a*) of Act No. 20 of 1981.]

(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.]

(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.]

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.]

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.

[S. 18 substituted by s. 16 of Act No. 65 of 1974 and by s. 7 of Act No. 17 of 1979.]

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.]

(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.]

(3) The council may, if so requested by any person to whom a notice under sub-section (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.]

(*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 sub-paragraph (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 sub-paragraph (iii) or paragraph (*a*) of that section.

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

(2) It shall be a sufficient defence in any prosecution for an offence under paragraph (*a*) of sub-section (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.]

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.]

(2) Any medicine sold in pursuance of any authority granted under sub-section (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.]

(3) The council may at any time by notice in writing withdraw any authority granted in terms of sub-section (1) if effect is not given to any determination made in terms of sub-section (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. 67 of Act No. 20 of 1981.]

(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.]

22A. Control of medicines and Scheduled substances.—(1) Subject to the provisions of this section, no person shall sell any medicine or Scheduled substance except in accordance with the prescribed conditions.

[Sub-s. (1) substituted by s. 7 of Act No. 71 of 1991.]

(2) . . . . . .

[Sub-s. (2) deleted by s. 7 of Act No. 71 of 1991.]

(3) Any Schedule 1 substance, not being any such substance prescribed for the purposes of this subsection, shall not be sold by any person other than a medical practitioner, dentist, pharmacist or veterinarian: Provided that any Schedule 1 substance shall not be sold to any person apparently under the age of sixteen years except upon a prescription issued by a medical practitioner, dentist or veterinarian and dispensed by a pharmacist, trainee pharmacist or pharmacist's assistant or by a medical practitioner or dentist or veterinarian or on a written order which discloses 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 sixteen years.

[Sub-s. (3) amended by s. (9) (*a*) of Act No. 17 of 1979 and by s. 7 of Act No. 71 of 1991.]

(4) Any Schedule 2 substance shall not be sold—

(*a*) by any person other than a pharmacist or a trainee pharmacist or pharmacist's assistant acting under the personal supervision of a pharmacist; and

(*b*) to any person apparently under the age of sixteen years except upon a prescription issued by a medical practitioner, dentist or veterinarian and dispensed by a pharmacist, trainee pharmacist or pharmacist's assistant or by a medical practitioner or dentist or veterinarian or on a written order which discloses 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 sixteen years; and

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

[Sub-s. (4) substituted by s. 9 (*b*) of Act No. 17 of 1979.]

(5) Any Schedule 3 substance shall not be sold—

(*a*) by any person other than a pharmacist or a trainee pharmacist or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by a medical practitioner, dentist or veterinarian or on the verbal instructions of a medical practitioner, dentist or veterinarian who is known to such pharmacist; or

[Para. (*a*) substituted by s. 9 (*c*) of Act No. 17 of 1979.]

(*b*) to any person other than a medical practitioner, dentist, veterinarian or pharmacist; and

(*c*) unless the seller, except a manufacturer of or wholesale dealer in pharmaceutical products, enters in the prescribed manner in a prescription book required to be kept in the prescribed manner, all the prescribed particulars of such sale; and

[Para. (*c*) substituted by s. 9 (*d*) of Act No. 17 of 1979.]

(*d*) in the case of a sale as provided in paragraph (*a*), in a quantity greater than that stated in the prescription or instructions referred to in that paragraph: Provided that such sale may, upon such prescription or instructions, be repeated for use in terms of such prescription or instructions during a period not exceeding six months as from the date of the first such sale.

(6) A Schedule 4 substance shall not be sold—

(*a*) by any person other than a pharmacist or a trainee pharmacist or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription of a medical practitioner, dentist or veterinarian or on the verbal instructions of a medical practitioner, dentist or veterinarian who is known to such pharmacist: Provided that a medical practitioner, dentist or veterinarian who has given such verbal instructions shall within seven days after giving such instructions furnish to such pharmacist a written prescription confirming such instructions; or

[Para. (*a*) amended by s. 9 (*e*) of Act No. 17 of 1979.]

(*b*) to any person other than a medical practitioner, dentist, veterinarian or pharmacist; and

(*c*) unless the seller, except a manufacturer of or wholesale dealer in pharmaceutical products, enters in the prescribed manner in a prescription book required to be kept in the prescribed manner, all the prescribed particulars of such sale; and

[Para. (*c*) substituted by s. 9 (*f*) of Act No. 17 of 1979.]

(*d*) in the case of a sale on a written prescription as provided in paragraph (*a*), in a quantity greater than that stated in the prescription: Provided that such sale may, if the person who issued the prescription indicated thereon the number of times it may be dispensed, be repeated accordingly: Provided further that every seller shall endorse on the prescription the date of sale and the quantity of the said substance sold, and that the last seller shall retain the prescription for a period of not less than three years as from the date of the last sale.

[Para. (*d*) amended by s. 9 (*g*) of Act No. 17 of 1979.]

(7) (*a*) Save as is permitted by the provisions of this subsection, no person shall use or have in his possession or manufacture any Schedule 5 substance, or collect, cultivate or keep any plant or portion thereof from which any such substance can be extracted, derived, produced or manufactured.

(*b*) A Schedule 5 substance shall not be sold—

(i) by any person other than a pharmacist or a trainee pharmacist or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription of a medical practitioner, dentist or veterinarian; or

[Sub-para. (i) substituted by s. 9 (*h*) of Act No. 17 of 1979.]

(ii) to any person other than a medical practitioner, dentist, veterinarian or pharmacist; and

(iii) unless the seller enters in the prescribed manner in a prescription book required to be kept in the prescribed manner, all the prescribed particulars of such sale; and

(iv) in the case of a sale as provided in subparagraph (i), in a quantity greater than that stated in the prescription: Provided that such sale may, if the person who issued the prescription indicated thereon the number of times and the intervals at which it may be dispensed, be repeated accordingly: Provided further that

every seller shall endorse on the prescription the date of sale and the quantity of the said substance sold, and that the last seller shall retain the prescription for a period of not less than three years as from the date of the last sale.

(*c*) A Schedule 5 substance shall not be administered or used for other than medicinal purposes: Provided that the Minister may grant authority, subject to compliance with such conditions or requirements as may be stated in such authority, for the administration outside any hospital or institution referred to in the definition of "medicinal purpose" in section 1, of any such substance for the satisfaction or relief of a habit or craving for the substance administered or for any other such substance, to the particular person referred to in such authority.

(*d*) A Schedule 5 substance shall not be manufactured or sold by wholesale or imported or exported unless the prescribed records relating thereto are kept in the prescribed manner.

(*e*) The Director-General may issue, subject to such conditions and requirements as the Director-General may determine, a permit to any person to acquire, possess or use any such substance, or to collect, cultivate or keep any plant or any portion thereof from which any such substance may be extracted, derived, produced or manufactured, for scientific, research, analytical or educational purposes.

[Para. (*e*) substituted by s. 9 (*i*) of Act No. 17 of 1979.]

(8) (*a*) Save as is permitted by the provisions of this subsection, no person shall use or have in his possession or manufacture any Schedule 6 substance, or collect, cultivate or keep any plant or portion thereof from which any such substance can be extracted, derived, produced or manufactured.

(*b*) A Schedule 6 substance shall not be sold—

(i) by any person other than a pharmacist or a trainee pharmacist acting under the personal supervision of a pharmacist, upon a prescription issued by a medical practitioner, dentist or veterinarian, presented for dispensing not later than thirty days as from the date of issue thereof and setting forth as the quantity of such substance to be sold thereunder, a quantity not greater than that required for continuous use for a period of thirty days, as determined by the person who issued the prescription, by the patient or, in the case of a prescription given by a veterinarian, by the person to whom such substance is to be delivered; or

(ii) to any person other than a medical practitioner, dentist, veterinarian or pharmacist on production of a written order signed by such medical practitioner, dentist, veterinarian or pharmacist; and

(iii) unless the seller enters in the prescribed manner in a prescription book or an order book required to be kept in the prescribed manner, all the prescribed particulars of such sale; and

(iv) in the case of a sale as provided in subparagraph (i) or (ii), in a quantity greater than that stated in the prescription or order, and not more than one issue of such substance shall be made on such prescription or order.

(*c*) Any seller shall, in the case of a sale as provided in subparagraph (i) or (ii) of paragraph (*b*), retain the prescription or order concerned for a period of not less than three years as from the date of such sale.

(*d*) Subject, *mutatis mutandis*, to the proviso to subsection (7) (*c*), a Schedule 6 substance shall not be administered or used for other than medicinal purposes.

