South Africa

Medicines and Related Substances Control Act, 1965

Act 101 of 1965

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Contents

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[Amended by Drugs Control Amendment Act, 1968 (Act 29 of 1968) on 1 April 1966]
[Amended by Drugs Control Amendment Act, 1968 (Act 29 of 1968) on 3 April 1966]
[Amended by Drugs Control Amendment Act, 1970 (Act 88 of 1970) on 21 October 1970]
[Amended by Drugs Laws Amendment Act, 1971 (Act 95 of 1971) on 6 December 1971]
[Amended by Drugs Control Amendment Act, 1974 (Act 65 of 1974) on 21 February 1975]
[Amended by Medicines and Related Substances Control Amendment Act, 1976 (Act 19 of 1976) on 31 March 1976]
[Amended by Health Laws Amendment Act, 1977 (Act 36 of 1977) on 30 March 1977]
[Amended by Medicines and Related Substances Control Amendment Act, 1979 (Act 17 of 1979) on 21 March 1979]
[Amended by Medicines and Related Substances Control Amendment Act, 1981 (Act 20 of 1981) on 4 March 1981]
[Amended by Transfer of Powers and Duties of the State President Act, 1986 (Act 97 of 1986) on 3 October 1986]
[Amended by Businesses Act, 1991 (Act 71 of 1991) on 24 May 1991]
[Amended by Medicines and Related Substances Control Amendment Act, 1991 (Act 94 of 1991) on 12 July 1991]

[The Act was amended by the substitution, wherever they occur, for the expressions "Department of Health" of the expression "Department of Health Welfare and Pensions", and "Secretary" of the expression "Director-General", by section 8 of Act 20 of 1981.]

(Afrikaans text signed by the State President.)

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 and for matters incidental thereto.

[long title substituted by section 37 of Act 65 of 1974, by section 15 of Act 17 of 1979 and by section 22 of Act 94 of 1991]

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

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

[paragraph (a) substituted by section 1(a) of Act 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 section 1(a) of Act 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 15B(4);

[definition of "certificate of registration" inserted by section 1(b) of Act 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 section 1(c) of Act 20 of 1981 and substituted by section 1(b) of Act 94 of 1991]

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

[definition of "export" inserted by section 1(a) of Act 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 section 1(b) of Act 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 section 1(c) of Act 94 of 1991]

"**medical practitioner**" means a person registered as such under the Medical Act, and includes an intern registered under that Act;

[definition "medical practitioner" substituted by section 1(c) of Act 17 of 1979 and by section 1(d) of Act 94 of 1991]

"**medicinal purpose**", *[definition of "medicinal purpose" deleted by section 1(e) of Act 94 of 1991]*

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

(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 section 1(d) of Act 17 of 1979]

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

[definition of "Minister" substituted by section 1(d) of Act 20 of 1981 and by section 1(f) of Act 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 section 1(g) of Act 94 of 1991]

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

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

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

[definition of "pharmacist" substituted by section 1(e) of Act 17 of 1979 and by section 1(h) of Act 94 of 1991]

"**pharmacist's assistant**" *[definition of "pharmacist's assistant" inserted by section 1(f) of Act 17 of 1979 and deleted by section 1(i) of Act 94 of 1991]*

"**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 section 1(j) of Act 94 of 1991]

"**pharmacy Board**" *[definition of "pharmacy Board" deleted by section 1(k) of Act 94 of 1991]*

"**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 section 1(l) of Act 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 section 1(e) of Act 20 of 1981]

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

"**registered**" means entered in the register;

"**registrar**" means the Registrar of Medicines appointed under section 12;

"**regulation**" means a regulation made and in force under this Act;

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

[definition of "Scheduled substance" substituted by section 1(m) of Act 94 of 1991]