(*e*) (i) A Schedule 6 substance shall not be manufactured or sold by wholesale or imported or exported unless the manufacturer, wholesaler, importer or exporter, as the case may be, causes to be entered in a book to be called the "Schedule 6 Substances Register" the prescribed particulars relating to such manufacture, sale, importation or exportation.

(ii) Every such book shall be kept in the prescribed manner, and shall be balanced so as to show clearly the quantity of every Schedule 6 substance remaining in stock as on the last day of March, June, September and December of each year, the balancing to be completed within the fourteen days following each of the abovementioned dates.

(*f*) (i) No person shall manufacture, import or export any Schedule 6 substance unless—

(*aa*) a permit for such manufacture has been issued to him by the Director-General on the recommendation of the Council, or for such importation or exportation has been issued to him by the Director-General, subject to the prescribed conditions; or

(*bb*) a permit has been issued to him by the Director-General, subject to the prescribed conditions, for the cultivation or collection of plants, or any portion thereof, from which any such substance can be extracted, derived, produced or manufactured.

(ii) The Director-General shall, on the recommendation of the council, at any time withdraw any such permit if any condition on which the permit has been issued, is not complied with.

[Para. (*f*) substituted by s. 9 (*j*) of Act No. 17 of 1979.]

(*g*) The Director-General may issue, subject to such conditions and requirements as the Director-General may on the recommendation of the council determine, a permit to any person to acquire, possess or use any Schedule 6 substance, or to collect, cultivate or keep, for scientific, research or educational purposes, any plant or any portion thereof from which any such substance can be extracted, derived, produced or manufactured.

[Para. (*g*) substituted by s. 9 (*k*) of Act No. 17 of 1979.]

(9) (*a*) Save as is permitted by the provisions of this subsection, no person shall use or have in his possession or manufacture any Schedule 7 substance, or collect, cultivate or keep any plant or portion thereof from which any such substance can be extracted, derived, produced or manufactured.

(*b*) A Schedule 7 substance shall not be sold—

(i) by any person other than a pharmacist or a trainee pharmacist acting under the personal supervision of a pharmacist, upon a prescription issued by a medical practitioner, dentist or veterinarian, presented for dispensing not later than thirty days as from the date of issue thereof and setting forth as the quantity of such substance to be sold thereunder, a quantity not greater than that required for continuous use for a period of thirty days, as determined by the person who issued the prescription, by the patient or, in the case of a prescription given by a veterinarian, by the person to whom such substance is to be delivered; or

(ii) to any person other than a medical practitioner, dentist, veterinarian or pharmacist on a prescribed written order issued in the prescribed manner; and

(iii) unless the seller causes to be entered in a book to be called the "Schedule 7 Substances Register" the prescribed particulars relating to such sale; and

(iv) in the case of a sale as provided in subparagraph (i) or (ii), in a quantity greater than that stated in the prescription or order, and not more than one issue of such substance shall be made on such prescription or order.

(*b*A) Any seller shall, in the case of a sale as contemplated in subparagraph (i) or (ii) of paragraph (*b*), retain the prescription or order concerned for a period of not less than three years as from the date of that sale.

[Para. (*b*A) inserted by s. 9 (*l*) of Act No. 17 of 1979.]

(*c*) Subject, *mutatis mutandis*, to the proviso to subsection (7) (*c*), a Schedule 7 substance shall not be administered or used for other than medicinal purposes.

(*d*) A Schedule 7 substance shall not be manufactured or sold by wholesale or imported or exported unless the manufacturer, wholesaler, importer or exporter, as the case may be, causes to be entered in the Schedule 7 Substances Register referred to in paragraph (*b*) (iii), the prescribed particulars relating to such manufacture, sale, importation or exportation.

(*e*) The said Schedule 7 Substances Register shall be kept in the prescribed manner, and shall be balanced so as to show clearly the quantity of every Schedule 7 substance remaining in stock as on the last day of March, June, September and December of each year, the balancing to be completed within the fourteen days following each of the above-mentioned dates.

(*f*) (i) No person shall manufacture, import or export any Schedule 7 substance unless—

(*aa*) a permit for such manufacture has been issued to him by the Director-General on the recommendation of the council, or for such importation or exportation has been issued to him by the Director-General, subject to the prescribed conditions; or

(*bb*) a permit has been issued to him by the Director-General, subject to the prescribed conditions, for the cultivation or collection of plants, or any portion thereof, from which any such substance can be extracted, derived, produced or manufactured.

(ii) The Director-General shall, on the recommendation of the council, at any time withdraw any such permit if any condition on which the permit has been issued, is not complied with.

[Para. (*f*) substituted by s. 9 (*m*) of Act No. 17 of 1979.]

(*g*) The Director-General may issue, subject to such conditions and requirements as the Director-General may on the recommendation of the council determine, a permit to any person to acquire, possess or use any Schedule 7 substance specified in such permit or to collect, cultivate or keep, for specified scientific, research, analytical or educational purposes, any plant or any portion thereof from which any such substance can be extracted, derived, produced or manufactured.

[Para. (*g*) substituted by s. 9 (*n*) of Act No. 17 of 1979.]

(10) No person shall—

(*a*) acquire, use, have in his possession, manufacture or import any Schedule 8 substance except for analytical or research purposes and unless a permit for such acquisition, use, possession, manufacture or importation has been issued to him by the Director-General on the recommendation of the council; or

(*b*) acquire, import, collect, cultivate, keep or export any plant or any portion thereof from which any such substance can be extracted, derived, produced or manufactured, unless a permit to acquire, import, collect, cultivate, keep or export such plant or any portion thereof, has been issued to him by the Director-General on the recommendation of the council.

(11) A Schedule 9 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 subject to such conditions as the Director-General, on the recommendation of the council, may determine.

(12) Notwithstanding the other provisions of this section, the Director-General may, after consultation with the Pharmacy Board, issue a permit to any person or organization performing a health service, authorizing such person or organization to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance, and such permit shall be subject to such conditions as the Director-General may determine.

(13) .....

[Sub-s. (13) deleted by s. 9 (*o*) of Act No. 17 of 1979.]

(14) Notwithstanding the other provisions of this section, 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: Provided that the quantity so sold shall not exceed or be less than, twenty-five per cent of the quantity specified in the prescription or order in question.

(15) Nothing in this section contained shall be construed as prohibiting—

(*a*) any medical practitioner, dentist or veterinarian from selling any Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7 substance in the course of lawfully carrying on this professional activities as such to or for any patient or animal under his care or treatment;

(*b*) any person employed by a manufacturer of or wholesale dealer in pharmaceutical products, and authorized thereto in writing by such manufacturer or dealer, from selling any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance to any medical practitioner, dentist, pharmacist or veterinarian on the prescribed conditions.

(*c*) a pharmacist from selling in an emergency and Schedule 5, Schedule 6 or Schedule 7 substance in a quantity not greater than that required for continuous use for a period of forty-eight hours, on the verbal instructions of a medical practitioner, dentist or veterinarian who is known to such pharmacist: Provided that a medical practitioner, dentist or veterinarian who has given such verbal instructions shall within seventy-two hours after giving such instructions furnish to such pharmacist a written prescription confirming such instructions;

[Para. (*c*) added by s. 9 (*p*) of Act No. 17 of 1979.]

(*d*) any veterinary assistant or veterinary nurse within the meaning of the Veterinary Act, 1933 (Act No. 16 of 1933), from selling, upon a written pre-

scription issued by a veterinarian or on the verbal instructions of a veterinarian, any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal.

[S. 22A inserted by s. 21 of Act No. 65 of 1974. Para (*d*) added by s. 9 (*p*) of Act No. 17 of 1979.]

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.]

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.]

(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 sub-section (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.]

(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.]

24. Appeal against decisions of council.—(1) Any person aggrieved by a decision of the council may within the prescribed period and in the prescribed manner appeal against such decision to an appeal committee appointed by the Minister for the purposes of the appeal concerned.

(2) An appeal committee shall consist of—

(*a*) a retired judge or an advocate of the Supreme Court of South Africa who has practised as such for a period of at least five years, and who shall be the chairman of the committee;

(*b*) a pharmacologist; and

(*c*) if the appeal relates to—

(i) a veterinary medicine, a veterinarian and a pharmacist;

(ii) a homoeopathic medicine, a practitioner;

(iii) a medicine, other than a veterinary and homoeopathic medicine, a medical practitioner who has a speciality in medicine entered in the appropriate register contemplated in section 18 of the Medical Act and a pharmacist;

(iv) a medical device, a specialist or a technician who has expert or special knowledge or experience of such a device,

who has no direct or indirect interest in the affairs of the appellant.

(3) An appeal under subsection (1) shall be heard on the date and at the place and time fixed by the appeal committee, which shall previously in writing notify the appellant as well as the council thereof.

(4) The appeal committee may for the purposes of an appeal lodged with it—

(*a*) summon any person who, in its opinion, may be able to give material information concerning the subject of the appeal or who it believes has in his possession or custody or under his control any document which has any bearing upon the subject of the appeal, to appear before it at a time and place specified in the summons, to be interrogated or to produce that document, and retain for examination any document so produced;

(*b*) administer an oath to or accept an affirmation from any person called as a witness at the appeal; and

(*c*) call any person present at the hearing of the appeal as a witness and interrogate him and require him to produce any document in his possession or custody or under his control.

(5) The procedure at the hearing of an appeal shall be determined by the chairman of the appeal committee.

(6) 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 in connection therewith.

(7) 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.

(8) The members of the appeal committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister determines with the concurrence of the Minister of Finance.

[S. 24 amended by s. 23 of Act No. 65 of 1974 and substituted by s. 11 of Act No. 94 of 1991.]

25. **Privileges of council and committees.**—No legal proceedings shall lie against the council or any committee appointed under sub-section (1) of section *nine* or any member of the council or of any such committee in respect of any act done by the council or any such committee in the exercise of its powers or the performance of its functions under this Act.

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.]

(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.]

(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.]

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.]

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

(*a*) enter upon any premises, place, vehicle, vessel or aircraft at or in which there is or is on reasonable grounds suspected to be any medicine or Scheduled substance;

[Para. (*a*) amended by s. 26 (*a*) of Act No. 65 of 1974.]

(*b*) inspect any medicine or Scheduled substance, or any book, record or document found in or upon such premises, place, vehicle, vessel or aircraft;

[Para. (*b*) amended by s. 26 (*a*) of Act No. 65 of 1974.]

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

[Para. (*c*) amended by s. 26 (*a*) of Act No. 65 of 1974.]

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

[Para. (*d*) amended by s. 26 (*a*) of Act No. 65 of 1974.]

(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.]

(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.]

(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.]

29. Offences.—Any person who—

(*a*) obstructs or hinders any inspector in the exercise of his powers or the carrying out of his duties under this Act; or

(*b*) contravenes or fails to comply with the provisions of sub-section (1) of section *fourteen* or section *eighteen*; or

(*c*) contravenes the provisions of sub-section (1) of section *nineteen* or fails to comply with a notice issued under sub-section (2) of that section; or

(*d*) contravenes the provisions of sub-section (1) of section *twenty*; or

(*e*) contravenes or fails to comply with any condition imposed under sub-section (7) of section *fifteen*; or

(*f*) fails to comply with any direction given under section *twenty-three* or contravenes the provisions of sub-section (3) of that section; or

(*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.]

(*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.]

(*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 or contravenes or fails to comply with any condition imposed thereunder;

[Para. (*k*) added by s. 27 (*d*) of Act No. 65 of 1974.]

(*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 not exceeding R40 000 or to imprisonment for a period not exceeding 10 years or to both such fine and such imprisonment.

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

(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.]

(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.]

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.]

(*b*) any person who is proved to have tampered with any sample shall be deemed to have acted with fraudulent intent unless the contrary is proved;

(*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.]

(2) No prosecution shall be instituted as a result of any test, examination or analysis carried out in terms of the provisions of section 28 unless a copy of the analyst's, pharmacologist's or pathologist's certificate has, at least fourteen days before the institution of such prosectuion, been handed or transmitted by registered post to the person who is to be the accused.

[Sub-s. (2) substituted by s. 13 of Act No. 17 of 1979.]

(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. **Special defences in case of prosecutions.**—It shall be sufficient defence for a person charged with the sale of any medicine in contravention of the provisions of section *nineteen* if he proves to the satisfaction of the court—

(*a*) that he purchased such medicine from a person residing in the Republic who had furnished him with a written warranty that such medicine complied with the prescribed requirements; and

[Para. (*a*) amended by s. 30 of Act No. 65 of 1974.]

(*b*) that he had no reason to believe that such medicine did not so comply.

[S. 32 amended by s. 30 of Act No. 65 of 1974. Para. (*b*) amended by s. 30 of Act No. 65 of 1974.]

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.

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

[S. 34 substituted by s. 14 of Act No. 94 of 1991.]

34A. **Delegation of powers.**—(1) The Minister may in writing authorise the Director-General or any officer of the Department of National Health and Population Development to exercise any of the powers conferred upon him 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.

(2) The Director-General may in writing authorize any officer of the Department of National Health and Population Development 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 and substituted by s. 15 of Act No. 94 of 1991.]

35. **Regulations.**—(1) The Minister may, on the recommendation of 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;

[Para. (i) substituted by s. 7 of Act No. 20 of 1981.]

(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 in 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;

(viA) prescribing the circumstances in which, the conditions on which and the persons or classes of persons to whom any medicine or Scheduled substance may be sold;

[Para. (viA) inserted by s. 16 (*a*) of Act No. 94 of 1991.]

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

(viii) 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;

(ix) 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 any advertisement relating to any medicine or Scheduled substance, or the distribution of any such advertisement to a specified person or a specified class or category of persons or to a specified organization or a specified class or category of organizations;

(x) prescribing the requirements with which any medicine or any component thereof shall comply in regard to composition, therapeutic suitablity and effect, purity or any other property;

(xi) prescribing the particulars which shall be published in the *Gazette* in respect of any application for registration referred to in subsection (11) of section 15;

(xii) 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;

[Para. (xii) substituted by s. 16 (*b*) of Act No. 94 of 1991.]

(xiii) .....

[Para. (xiii) deleted by s. 7 of Act No. 71 of 1991.]

(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) .....

[Para. (xv) deleted by s. 16 (*d*) of Act No. 94 of 1991.]

(xvi) .....

[Para (xvi) substituted by s. 7 of Act No. 71 of 1991 and deleted by s. 16 (*d*) of Act No. 94 of 1991.]

(xvii) 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;

(xviii) requiring the furnishing of returns and 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;

[Para. (xviii) substituted by s. 16 (*e*) of Act No. 94 of 1991.]

(xix) as to the transshipment or the exportation from or importation to the Republic of any Scheduled substance, and specifying the ports or places at which such substance may be brought into the Republic;

[Para. (xix) substituted by s. 16 (*e*) of Act No. 94 of 1991.]

(xx) authorizing and regulating or restricting the transmission through the Republic of Scheduled substances;

[Para. (xx) substituted by s. 16 (*e*) of Act No. 94 of 1991.]

(xxi) 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;

[Para. (xxi) substituted by s. 16 (*e*) of Act No. 94 of 1991.]

(xxii) authorizing 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;

(xxiii) authorizing and regulating the purchase, acquisition, keeping or use of Scheduled substances by particular persons or classes of persons;

[Para. (xxiii) substituted by s. 3 (*a*) of Act No. 19 of 1976.]

(xxiv) .....

[Para. (xxiv) deleted by s. 16 (*f*) of Act No. 94 of 1991.]

(xxv) authorizing and regulating the possession by persons entering or departing from the Republic of specified quantities of Scheduled substances for personal medicinal use;

[Para. (xxv) substituted by s. 16 (*g*) of Act No. 94 of 1991.]

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

[Para. (xxvA) inserted by s. 14 (*a*) of Act No. 17 of 1979 and substituted by s. 16 (*g*) of Act No. 94 of 1991.]

(xxvi) 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;

(xxviA) 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;

[Para. (xxviA) inserted by s. 3 (*b*) of Act No. 19 of 1976 and substituted by s. 14 (*b*) of Act No. 17 of 1979.]

(xxvii) as to the importation, 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. (xxvii) substituted by s. 14 (*c*) of Act No. 17 of 1979.]

(xxviii) 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;

(xxix) 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;

(xxx) prescribing the fee to be paid to the registrar in respect of the application for the registration, and in respect of the registration, of a medicine or medical device, the fee to be paid annually to the registrar in respect of the retention of the registration of a medicine or medical device and by a person who may in terms of section 14 (3) sell unregistered medicine, and the date on which the said annual fee shall be so paid;

[Para. (xxx) substituted by s. 14 (*d*) of Act No. 17 of 1979 and by s. 16 (*h*) of Act No. 94 of 1991.]

(xxxA) as to the safekeeping of medicine and Scheduled substances;

[Para. (xxxA) inserted by s. 16 (*i*) of Act No. 94 of 1991.]

(xxxB) authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, storage, transportation, sale, use or destruction of any medical device or class of medical devices;

[Para. (xxxB) inserted by s. 16 (*i*) of Act No. 94 of 1991.]

(xxxi) with regard to any matter which in terms of this Act may be prescribed by regulation; and

(xxxii) 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 intention to make that regulation and inviting interested persons to furnish him 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 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) No regulation shall be made under paragraph (xxx) of subsection (1) except in consultation with the Minister of Finance.