"**Schedule 1 substance**" *[definition of "Schedule 1 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Schedule 2 substance**" *[definition of "Schedule 2 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Schedule 3 substance**" *[definition of "Schedule 3 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Schedule 4 substance**" *[definition of "Schedule 4 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Schedule 5 substance**" *[definition of "Schedule 5 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Schedule 6 substance**" *[definition of "Schedule 6 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Schedule 7 substance**" *[definition of "Schedule 7 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Schedule 8 substance**" *[definition of "Schedule 8 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Schedule 9 substance**" *[definition of "Schedule 9 substance" deleted by section 1(n) of Act 94 of 1991]*

"**Secretary**" *[definition of "Secretary" deleted by section 1(f) of Act 20 of 1981]*

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

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

"**the territory**" *[definition of "the territory" deleted by section 1(o) of Act 94 of 1991]*

"**trainee pharmacist**" *[definition of "trainee pharmacist" deleted by section 1(o) of Act 94 of 1991]*

"**unqualified assistant**" *[definition of "unqualified assistant" deleted by section 1(g) of Act 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 section 1(p) of Act 94 of 1991]

"**veterinary medicine**" means any substance or mixture of substances, other than a stock remedy or farm feed to be registered in terms of the 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 section 1(h) of Act 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 purposes of this Act not be

regarded as being the same medicine as that other medicine if registration thereof is not applied for by the holder of the certificate of registration issued in respect of that other medicine.

[subsection (2) substituted by section 1(i) of Act 17 of 1979 and by section 1(g) of Act 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.

[subsection (3) substituted by section 1(j) of Act 17 of 1979]

[section 1 substituted by section 1(1) of Act 65 of 1974]

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.

[subsection (1), previously unnumbered, numbered by section 2 of Act 94 of 1991]

(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.

[subsection (2) added by section 2 of Act 94 of 1991]

[section 2 substituted by section 2(1) of Act 65 of 1974]

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.

[subsection (1) substituted by section 3(a) of Act 65 of 1974, by section 1 of Act 36 of 1977 and by section 2(a) of Act 17 of 1979, amended by section 46 of Act 97 of 1986, and substituted by section 3(a) of Act 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;

[paragraph (a) substituted by section 3(b) of Act 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;

[paragraph (c) amended by section 3(c) of Act 65 of 1974]

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

[paragraph (d) substituted by section 3(d) of Act 65 of 1974 and by section 3(b) of Act 94 of 1991]

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

[paragraph (e), inserted by section 2(b) of Act 17 of 1979 and substituted by section 3(b) of Act 94 of 1991]

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

[paragraph (f), substituted by section 3(b) of Act 94 of 1991]

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

[paragraph (g), substituted by section 3(b) of Act 94 of 1991]

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

[paragraph (h) added by section 3(b) of Act 94 of 1991]

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

[paragraph (i) added by section 3(b) of Act 94 of 1991]

(j) not more than four other persons.

[paragraph (j) added by section 3(b) of Act 94 of 1991]

[subsection (2) amended by section 46 of Act 97 of 1986]

(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.

[subsection (4) substituted by section 4(1) of Act 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.

[subsection (1) amended by section 46 of Act 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

[paragraph (b) substituted by section 5(a) of Act 65 of 1974, by section 3(b) of Act 17 of 1979 and by section 4(a) of Act 94 of 1991]

(c) *[paragraph (c) substituted by section 5(b) of Act 65 of 1974 and deleted by section 4(b) of Act 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);

[paragraph (c) substituted by section 5(c) of Act 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.

[subsection (3) amended by section 46 of Act 97 of 1986]

(4) *[subsection (4) substituted by section 5(d) of Act 65 of 1974, by section 3(b) of Act 17 of 1979 and deleted by section 4(c) of Act 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.

[subsection (2) substituted by section 6 of Act 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.

[subsection (4) substituted by section 7 of Act 65 of 1974]

10. ***

[section 10 substituted by section 8(1) of Act 65 of 1974, amended by section 4(a) of Act 17 of 1979 and by section 46 of Act 97 of 1986, and repealed by section 5 of Act 94 of 1991]

11. ***

[section 11 amended by section 9(d) of Act 65 of 1974, by section 5 of Act 17 of 1979, by section 46 of Act 97 of 1986 and repealed by section 6 of Act 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 Director-General of the council.