(5) Regulations made under subsection (1) (x) 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 recognized 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) Any regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith, not exceeding a fine of R4 000 or imprisonment for a period of 12 months.

[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 and substituted by s. 31 (1) of Act No. 65 of 1974. Sub-s. (7) substituted by s. 16 (*j*) of Act No. 94 of 1991.]

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.]

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. Medicines manufactured for export.—Notwithstanding anything to the contrary in this Act contained, the provisions of this Act relating to the registration of medicines shall not apply in respect of any medicine or any quantity of any medicine which is manufactured in or imported into the Republic solely for the purpose of export from the Republic and is not used or disposed of for use in the Republic and in respect of which the council has granted a certificate that it is satisfied in regard to its quality, purity and safety.

[S. 37 substituted by s. 33 of Act No. 65 of 1974 and by s. 18 of Act No. 94 of 1991.]

37A. Amendment of Schedules.—The Minister may, on the recommendation of the council, from time to time by notice in the *Gazette* amend any Schedule to this Act 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.]

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. .....

[S. 39 repealed by s. 20 of Act No. 94 of 1991.]

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

[S. 40 substituted by s. 35 of Act No. 65 of 1974.]

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 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 and amended by Government Notice No. R.2841 of 7 December, 1990.]

All substances referred to in this Schedule are excluded when specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes.

All substances, preparations and mixtures referred to in this Schedule are also excluded when registered and sold in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

All substances referred to in this Schedule include the following:

(*a*) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(*b*) all preparations and mixtures of such substances where such preparations and mixtures are not expressly excluded.

Acetanilide and alkyl acetanilides.

Acetyldihydrocodeine; preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine per recommended or prescribed dose. (S7)

Aconite alkaloids; substances, preparations and mixtures containing less than 0.02 per cent thereof. (S2)

Adrenaline (epinephrine), except inhalants and except preparations for injection and except ophthalmic preparations when intended for glaucoma. (S2, S3, S4)

Amyl nitrite.

Anethole trithione.

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

Antimalarials; preparations containing substances in the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyrimidine groups of compounds, 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; preparations and mixtures containing less than 1,0 per cent thereof. (S2)

Antipyrine (phenazone): preparations and mixtures, when intended for application to the skin. (S2)

Apomorphine: preparations and mixtures containing less than 0,2 per cent thereof. (S2)

Arsenic: substances, preparations and mixtures containing the equivalent of less than 0.01 per cent of arsenic trioxide. (S2)

Atropine; substances, preparations and mixtures containing less than 0,1 per cent thereof, except ophthalmic preparations. (S2, S3)

Azelaic acid.

Barbituric acid and its derivatives, unless listed in another Schedule, excluding amobarbital, cyclobarbital, pentobarbital and secobarbital; preparations and mixtures containing 30 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in asthma, and 90 milligrams or less phenobarbitone per minimum recommended or prescribed dose, when intended for continued use in epilepsy. (S2, S5, S6, S7)

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

Belladonna alkaloids; substances, preparations and mixtures containing less than 0,1 per cent thereof, and including belladonna plasters. (S2)

Benorylate.

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

Beta-carotene, when intended for medicinal purposes.

Bioallethrin.

Bitolterol.

Calabar bean alkaloids; substances, preparations and mixtures containing less than 0.2 per cent thereof. (S2)

Calcium salts; preparations thereof, when intended for injection.

Camylofin.

Cantharidin; substances, preparations and mixtures containing less than 0,01 per cent thereof. (S2)

Canthaxanthin, when intended for medicinal purposes.

Chloramine, when intended for human vaginal use.

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne; preparations and mixtures containing 5,0 per cent or less of chlorodyne in combination with other active medicinal ingredients. (S7)

Chloroform, except substances, preparations and mixtures containing less than 20 per cent of chloroform.

Clanobutin.

Clonidine when intended for treatment of migraine. (S3)

Codeine (methylmorphine); preparations and mixtures containing 20 milligrams or less of codeine per recommended or prescribed dose. (S7)

Contrast media.

Cresol and phenol; preparations and mixtures containing 3,0 per cent or more of either of these substances.

Dapsone and its derivatives, unless listed in another Schedule; preparations and mixtures intended specifically for malaria prophylaxis. (S4)

Dextromethorphan. (S7)

Dialysate preparations.

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

Dihydrocodeine; preparations and mixtures containing 20 milligrams or less of dihydrocodeine per recommended or prescribed dose. (S7)

Ephedra alkaloids (natural of synthetic); 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. (S2)

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

Ethacridine.

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

Ethylmorphine; preparations and mixtures containing 20 milligrams or less of ethylmorphine per recommended or prescribed dose. (S7)

Ethylphenylephrine.

Etofenamate, when intended for application to the skin.

Fedrilate.

Fenbendazole.

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

Fluorescein, when intended for ophthalmic use.

Fluorides; oral medicinal preparations and mixtures thereof containing less than 0.25 milligrams of fluorine as fluoride per recommended daily dose. (S2)

Gadopentetic acid.

Gamma benzene hexachloride; human medicinal preparations and mixtures containing more than 1,0 per cent thereof, when intended for application to the skin.

Gelsemium alkaloids; substances, preparations and mixtures containing less than 0,1 per cent thereof. (S2)

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

Homatropine; preparations and mixtures containing less than 0,1 per cent thereof, except ophthalmic preparations. (S2, S3)

Hormones (natural or synthetic), with either hormonal or anti-hormonal action, when intended for application to the skin or for human vaginal use. (S3, S4)

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

Hyoscine; substances, preparations and mixtures containing less than 0,1 per cent thereof, except transdermal preparations when intended for the prevention of the symptoms of motion sickness. (S2)

Indanazoline.

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

Injections, unless listed in another Schedule.

Iopromide.

Ipecacuanha alkaloids; substances, preparations and mixtures thereof containing more than 0,01 per cent and less than 0,2 per cent alkaloids, calculated as emetine. (Also see Schedule 4 under "emetine".)

Lactobacillus acidophilus and *Lactobacillus bifidus*, when intended for therapeutic purposes.

Lead acetate.

Lead plaster and its combinations.

Live attenuated measles virus.

Live attenuated rubella virus.

Lobelia alkaloids; substances, preparations and mixtures containing less than 0,5 per cent thereof. (S2)

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

Lodoxamide.

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

Macrogolethers, when intended for human vaginal use.

Mercuric ammonium chloride.

Mercuric chloride; substances, preparations and mixtures containing less than 1,0 per cent thereof. (S2)

Mercuric iodide.

Mercuric oxides; substances, preparations and mixtures thereof, except those containing less than 3,0 per cent of mercury.

Mercury organic compounds; substances, preparations and mixtures intended for application to the skin and mucous membranes and containing less than the equivalent of 0,6 per cent of elemental mercury, except when in the form of aerosols. (S2)

Metacresol sulphonic acid formaldehyde, when intended for human vaginal use.

Methoxyphenamine.

Microfibrillar collagen hydrochloride.

Morphine; mixtures containing 0,2 per cent or less of morphine, calculated as anhydrous morphine. (S7)

N-acetyl-aspartyl-glutamic acid.

Naphazoline, when intended for nasal use.

Nicotinic acid; oral medicinal preparations and mixtures thereof containing more than 30 milligrams per recommended daily dose.

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

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

Nitroscanate.

Norcodeine; preparations and mixtures containing 20 milligrams or less of norcodeine per recommended or prescribed dose. (S7)

Nux vomica; substances, preparations and mixtures containing less than 0,2 per cent of strychnine. (S2)

Opium; mixtures containing not more than 0.2 per cent of morphine, calculated as anhydrous morphine. (S7)

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

Oxibendazole.

Oxymetazoline, when intended for nasal use.

Pancreatic enzyme-containing preparations, unless listed in another Schedule.

Pancrelipase.

Papaverine; substances, preparations and mixtures containing less than 0,2 per cent thereof. (S2)

Phenylbutazone and its derivatives, when intended for application to the skin, unless listed in another Schedule. (S4)

Phenylephrine, except ophthalmic preparations containing 0.2 per cent or less of phenylephrine.

Pholcodine; preparations and mixtures containing 20 milligrams or less of pholcodine per recommended or prescribed dose. (S7)

Pholedrine.

Phospholipids, when applied for therapeutic purposes.

Piperonyl butoxide.

Potassium chloride, when intended for intravenous infusion or for injection. (S2)

Potassium dichromate.

Proguanil.

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 injection and except when intended for soft contact lens cleaners. (S4)

Pyridoxilate.

Quinine; preparations and mixtures containing more than 1,0 per cent thereof.