[section 12 substituted by section 10(1) of Act 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.

[section 13 amended by section 11(1) of Act 65 of 1974 and substituted by section 2 of Act 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 section 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.

[paragraph (b) substituted by section 7(a) of Act 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 ofsection 15(10) or section 17(a).

[subsection (3) amended by section 7(b) of Act 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.

[subsection (4) substituted by section 6 of Act 17 of 1979 and by section 7(c) of Act 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.

[section 14 substituted by section 1(1) of Act 29 of 1968 and by section 12 of Act 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

[paragraph (a) substituted by section 8 of Act 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.

[section 15 amended by section 2 of Act 29 of 1968 and substituted by section 13 of Act 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.

[section 15A inserted by section 3 of Act 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.

[section 15B inserted by section 3 of Act 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.

[subsection (1) substituted by section 4(a) of Act 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.

(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.

[subsection (4) substituted by section 4(b) of Act 20 of 1981]

[section 16 amended by section 3 of Act 29 of 1968 and by section 14 of Act 65 of 1974]

17. Notification of registration or cancellation of registration in *Gazette*

(1) 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.

[paragraph (b) substituted by section 5 of Act 20 of 1981]

[section 17 amended by section 4 of Act 29 of 1968 and substituted by section 15 of Act 65 of 1974]

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.

[section 18 substituted by section 16 of Act 65 of 1974 and by section 7 of Act 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.

(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.

(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.

[section 19 amended by section 17 of Act 65 of 1974]

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

(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 subparagraph (iii) of paragraph (a) of that section.

(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.

[section 20 amended by section 18 of Act 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.

(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.

(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).

[section 21 amended by section 19 of Act 65 of 1974]

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.

[paragraph (b) substituted by section 6 of Act 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.

[section 22 substituted by section 20 of Act 65 of 1974 and by section 8 of Act 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.

[subsection (1) substituted by section 7 of Act 71 of 1991]

(2) *[subsection (2) deleted by section 7 of Act 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.

[subsection (3) amended by section 9(a) of Act 17 of 1979 and by section 7 of Act 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.

[subsection (4) substituted by section 9(b) of Act 17 of 1979]

(5) (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

[paragraph (a) substituted by section 9(c) of Act 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 pharmaceuticals 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

[paragraph (c) substituted by section 9(d) of Act 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

[paragraph (a) amended by section 9(e) of Act 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

[paragraph (c) substituted by section 9(f) of Act 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.

[paragraph (d) amended by section 9(g) of Act 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

[subparagraph (i) substituted by section 9(h) of Act 17 of 1979]

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

[paragraph (e) substituted by section 9(i) of Act 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 above-mentioned 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.

[paragraph (f) substituted by section 9(j) of Act 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.

[paragraph (g) substituted by section 9(k) of Act 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.

(bA) 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.

[paragraph (bA) inserted by section 9(l) of Act 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 abovementioned 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.

[paragraph (f) substituted by section 9(m) of Act 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.

[paragraph (g) substituted by section 9(n) of Act 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) *[subsection (13) deleted by section 9(o) of Act 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) (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 his 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 any 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;

[paragraph (c) inserted by section 9(p) of Act 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 prescription 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.

[paragraph (d) added by section 9(p) of Act 17 of 1979]

[section 22A inserted by section 21 of Act 65 of 1974]

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.

[section 22B inserted by section 10 of Act 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 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.

(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.

(3) No person shall sell any medicine which is the subject of a notice under sub-section (1) which has not been set aside on appeal.

[section 23 amended by section 22 of Act 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 oi 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 piace 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.

[section 24 amended by section 23 of Act 65 of 1974 and substituted by section 11 of Act 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.

[subsection (1) substituted by section 10 of Act 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.

[subsection (2) substituted by section 1 of Act 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 thereby, the certificate referred to in subsection (2).

[section 26 substituted by section 24(1) of Act 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.

[section 27 substituted by section 25(1) of Act 65 of 1974 and by section 11 of Act 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;

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

(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;

(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.