Radix valerianae and its extracts; preparations and mixtures containing more than 10 per cent thereof.

Sabadilla alkaloids; substances, preparations and mixtures containing less than 1,0 per cent thereof. (S2)

Sodium cromoglycate.

Sodium pentosan polysulphate.

Solcoseryl; preparations thereof intended for application to the skin, to the mucous membranes of the mouth and to the lips. (S3, S4)

Strychnine; preparations and mixtures containing less than 0,2 per cent thereof, except the substance. (S2, S4)

Sulphonamides, when intended for application to the eyes, nares and vagina. (S4)

Tetrahydrozoline, when intended for nasal use.

Theophylline and its derivatives, unless listed in another Schedule, except preparations for injection and except inhalants. (S2, S4)

Ticlatone.

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.

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 and amended by Government Notices No. R.1132 of 2 June, 1989, No. R.1862 of 10 August, 1990 and No. R.2841 of 7 December, 1990.]

All substances referred to in this Schedule are excluded when specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes.

All substances, preparations and mixtures referred to in this Schedule are also excluded when registered and sold in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

All substances referred to in this Schedule include the following:

(*a*) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(*b*) all preparations and mixtures of such substances, where such preparations and mixtures are not expressly excluded.

Acetarsol, when intended for human vaginal use.

Acetylcysteine.

Aconite alkaloids; substances, preparations and mixtures containing 0,02 per cent or more thereof. (S1)

Acrivastiné.

Adrenaline (epinephrine), when intended for inhalation. (S1, 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.

Aminopentamide.

Amobarbital, cyclobarbital and pentobarbital; preparations and mixtures thereof containing 30 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in asthma, and 50 milligrams or less per minimum recommended or prescribed dose, when intended for continued use in epilepsy. (S1, S5, S6)

Antihistaminics, irrespective of indication or dosage form, unless listed in another Schedule. (S5)

Antimicrobial substances, namely clotrimazole, mupirocin, natamycin and nystatin, when intended for application to the skin, nares and external ear, as excluded from the conditions of Schedule 4. (S1, S4)

Antimony potassium tartrate and antimony sodium tartrate; substances, preparations and mixtures containing 1,0 per cent or more thereof. (S1)

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

Apomorphine; preparations and mixtures containing 0,2 per cent or more thereof. (S1)

Aptocaine.

Arecoline.

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

"AS XVII" ("Spasmo-Urgenin").

Atropine; substances, preparations and mixtures containing 0,1 per cent or more thereof, except ophthalmic preparations. (S1, S3)

Belladonna alkaloids; substances. preparations and mixtures containing 0,1 per cent or more thereof, excluding belladonna plasters. (S1)

Benproperine.

Benzethonium chloride, when intended for human vaginal use.

Bifonazole, when intended for application to the skin.

Biologicals, when intended for human use.

Bismuth, when intended for oral use.

Bovonium metilsulphate.

Bromhexine.

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

Bufexamac, when intended for application to the skin.

Butinoline.

Calabar bean alkaloids; substances, preparations and mixtures containing 0,2 per cent or more thereof. (S1)

Calcium dobesilate.

Camphorated Opium Tincture BP.

Cantharidin; substances, preparations and mixtures containing 0,01 per cent or more thereof. (S1)

Carbocisteine.

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

Carisoprodol.

Chlorhexidine. when intended for human vaginal use.

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

Chlorprenaline.

Chlorzoxazone.

Cyclandelate.

Cylopentolate, except ophthalmic preparations thereof. (S3)

Dicyclomine.

Difenoxin (or diphenoxylic acid); mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5,0 per cent of such quantity of difenoxin. calculated as the base. as is present in the mixture. (S7)

Diosmine.

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. (S7)

Dithiazanine.

D-norpseudoephedrine.

Domperidone.

Econazole. when intended for application to the skin. (S4)

Emepronium.

Ephedra alkaloids (natural or synthetic), except preparations and mixtures intended for application to the skin, eyes, ears and nares and containing 1,0 per cent or less of ephedra alkaloids, and other preparations and mixtures containing 30 milligrams or less of ephedrine or ephedra alkaloids per dose. (S1)

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

Exalamide.

Felbinac, when intended for application to the skin.

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

Fenticonazole, when intended for application to the skin.

Flavoxate.

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

Fluorides; oral medicinal preparations and mixtures thereof containing 0,25 milligrams or more of fluorine as fluoride per recommended daily dose. (S1)

Furazolidone, except preparations thereof intended for addition to animal feeds. (S4)

Gelsemium alkaloids; substances, preparations and mixtures containing 0,1 per cent or more thereof. (S1)

Glycopyrronium.

Hexametazime.

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 containing 0,1 per cent or more thereof, except ophthalmic preparations. (S1, S3)

Hydrocortisone and hydrocortisone acetate when used as a single active ingredient in a maximum concentration of 0,5 per cent in preparations intended for application to the skin. (S4)

Hydroquinone; preparations and mixtures containing 2 per cent or less thereof, when intended for application to the skin. (S3)

Hyoscine; substances, preparations and mixtures containing 0,1 per cent or more thereof, and transdermal preparations when intended for the prevention of the symptoms of motion sickness. (S1)

Ibuprofen, when used in oral medicinal preparations as a single active ingredient 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, except when intended for treatment of inflammatory joint diseases. (S3)

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

Imidazole, when intended for application to the skin.

Insulin, in cases of emergency. (S3)

Ipratropium bromide.

Isoaminile.

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

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

Isopropamide.

Isosorbide, in cases of emergency. (S3)

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

Ketotifen.

Lobelia alkaloids; substances, preparations and mixtures containing 0,5 per cent or more thereof. (S1)

Loperamide.

Loratadine.

Malathion.

Mebendazole.

Mebeverine.

Mepenzolate bromide.

Mephenesin.

Mercuric chloride; substances, preparations and mixtures containing 1,0 per cent or more thereof. (S1)

Mercury organic compounds; substances, preparations and mixtures containing the equivalent of 0,6 per cent or more of elemental mercury, or substances, preparations and mixtures in the form of aerosols, intended for application to the skin and mucous membranes. (S1)

Mesna.

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

Methenamine (hexamine), except when intended for application to the skin.

Methixene.

Methocarbamol.

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

Nitroglycerine, when intended for medicinal use in cases of emergency. (S3)

Nux vomica; substances, preparations and mixtures containing 0,2 per cent or more of strychnine. (S1)

Octatropine methylbromide.

Oleoresin of aspidium (Filix Mas).

Orphenadrine.

Orthodichlorobenzene, when intended for human medicinal use.

Oxyphencyclimine.

Oxyphenonium.

Papaverine; substances, preparations and mixtures containing 0,2 per cent or more thereof. (S1)

Paradichlorobenzene, when intended for human medicinal use.

Pentaerythritol tetranitrate, in cases of emergency. (S3)

Pentoxifylline.

Phenazopyridine.

Phenylpropanolamine.

Pinaverium.

Pipenzolate.

Pipoxolan.

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

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

Podophyllum resin; preparations and mixtures containing 20 per cent or less thereof. (S4)

Poldine methylsulphate.

Potassium chloride, where the recommended dose is more than 20 millimol of potassium (1 500 milligrams of potassium chloride) per 24 hours, except when intended for intravenous infusion or for injection (S1) and except when contained in oral rehydration preparations.

Povidone iodine, when intended for human vaginal use.

Prifinium bromide.

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

Procyclidine.

Proglumide.

Propantheline bromide.

Propentofylline, when intended for veterinary use.

Propyphenazone.

Pyrodifenium.

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 per cent or more thereof. (S1)

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)

Siccanin, when intended for application to the skin.

Strychnine; preparations and mixtures containing 0.2 per cent or more thereof, except the substance. (S1, S4)

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

Theophylline, when intended for inhalation. (S1, S4)

Thiabendazole, when intended for application to the skin (S4)

Timepidium.

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

Trimebutine.

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

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 and amended by Government Notice No. R.2841 of 7 December, 1990.]

All substances referred to in this Schedule are excluded when specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes.

All substances, preparations and mixtures referred to in this Schedule are also excluded when registered and sold in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

All substances referred to in this Schedule include the following:

(*a*) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(*b*) all preparations and mixtures of such substances, where such preparations and mixtures are not expressly excluded.

Acebutolol.

Acetazolamide.

Acetohexamide.

Acetylcholine, when intended for ophthalmic use.

Acipimox.

Adrenaline (epinephrine); ophthalmic preparations thereof, when intended for glaucoma. (S1, S2, S4)

Alclofenac.

Allopurinol.

Alprenolol.

Amiloride.

5-aminosalicylic acid.

Ancrod.

Anthiolimine, when intended for injection.

Arsanilic acid.

Atenolol.

Atropine; ophthalmic preparations thereof. (S1, S2)

Azapropazone.

Beclamide.

Benfluorex.

Benoxaprofen.

Benzbromarone.

Benzydamine.

Bepridil.

Beta-benzalbutyramide.

Beta-galactosidase, when intended for therapeutic purposes.

Betahistine.

Betaxolol.

Bethanidine.
Bevantolol.
Bezafibrate.
Bisoprolol.
Bopindolol.
Buflomedil.
Buformin.
Bumetanide.
Cadralazine.
Calcium carbimide.
Calcium disodium edetate, when intended for injection.
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.
Chenodeoxycholic acid.
Chlorazanil.
Chlorexolone.
Chlorothiazide and other derivatives of benzo-1,2,4-thiadiazine-7-sulphonamide-1,1-dioxide, whether hydrogenated or not, including hydrochlorothiazide, bendrofluazide, benzthiazide, cyclopenthiazide, hydroflumethiazide, metchlorothiazide and polythiazide.
Chlorpropamide.
Chlorthalidone.
Cholestipol.
Chromonar.
Clofibrate.
Clonidine, except when intended for the treatment of migraine. (S1)
Colchicine.
Copper salts, when intended for injection for veterinary use.
Cyclopentolate; ophthalmic preparations thereof. (S2)
Debrisoquine.
Dichlorphenamide.
Diclophenac, except when intended for application to the skin. (S1)
Diflunisal.
Diftalone.
Dihydroergocristine.
Digitalis; its glycosides and other active principles thereof, unless diluted below one unit (BP) in each 2.0 grams.
Dilevalol.
Diltiazem.
Dimercaprol, when intended for injection.
Dipivefrin.
Dipyridamole.
Dipyrocetyl.
Dithranol.
Doxazosin.
Endralazine.
Escin (aescin), except preparations and mixtures thereof intended for application to the skin and containing 1.0 per cent 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.
Fenbufen.
Fenclofenac.
Fendiline.
Fenofibrate.
Fenoprofen.
Fenoterol, when contained in respirator solutions. (S2, S4)
Fentiazac.
Floctafenine.
Flufenamic acid, except preparations and mixtures intended for application to the skin. (S1)
Flunixim meglumine.
Flurbiprofen, except when intended for ophthalmic use. (S4)
Furosemide.
Gamma globulin, when intended for injection.
Gemfibrozil.
Glafenine.
Glibenclamide.
Glibornuride.
Gliclazide.
Glimidine.
Glipizide.
Guanabenz.
Guanethidine.
Guanfacine.
Guanoxan.
Hexoprenaline, when contained in respirator solutions. (S2, S4)
Homatropine; ophthalmic preparations thereof. (S1, S2)
Hormones (natural or synthetic), when intended for oral contraception. (S1, S4)
Hydralazine.
Hydroquinone: preparations and mixtures thereof containing more than 2,0 per cent hydroquinone. (S2)
Ibuprofen, when specifically intended for the treatment of inflammatory joint diseases. (S2)
Indapamide.
Indomethacin, except when intended for application to the skin. (S1)
Indoprofen.
Indoramin.
Insulin, except in cases of emergency. (S2)
Iron salts, when intended for injection.
Isoniazid and its derivatives, unless listed in another Schedule.
Isoprenaline (isoproterenol), when contained in respirator solutions. (S2, S4)
Isosorbide, except in cases of emergency. (S2)
Isoxicam.
Isradipine.
Ivermectin.
Ketanserin.
Ketoprofen.
Labetalol.
Levobunolol.
Lidoflazine.

Lonazolac.
Meclofenamic acid.
Mefenamic acid.
Mepindolol.
Mesulphene.
Metaproterenol (orciprenaline), when contained in respirator solutions. (S2, S4)
Metformin.
Methimazole.
Methsuximide.
Methyldopa and its esters.
Metipranolol.
Metolazone.
Metoprolol.
Nabumetone.
Nadolol.
Naftidrofuryl.
Naproxen.
Nicardipine.
Nicotine, when intended for human medicinal use.
Nifedipine.
Niflumic acid.
Nimodipine.
Nitrendipine.
Nitroglycerine, when intended for medicinal use, except in cases of emergency. (S2)
Oxaprozin.
Oxcarbazepine.
Oxiracetam.
Oxovinca.
Oxprenolol.
Oxybutynin.
Para-aminosalicylic acid and its esters.
Penbutolol.
Penicillinase, when intended for injection.
Pentaerythritol tetranitrate, except in cases of emergency. (S2)
Pentolinium.
Phenformin.
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.
Piracetam.
Pirbuterol, when contained in respirator solutions. (S2)
Piretanide.
Piroxicam.
Pirprofen.
Potassium canrenoate.
Practolol.
Pralidoxime, when intended for injection.
Prazosin.
Primidone.

Probenecid.
Probucol.
Procaterol, when contained in respirator solutions. (S2)
Proctofene.
Propranolol.
Proquazone.
Proscillaridine.
Prothionamide, when intended for oral use.
Pygeum africanum (lipido-sterolic complex extract thereof).
Pyrazinamide, when intended for oral use.
Pyrithioxin.
Raubasine.
Rauwolfia alkaloids.
Reproterol, when contained in respirator solutions. (S2)
Reserpine (natural or synthetic).
Rimiterol, when contained in respirator solutions. (S2, S4)
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. (S1, S4)
Sotalol.
Spironolactone.
Strophanthus; its glycosides and their hydrolysis products, and their derivatives, unless listed in another Schedule.
Sulindac.
Suloctidil.
Sulphinpyrazone.
Sulthiame.
Suprofen.
Sylimarin.
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.
Tiaprofenic acid.
Timolol.
Tolamolol.
Tolazamide.
Tolbutamide.
Tolfenamic acid.
Tolmetin, except when intended for application to the skin. (S1)
Tretinoin.
Triamterene.
Tricaine.
Trimethadione.
Tropicamide.
Tulobuterol, when contained in respirator solutions. (S2)
Ursodeoxycholic acid.
Valproic acid and its derivatives, unless listed in another Schedule.
Verapamil (iproveratril).
Veratrum alkaloids.
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.

Vitamin D; preparations thereof for injection and oral preparations and mixtures thereof containing more than 500 I.U. per recommended daily dose.

Xamoterol.

Xipamide.

Zinc salts for oral ingestion where the daily dose is more than 50 milligrams of elemental zinc.

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 and amended by Government Notice No. R.2841 of 7 December, 1990.].

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All substances referred to in this Schedule include the following:

(*a*) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(*b*) all preparations and mixtures of such substances, where such preparations and mixtures are not expressly excluded.

Acetarsone diethylamine salt, when intended for injection.

Acyclovir.

Adrenaline, when intended for injection. (S1, S2, S3)

Albendazole.

Alcuronium.

Alisapride.

Almitrine.

Alphacalcidol.

Alpha-chymotrypsin, when intended for ophthalmic use.

Alpha-2-interferon.

Alpha-2b-interferon.

Alprostadil.

Amantadine.

Aminoglutethimide.

Aminopyrine (amidopyrine).

Amiodarone.

Amiphenazole.

Amrinone.

Amsacrine.

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

Antihemophilic factor.

Antimalarials, excluding the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyrimidine groups of compounds and preparations thereof, when these are intended specifically for malaria prophylaxis. (S1)

Antimicrobial substances (chemotherapeutic 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)
clotrimazole; (S2)
gramicidin; (S1)
mupirocin; (S2)
natamycin; (S2)
nystatin; (S2)
polymixin B; (S1)
tyrothricin; (S1)

and except when intended for use as germicides and antiseptics, and except phenoxymethylpenicillin when intended for the prophylaxis of rheumatic fever. (S3)

Antisera for veterinary use.
Apraclonidine.
Aprotinin.
Arabinosylcytosine.
Arsenamide, when intended for injection.
L-Asparaginase.
Atracurium besilate.
Auranofin.
Azathioprine.
Baclofen.
Bee venom, except preparations intended for application to the skin. (S1)
Bemegride.
Benazepril.
Bethanechol.
Biperiden.
Bleomycin.
Bretylium tosylate.
Bromocriptine.
Bufenoide.
Bumadizone.
Buserelin.
Busulphan.
Calcitonin.
Calcitriol.
Calcium polystyrene sulphonate, when intended for therapeutic purposes.
Captopril.
Carbachol, except ophthalmic preparations thereof, when intended for glaucoma. (S3)
Carbidopa.
Carboplatin.
Carbuterol, when intended for injection (S2).
Carmustine.
Ceruletide.
Chlorambucil.
Chlordantoin, when intended for human vaginal use.
Chloroquine, when intended for antirheumatic use (S1).
Cholestyramine resin.
Chymopapain, when intended for injection.
Cimetidine.
Cisapride.
Cisplatin.
Clofazimine.
Clomiphene.