[subsection (1) amended by section 26(a) of Act 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 form 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.

[subsection (2) amended by section 26(a) of Act 65 of 1974 and substituted by section 12(a) of Act 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.

[subsection (3) substituted by section 12(b) of Act 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.

[subsection (4) substituted by section 26(b) of Act 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

[paragraph (h) substituted by section 27(a) of Act 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

[paragraph (i) substituted by section 27(b) of Act 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

[paragraph (j) amended by section 27(c) of Act 65 of 1974]

(k) contravenes any provision of section 22A or contravenes or fails to comply with any condition imposed thereunder,

[paragraph (k) added by section 27(d) of Act 65 of 1974]

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

[paragraph (l) added by section 12 of Act 94 of 1991]

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

[paragraph (m) added by section 12 of Act 94 of 1991]

shall be guilty of an offence.

30. Penalties

(1) Any person who is convicted of an offence referred to in section 29 shall be liable to a fine not exceeding R40 000 or to imprisonment for a period not exceeding 10 years or to both such fine and such imprisonment.

[subsection (1) substituted by section 13 of Act 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.

[subsection (2) amended by section 28(a) of Act 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.

[subsection (3) substituted by section 28(b) of Act 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;

[paragraph (a) amended by section 29 of Act 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.

[paragraph (d) amended by section 29 of Act 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 prosecution, been handed or transmitted by registered post to the person who is to be the accused.

[subsetion (2) substituted by section 13 of Act 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 a 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

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

[section 32 amended by section 30 of Act 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.

[section 34 substituted by section 14 of Act 94 of 1991]

34A. Delegation of powers

(1) The Minister may in writing authorize 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.

[section 34A inserted by section 2 of Act 19 of 1976 and substituted by section 15 of Act 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;

[paragraph (i) substituted by section 7 of Act 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;

[paragraph (viA) inserted by section 16(a) of Act 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 suitability and effect, purity or any other property;

(xi) prescribing the conditions on which Schedule 1 substances or certain specitied Schedule 1 substances may be sold under section 22A(1);

[paragraph (xi) substituted by section 7 of Act 71 of 1991]

(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;

[paragraph (xii) substituted by section 16(b) of Act 94 of 1991]

(xiii) *[paragraph (xiii) deleted by section 7 of Act 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) prescribing the conditions on which a person referred to in section 22A (15)(b) may carry and sell such Scheduled substances as are referred to in that section;

(xvi) prescribing the conditions on which Schedule 1 substances or certain specified Schedule 1 substances may be sold under section 22A(1);

[paragraph (xvi) substituted by section 7 of Act 71 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 Schedule 6 and Schedule 7 substances and specified Schedule 5 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;

(xix) as to the transhipment or the exportation from or importation to the Republic or the territory of any Schedule 5, Schedule 6, Schedule 7, Schedule 8 or Schedule 9 substance, and specifying the ports or places at which such substance may be brought into the Republic or the territory;

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

(xxi) prescribing the manner in which packages containing Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substances shall be labelled when imported into or manufactured in the Republic or the territory and the persons by whom and the manner in which they shall be kept;

(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;

[paragraph (xxiii) substituted by section 3(a) of Act 19 of 1976]

(xxiv) authorizing and regulating the purchase, acquisition, keeping, administration or use of Scheduled substances by persons registered or enrolled as nurses, midwives or nursing assistants in terms of the Nursing Act, 1957 (Act No. 69 of 1957);

(xxv) authorizing and regulating the possession by persons entering or departing from the Republic or the territory of specified quantities of Schedule 5, Schedule 6, Schedule 7 and Schedule 9 substances for personal medicinal use;

(xxvA) as to the disposal or destruction of a Scheduled substance included in Schedule 8 in terms of section 37A, and the records which shall be kept in respect thereof;

[paragraph (xxvA) inserted by section 14(a) of Act 17 of 1979]

(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;

[paragraph (xxvB) inserted by section 14(a) of Act 17 of 1979]

(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 a Scheduled substance which has become unfit for use, and the report to be furnished in respect thereof;

[paragraph (xxviA) inserted by section 3(b) of Act 19 of 1976 and substituted by section 14(b) of Act 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;

[paragraph (xxvii) substituted by section 14(c) of Act 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, the fee to be paid annually to the registrar in respect of the retention of the registration of a medicine and the date on which the lastmentioned fee shall be so paid;

[paragraph (xxx) substituted by section 14(d) of Act 17 of 1979]

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

[paragraph (xxxA) inserted by section 16(i) of Act 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;

[paragraph (xxxB) inserted by section 16(i) of Act 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.

[subsection (7) substituted by section 16(j) of Act 94 of 1991]

[section 31 amended by section 5 (1)(a), (1)(b) and (1)(c) of Act 29 of 1968, by section 1 of Act 88 of 1970, by section 7 of Act 95 of 1971 and substituted by section 31(1) of Act 65 of 1974]

36. Exclusion of any medicine 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 of the provisions of this Act, and may in like manner amend or withdraw any such notice.

[section 36 amended by section 32 of Act 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.

[section 36A inserted by section 17 of Act 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.

[section 37 substituted by section 33 of Act 65 of 1974 and by section 18 of Act 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.

[section 37A inserted by section 34 of Act 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. ***

[section 39 repealed by section 20 of Act 94 of 1991]

40. Short title

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

Schedule 1

All preparations and admixtures which are not included in Schedule 2 and contain a substance listed in this Schedule or in Schedule 2, except substances, preparations and admixtures excluded specifically from this Schedule.

Acetanilide and alkyl acetanilides.

Acetyldihydrocodeine; preparations containing 2,5 per cent or less acetyldihydrocodeine.

Alclofenac.

All preparations for injection, unless otherwise scheduled.

Amyl nitrite.

Anethole trithione.

Antibiotics for external use which are exempted from the provisions of Schedule 5.

Anticoagulants; preparations and admixtures thereof intended for external use. Antimalarials; preparations containing substances in the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyrimidine groups of compounds when intended specifically for malaria prophylaxis.

Barbituric acid, its salts or derivatives and salts of barbituric acid derivatives; admixtures thereof containing 15 milligrams or less per minimum prescribed or recommended dose of any of these in combination with other medicines and such admixtures intended solely for continued use in asthma and epilepsy.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene; such preparations and admixtures thereof as are exempted from the provisions of Schedule 6.

Camylofin and its salts.

Chlormezanone; admixtures thereof containing 100 milligrams or less per minimum recommended or prescribed dose.

Chloroform; all substances, preparations and admixtures containing more than 20 per cent Clonidine and its salts; preparations and admixtures thereof when intended for the treatment of migraine.

Cocaine; preparations containing 0,1 per cent or less cocaine, calculated as cocaine alkaloid. Codeine (methylmorphine); admixtures containing 2,5 per cent or less codeine. Cresol and phenol; all preparations and admixtures containing 3,0 per cent or more of any one of these substances.

Dicyclomine and its salts.

Diphenoxylate; admixtures containing 2,5 milligrams or less of diphenoxylate, calculated as base, per dosage unit.

Epinephrine and its salts.

Escin (aescin) and its salts; preparations and admixtures thereof intended for external use and containing 1,0 per cent or less escin.

Ethacridine and its salts.

Ether (diethyl ether).

Ethylmorphine; admixtures containing 2,5 per cent or less ethylmorphine.

Ethylphenylephrine.

Fenoterol and its salts.

Flufenarnic acid and its salts; preparations and admixtures thereof intended for external use.

Hexamine.

Hexoprenaline and its salts.

Hormones (natural or synthetic); such preparations thereof intended solely for topical application to the epidermis or for vaginal use.

Isoproterenol and its salts.

Ketoprofen.

Lead acetate.

Lead plaster and its combinations.

Local anaesthetics; preparations for topical application to the skin or mucous membranes. Mercuric iodide.

Mercuric oxides; substances, preparations and admixtures thereof except those containing less than 3,0 percent of mercury.