Corticosteroids (natural or synthetic), except hydrocortisone and hydrocortisone acetate, when used as a single active ingredient in a maximum concentration of 0,5 per cent in preparations intended for application to the skin. (S2)

Cotetroxazine

Co-trimoxazole.

Cyclofenil.

Cyclophosphamide and its derivatives, unless listed in another Schedule.

Cyclosporin.

Cyproterone acetate.

Cytarabine.

Dacarbazine.

Dactinomycin (actinomycin D).

Dantrolene.

Dapsone and its derivatives, unless listed in another Schedule, except preparations and mixtures intended specifically for malaria prophylaxis. (S1)

Daunomycin (daunorubicin).

Demecarium.

Diazoxide.

Diclazuril.

Diclodronic acid.

Diethylcarbamazine.

Dihydralazine.

Dihydrotachysterol.

Di-isopropyl fluorophosphate.

Dilazep.

Diloxanide furoate.

Dimethyl sulphoxide.

Dinitrophenol.

Dinoprostone.

Diphemethoxidine.

Diphenidol.

Diprenorphine.

Disodium pamidronate.

Disopyramide.

Distigmine.

Disulfiram.

Ditazol.

Dobutamine.

Dopa.

Dopamine.

Doxapram.

Doxorubicin.

Econazole, except preparations and mixtures when intended for application to the skin (S2).

Edrophonium.

Emetine, except substances, preparations and mixtures containing less than 0.2 per cent of alkaloids, calculated as emetine.

Enalapril.

Encainide.

Enoxacin.

4-epidoxorubicin.

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

Estramustine.

Etidronate.

Ethoglucid.

Etofamide.

Etoposide.

Famotidine.

Fazadinium.

Fenchlorphos.

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

Fertirelin.

Flecainide.

Fluconazole.

Flucytosine, except preparations and mixtures intended for application to the skin. (S2)

Flugestone.

Flunisolide.

5-fluorouracil.

Flurbiprofen, when intended for ophthalmic use. (S3)

Flutamide.

Fosinopril.

Ftorafur.

Furazolidone, when intended for addition to animal feeds. (S2)

Gallamine.

Gestrinone.

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

Goserelin.

Halofantrine.

Halofenate.

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

Heptaminol.

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

Hormones (natural or synthetic), with either hormonal or antihormonal action, except when intended for application to the skin, when intended for human vaginal use and when intended for oral contraception, and excluding insulin and epinephrine (adrenaline). (S1, S2, S3)

Hyaluronic acid-B.

Hycanthone.

Hydroxyurea.

Idoxuridine, except when intended for application to the skin. (S2)

Inosiplex (inosine pranabex).

Intra-uterine devices.

Isoconazole, except when intended for application to the skin. (S2)

Isopirin.

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

Itraconazole.

Ketoconazole, except when intended for application to the skin. (S2)

Levallorphan.

Levamisole.

Lisinopril.

Local anaesthetics, when intended for ophthalmic and parenteral use. (S1)

Lomustine.

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

Mecamylamine.

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.
Metaproterenol (orciprenaline), when intended for the prevention or delay of labour and preparations thereof for injection. (S2)
Metergoline.
Methacholine.
Methampyrone.
Methotrexate.
Methoxsalen.
Methysergide.
Metoclopramide.
Metronidazole.
Mexiletine.
Miconazole, except preparations and mixtures intended for application to the skin. (S2)
Milrinone.
Minoxidil.
Misoprostol.
Mitomycin C.
Mitoxantrone.
Mofebutazone.
Mometasone.
Morazone.
Morphazinamide.
Morphethylbutyne.
Muromonab.
Nalidixic acid.
Nalorphine.
Naloxone.
Naltrexone.
Nefopam.
Neostigmine.
Nifuratel.
Nikethamide.
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)
Nitroxoline.
Nizatidine.
Obidoxime.
Octreotide.
Olsalazine.
Omeprazole.
Ondansetron.
Ornidazole, except when intended for application to the skin. (S1)
Oxamniquine.
Oxolinic acid.
Pancuronium.
Penicillamine.
Pentamidine isethionate.

Perhexiline.

Perindopril.

Phenacetin, except preparations and mixtures intended for external use and containing not more than 0,1 per cent phenacetin as stabilizer.

Phenopyrazone.

Phenoxybenzamine.

Phenylbutazone and its derivatives, unless listed in another Schedule, except preparations intended for application to the skin. (S1)

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

Picrotoxin.

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

Pipemidic acid.

Pirenzepine.

Piribedil.

Piromidic acid.

Podophyllum resin; preparations and mixtures containing more than 20 per cent of podophyllum resin. (S2)

Polyglycerylene-dextran.

Pravastatin.

Praziquantel.

Procaine amide.

Procarbazine.

Propafenone.

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

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

Pyridinolcarbamate.

Pyridostigmine.

Quinapril.

Radio-active compounds, when used for diagnostic purposes.

Ramipril.

Ranitidine.

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

Rimiterol, when intended for injection. (S2)

Ritodrine.

Rosoxacin.

Roxatidine.

Salbutamol, when intended for injection. (S2)

Salmefamol, when intended for injection. (S2)

Selegiline.

Simvastatin.

Sodium aurothiomalate.

Sodium dihydroazapentacene polysulphonate.

Sodium fluoride; preparations and mixtures thereof containing 40 milligrams or more per daily dose.

Sodium nitroprusside.

Solcoseryl, except ophthalmic preparations thereof and except preparations intended for application to the skin, to the mucous membranes of the mouth and to the lips. (S1, S3)

Somatotropin.

Streptokinase.

Strychnine, except preparations and mixtures thereof. (S1, S2)

Styramate.

Sulphonamides, except those substances, preparations and mixtures intended for application to the eyes, nares and vagina. (S1)

Suramin.

Suxamethonium.

Suxethonium.

Tamoxifen.

Teniposide.

Terconazole.

Tetramisole.

Theophylline and its derivatives, unless listed in another Schedule, when intended for injection. (S1, S2)

Thiabendazole, except when intended for application to the skin. (S2)

Thioguanine.

Thymopentin.

Tibolone.

Tin fluoride, when intended for injection.

Tinidazole.

Tioconazole, except when intended for application to the skin. (S2)

Tocainide.

Toltrazuril.

Tranexamic acid.

Treosulfan.

Triethylene thiophosphoramide.

Trifluorothymidine.

Trimetaphane.

Trimethoprim.

Trioxsalen.

Triptorelin.

Tromantadine.

Tubocurarine.

Urapidil.

Urethane.

Urokinase.

Vaccines for veterinary use.

Vanillic acid diethylamide.

Vecuronium bromide.

Vidarabine.

Vinblastine.

Vincristine.

Vindesine.

Zidovudine (AZT).

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 and amended by Government Notice No. R.2841 of 7 December, 1990.]

All substances, preparations and mixtures referred to in this Schedule are excluded when registered and sold in terms of the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

All substances referred to in this Schedule include the following:

(*a*) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(*b*) all preparations and mixtures of such substances, where such preparations and mixtures are not expressly excluded.

Acitretin.

Amitryptiline and its derivatives, unless listed in another Schedule.

Amoxapine.

Anaesthetic preparations containing pregnanedione derivatives.

Aponal.

Apronalide.

Azacyclonol.

Barbituric acid and its derivatives, unless listed in another Schedule, excluding amobarbital, cyclobarbital, pentobarbital, and secobarbital; and except preparations and mixtures containing not more than 30 milligrams per minimum recommended or prescribed dose when intended for continued use in asthma, and not more than 90 milligrams of phenobarbitone per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S1, S2, S6, S7)

Benactyzine and its derivatives, unless listed in another Schedule.

Benfluramate.

Benzoctamine.

Benzodiazepines and their derivatives, unless listed in another Schedule.

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 when used as vasoconstrictors and decongestants in antihistamine nose and eye preparations and except when contained in appliances for inhalation in which the substance is absorbed in solid material and excluding d-norpseudoephedrine, ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and mixtures thereof except substances listed in Schedules 8 and 9 (S1, S2).

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 and non-medicinal laboratory purposes. (S2)

Bromisovalum.

Brotizolam.

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.

Clomacran.

Clomethiazole.

Clopenthixol.

Clothiapine.

Clozapine.

Cyclobenzaprine.

Deanol and its derivatives, unless listed in another Schedule, except when specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes.

Detomidine.

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 per cent in undivided preparations. (S7)

Diprenorphine.

Dothiepin.