Mercuric ammonium chloride.

Metaproterenol and its salts.

Methylacetanilide.

Morphine; admixtures containing 0,2 per cent or less morphine calculated as anhydrous morphine.

Naproxen.

Nonoxynol.

Oral antidiabetic preparations.

Phenacetin.

Phenylephrine and its salts; preparations and admixtures thereof, except eye drops containing 0,2 per cent or less phenylephrine or its salts.

Pholcodine; admixtures containing 2,5 per cent or less pholcodine.

Piracetam.

Potassium dichromate.

Propylhexedrine and its salts; nose drops and preparations for inhalation containing the above substances.

Pyridoxilate; preparations and admixtures thereof.

Quinine and its salts; preparations and admixtures thereof containing more than 1,0 per cent.

Sodium cromoglycate.

Sulfonamides; preparations and admixtures thereof intended for external use.

Terbutaline and its salts.

Tretinoin.

[Schedule 1 added by section 36 of Act 65 of 1974]

Schedule 2

Aconite alkaloids; substances, preparations and admixtures containing 0,02 per cent or more.

Alkaloids and glycosides; all poisonous alkaloids and glycosides, and their salts, not specifically named in any Schedule; substances, preparations and admixtures containing in each single dose more than one-half of the maximum dose of the poison shown in any recognized formulary declared to be such by the Minister by notice in the *Gazette*.

Antihistaminics, except when intended specifically for the treatment of travel sickness or topical application.

Antimony potassium tartrate and antimony sodium tartrate; substances, preparations and admixtures containing 1,0 per cent or more thereof.

Antipyrine (phenazone) and its salts; preparations and admixtures thereof, except preparations and admixtures intended for external use.

Apomorphine; substances, preparations and admixtures containing 0,2 per cent or more.

Aptocaine and its salts; preparations and admixtures thereof.

Arsenic; substances, preparations and admixtures containing 0,01 per cent or more of the equivalent of arsenic trioxide.

"AS XVII" (Spasmo-urgenin).

Atropine; substances, preparations and admixtures containing 0,1 per cent or more.

Belladonna alkaloids; substances, preparations and admixtures containing 0,1 per cent or more, except belladonna plasters.

Calabar bean alkaloids and their salts; substances, preparations and admixtures containing 0,2 per cent or more.

Calcium dobesilate.

Camphorated Opium Tincture B.P.

Cantharidin; substances, preparations and admixtures containig 0,01 per cent or more Chloroform.

Cyclandelate.

Cyclopentolate.

Dextromethorphan and its salts.

Dimenhydrinate; preparations and admixtures thereof.

Dipyridamole.

Dithiazanine and its salts; preparations and admixtures thereof.

Emepronium bromide.

Ephedra alkaloids (natural or synthetic) and their salts; substances, preparations and admixtures thereof, except preparations and admixtures for external use containing not more than one per cent, and other preparations and admixtures containing not more than 30 milligrams per dose of ephedrine or ephedra alkaloids.

Epinephrine (adrenaline) and its salts; preparations and admixtures thereof.

Ergot alkaloids (natural or synthetic) and their salts; preparations and admixtures thereof.

Fenoterol and its salts; preparations and admixtures thereof. Flavoxate hydrochloride.

Flucytosine; preparations and admixtures thereof when intended for external use.

Furazolidone and its salts; preparations and admixtures thereof.

Gelsenium alkaloids; substances, preparations and admixtures containing 0,1 per cent or more.

Glycopyrronium bromide.

Hexoprenaline and its salts; preparations and admixtures thereof.

Hyoscine; substances, preparations and admixtures containing 0,1 per cent or more.

Inhalants containing epinephrine, fenoterol, hexoprenaline, isoproterenol, metaproterenol, salbutamol or the salts of the above substances in any amount.

Isoprenaline (isoproterenol) and its salts; preparations and admixtures thereof.

Lobelia alkaloids; substances, preparations and admixtures containing 0,5 per cent or more.

Metaproterenol (Orciprenaline) and its salts; preparations and admixtures thereof.

Mercuric chloride; substances, preparations and admixtures containing one per cent or more.

Mercuric organic compounds; preparations and admixtures thereof, except substances, preparations and admixtures not being in the form of aerosols intended for topical application to the skin or mucous membranes and containing less than the equivalent of 0,6 percent of mercury.

Naloxone hydrochloride.

Nitrofurazone and its salts; preparations and admixtures thereof.

Nux vomica; substances, preparations and admixtures containing 0,2 per cent or more of strychnine.

Oleoresin of Aspidium (Filix Mas); preparations and admixtures thereof.

Papaverine; substances, preparations and admixtures containing 0,2 per cent or more.

Phenylephrine and its salts; preparations and admixtures of the above substances, except eye drops containing 0,2 per cent or less thereof.

Phenylpropanolamine; preparations and admixtures thereof.

Pilocarpine; substances, preparations and admixtures containing 0,5 per cent or more.

Pimethixene.

Procaine and its salts when used internally.

Procyclidine and its salts; preparations and admixtures thereof.

Propyphenazone; preparations and admixtures thereof.

Pyrodifenium bromide.

Sabadilla alkaloids; substances, preparations and admixtures containing 1,0 per cent or more.

Strychnine; substances, preparations and admixtures containing 0,2 per cent or more

[Schedule 2 added by section 36 of Act 65 of 1974]

Schedule 3

Allopurinol; preparations and admixtures thereof.

Chromonar and its salts; preparations and admixtures thereof.

Clofibrate; preparations and admixtures thereof.

Digitalis, its glycosides and other active principles thereof unless diluted below one Lnit (B.P.) in each two grams.

Insulin; preparations and admixtures thereof.

Isoniazid and its derivatives; preparations and admixtures thereof.

Para-aminosalicylic acid and its salts and esters; preparations and admixtures thereof. Phenytoin and its salts; preparations and admixtures thereof.

Strophanthus, its glycosides and their hydrolysis products, their salts and derivatives; preparations and admixtures thereof.

Thyroid gland and its active principles and derivatives; preparations and admixtures thereof.

Trimethadione; preparations and admixtures thereof.

[Schedule 3 added by section 36 of Act 65 of 1974]

Schedule 4

Acetazolamide and its salts; preparations and admixtures thereof.

Alprenalol and its salts; preparations and admixtures thereof.

Amantadine and its salts; preparations and admixtures thereof.

Aminopyrine (amidopyrine) and its salts; preparations and admixtures thereof.

Antihemophilic Factor; preparations and admixtures thereof.

Antimalarials; preparations thereof except the 4-aminoquinoline, 8-arninoquinoline, digu-anide and diaminopyridine groups of compounds and preparations thereof when these are intended specifically for malaria prophylaxis.

Antimicrobial substances (chemotherapeutic substances) synthesised in-nature or laboratory, being substances used in the specific treatment of infections; preparations and admixtures containing them, except the following when intended for topical application to the epidermis:

bacitracin

tyrothricin

nystatin

polymixin B

framycetin

neomycin

natamycin

gramicidin

and except when intended to be used as germicides and antiseptics, and except those substances, preparations and admixtures registered and sold under the provisions qf the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1917 (Act No. 36 of 1947).

Azapropazone; preparations and admixtures thereof.

Baclofen; preparations and admixtures thereof.

Bee venom; preparations and admixtures thereof, except preparations for external application.

Benzbromarone; preparations and admixtures thereof.

Bufenolide; preparations and admixtures thereof.

Carbidopa; preparations and admixtures thereof.

Chlorothiazide and other derivatives of benzo-1, 2, 4-thiadiazine-7-sulfonamide-1, 1-dioxide, whether or not hydrogenated, including hydrochlorothiazide, bendroflumethiazide, benzthiazide, cyclothiazide, hydroflumethiazide, methchlorothiazide; preparations and admixtures thereof.

Chlortalidone and its salts; preparations and admixtures thereof.

Cholestyramine resin; preparations and admixtures thereof.