Doxepin.

Droperidol.

Drostanolone.

Echothiopate.

Emylcamate.

Enflurane.

Ethclorvynol.

Ethinamate and its derivatives, unless listed in another Schedule.

Etodroxizine, except preparations and mixtures thereof when used solely as an antihistaminic. (S2)

Etomidate.

Etretinate.

Fencamfamine.

Fenfluramine.

Flumazenil.

Fluoxetine.

Flupenthixol.

Fluspirilene.

Fluvoxamine.

Halothane.

Hedonal and its esters, except when specifically packaged, labelled and used for industrial and non-medicinal laboratory purposes.

Heminevrin.

Hydroxyzine.

Imipramine and its derivatives, unless listed in another Schedule.

Iproniazid.

Isoflurane.

Isotretinoin.

Ketamine.

Lithium salts, when intended for medicinal use.

Lofepramine.

Loxapine.

Maprotiline.

Mazindol.

Mechlorethamine and its derivatives, unless listed in another Schedule.

Meclofenoxate.

Melitracene.

Mephenoxalone.

Meprobamate.

Methoxyflurane.

Mianserin.

Moclobemide.

Molindone.

Nalbuphine.

Nomifensine.

Oxypertine.

Paraldehyde.

Pargyline.

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

Phentermine.

Pimethixene, except preparations and mixtures thereof when used solely as an antihistaminic. (S2)

Pimozide.

Pipradol.

Pizotifen, except preparations and mixtures thereof when used solely as an antihistaminic or when intended for the prophylaxis of migraine. (S2)

Prolintane.

Propofol.

Quinupramine.

Sulphonmethane.

Sulpyride.

Tiapride.

Thiguanosine.

Thiothixene.

Tizanidine.

Tramadol.

Tranylcypromine.

Trazodone.

Trihexyphenidyl.

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

Viloxazine.

Xylazine.

Zimelidine.

Zolazepam.

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 and substituted by Government Notice No. 225 of 17 February, 1989.]

All substances referred to in this Schedule include the following:

(*a*) The salts and esters of such substances, where the existence of such salts and esters is possible; and

(*b*) all preparations and mixtures of such substances, where such preparations and mixtures are not expressly excluded.

Amobarbital, cyclobarbital and pentobarbital, except preparations and mixtures containing not more than 30 milligrams per minimum recommended or prescribed dose when intended for continued use in asthma, and not more than 50 milligrams per minimum recommended or prescribed dose when intended for continued use in epilepsy. (S1, S2, S5)

Buprenorphine.

Chlorphentermine.

Diethylpropion (amfepramone).

Glutethimide.

Meptazinol.

Pentazocine.

Tiletamine.

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 and amended by Government Notice No. R.2841 of 7 December, 1990.]

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 specific 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.

Acetorphine.

Acetyldihydrocodeine, except preparations and mixtures containing 20 milligrams or less of acetyldihydrocodeine per recommended or prescribed dose. (S1)

Acetylmethadol.

Alfentanil.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Chlorodyne (Chloroform and Morphine Tincture BP 1980) or any preparation or mixture thereof described as chlorodyne; except preparations and mixtures containing 5,0 per cent or less of chlorodyne in combination with other active medicinal substances. (S1)

Clonitazene.

Coca leaf and any salt, compound, derivative or preparation of coca leaf and any salt, compound, derivative or preparation thereof that is chemically equivalent or identical to any of these substances, whether obtained directly or indirectly by extraction from material or substances obtained from plants, or obtained independently by chemical synthesis, or by a combination of extraction and chemical synthesis, except decocainized coca leaf and extractions of coca leaf where such extractions contain no cocaine or ecgonine.

Codeine (methylmorphine), except preparations and mixtures containing 20 milligrams or less of codeine per recommended or prescribed dose. (S1)

Codoxime.

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 per cent in undivided preparations. (S5)

Diampromide.

Diethylthiambutene.

Difenoxin (or diphenoxylic acid), except mixtures containing, per dosage unit, 0,5 milligrams or less of difenoxin, calculated as the base, and a quantity of atropine sulphate equal to at least 5,0 per cent of such quantity of difenoxin, calculated as the base, as is present in the mixture. (S2)

Dihydrocodeine, except preparations and mixtures containing 20 milligrams or less of dihydrocodeine per recommended or prescribed dose. (S1)

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. (S2)

Dipipanone.

Drotebanol.

Ecgonine, and the esters and derivatives thereof that are convertible to ecgonine and cocaine.

Ethylmethylthiambutene.

Ethylmorphine, except preparations and mixtures containing 20 milligrams or less of ethylmorphine per recommended or prescribed dose. (S1)

Etonitazene.

Etorphine.

Etoxeridine.

Fenproporex.

Fentanyl. (S8)

Furethidine.

Hydrocodone (dihydrocodeinone).

Hydromorphinol (14-hydroxydihydromorphine).

Hydromorphone (dihydromorphinone).

Hydroxypethidine.

Isomethadone.

Ketobemidone.

Levomoramide.

Levophenacylmorphan.

Levorphanol.

Mecloqualone.

Mefenorex.

Metazocine.

Methadone.

Methadone-intermediate.

Methorphan, including levomethorphan and racemethorphan, but excluding dextromethorphan. (S1)

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 per cent or less of morphine, calculated as anhydrous morphine. (S1)

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 containing 20 milligrams or less of norcodeine per recommended or prescribed dose. (S1)

Norlevorphanol.

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. (S1)

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).

Pethidine, pethidine-intermediate A, pethidine-intermediate B and pethidine-intermediate C. (S8)

Phenadoxone.

Phenampromide.

Phenazocine.

Phendimetrazine.

Phenomorphan.

Phenoperidine.

Pholcodine, except preparations and mixtures containing 20 milligrams or less of pholcodine per recommended or prescribed dose. (S1)

Piminodine.

Piritramide.

Proheptazine.

Properidine.

Propiram.

Racemoramide.

Racemorphan.

Secobarbital.

Sufentanil.

Thebacon.

Thebaine.

Tilidine.

(-)-transdelta-9-tetrahydrocannabinol, when intended for therapeutic purposes. (S8)

Trimeperidine.

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 and amended by Government Notices No. R.1133 of 2 June, 1989 and No. R.2841 of 7 December, 1990.]

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 specific 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. (S9)

Bufotenine (N,N-dimethylserotonin).

Cannabis (dagga), the whole plant or any portion or product thereof, except (-)-transdelta-9-tetrahydrocannabinol, when intended for therapeutic purposes. (S7)

Dexamphetamine. (S9)

Diethyltryptamine [3-(2-(diethylamino)-ethyl)-indole].

Dimethyltryptamine [3-(2-(dimethylamino)-ethyl)-indole].

Fentanyl-analogues (unless listed in another Schedule):

acetyl-alpha-methyl-fentanyl;

alpha-methyl-fentanyl;

alpha-methyl-fentanyl-acetanilide;

alpha-methyl-thio-fentanyl;

benzyl-fentanyl;

beta-hydroxy-fentanyl;

beta-hydroxy-3-methyl-fentanyl;

3-methyl-fentanyl 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-fluoro-fentanyl; (S7)

thiofentanyl.

Harmaline (3,4-dihydroharmine).

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

Heroin (diacetylmorphine).

Lysergide (Lysergic acid diethylamide).

Mescaline (3,4,5-trimethoxyphenethylamine).

Methamphetamine and methamphetamine racemate.

Methaqualone and any preparation containing methaqualone.

Methylenedioxyamphetamine (MDA).

N-ethyl-methylenedioxyamphetamine,

N-hydroxy-methylenedioxyamphetamine.

4-methyl-2,5-dimethoxyamphetamine (DOM) and its derivatives.

4 methylaminorex.

Nabilone. (S9)

Pethidine-analogues:

1-methyl-4-phenyl-4-propionoxy-piperidine (MPPP);

1-methyl-4-phenyl-1.2,5,6-tetrahydropiperidine (MPTP); and

1-phenylethyl-4-phenyl-4-acetyloxy-piperidine (PEPAP).

Phencyclidine and its congeners N-ethyl-1-phenylcyclohexylamine (PCE), 1-(1-phenylcyclohexyl) pyrrolidine (PHP or PCPY) and 1-[1-(2-thienyl) cyclohexyl] piperidine (TCP).

Phenmetrazine.

Psilocin (4-hydroxydimethyltryptamine).

Psylocybin (4-phosphoryloxy-N, N-dimethyltryptamine).

Tetrahydrocannabinol.

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 and substituted by Government Notice No. 225 of 17 February, 1989.]

Amphetamine and its salts; preparations thereof. (S8)

Dexamphetamine and its salts; preparations thereof. (S8)

Nabilone.