Clofazimine; preparations and admixtures thereof.

Chloriine and its salts; preparations and admixtures thereof, except preparations and admixtures intended for the treatment of migraine.

Corticosteroids (natural or synthetic); preparations and admixtures thereof.

Cyclofenil; preparations and admixtures thereof.

Dapsone and its derivatives; preparations and admixtures thereof, except preparations intended specifically for malaria prophylaxis and except products which are registered under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

Debrisoquine and its salts; preparations and admixtures thereof.

Diazoxide; preparations and admixtures thereof.

Di-isopropyl fluorophosphate; preparations and admixtures thereof.

Dimethyl sulfoxide; preparations and admixtures thereof.

Dinitrophenol and its salts; preparations and admixtures thereof.

Diphenhydramine and its salts; preparations and admixtures thereof.

Diphenidol and its salts; preparations and admixtures thereof.

Dipyridamole; preparations and admixtures thereof.

Disulfiram; preparations and admixtures thereof.

Dopa; preparations and admixtures thereof.

Etafedrine and its salts; preparations and admixtures thereof.

Escin (escin) and its salts; preparations and admixtures thereof, except preparations and admixtures for external use containing 1,0 or less percent escin.

Ethacrynic acid and its salts; preparations and admixtures thereof.

Ethambutol and its salts; preparations and admixtures thereof.

Ethionamide; preparations and admixtures thereof.

Eyedrops containing local anaesthetics.

Flucytosine; preparations and admixtures thereof, except preparations and admixtures intended for external use.

Flufenamic acid and its salts; preparations and admixtures thereof, except preparations and admixtures intended for external use.

Furosemide; preparations and admixtures thereof.

Glaphepine; preparations and admixtures thereof.

Guanacline and its salts; preparations and admixtures thereof.

Halofenate; preparations and admixtures thereof.

Hormones (natural or synthetic); preparations and admixtures thereof, except those preparations and admixtures intended solely for topical application to the epidermis, and except preparations for vaginal use, and except those registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), and except insulin and epinephrine (adrenaline).

Indapamide; preparations and admixtures thereof.

Indomethacin and its salts; preparations and admixtures thereof.

Local anaesthetics; preparations and admixtures thereof, except preparations for external application to the skin and mucous membranes.

Mefenamic acid and its salts; preparations and admixtures thereof.

Mephenternine and its salts; preparations and admixtures thereof.

2-Mercaptoimidazoline; preparations and admixtures thereof.

Methanamphrone; preparations and admixtures thereof.

Methyldopa and its salts; preparations and admixtures thereof.

Methysergide and its salts; preparations and admixtures thereof.

Morphazinamide and its salts; preparations and admixtures thereof.

Morphethylbutyne hydrochloride; preparations and admixtures thereof.

Nalidixic acid; preparations and admixtures thereof.

Nalorphine hydrobromide; preparations and admixtures thereof.

Niflumic acid; preparations and admixtures thereof.

Niridazole; preparations and admixtures thereof.

Nitrofurantoin and its salts; preparations and admixtures thereof.

Nitroxoline and its salts; preparations and admixtures thereof.

Oxolinic acid; preparations and admixtures thereof.

Oxprenalol and its salts; preparations and admixtures thereof.

Pancuronium and its salts; preparations and admixtures thereof.

Penicillamine; preparations and admixtures thereof.

Pentoxifylline; preparations and admixtures thereof.

Perhexiline maleate; preparations and admixtures thereof.

Phentolamine and its salts; preparations and admixtures thereof.

Phenylbutazone and its salts; preparations and admixtures thereof, except preparations for topical application to the epidermis.

Picrotoxin; preparations and admixtures thereof.

Polyglycerylene-dextran and its salts; preparations and admixtures thereof.

Potassium canrenoate; preparations and admixtures thereof.

Practolol and its salts; preparations and admixtures thereof.

Prazosin and its salts; preparations and admixtures thereof.

Prindolol; preparations and admixtures thereof.

Procaine amide; preparations and admixtures thereof.

Propanediol derivatives and their salts; preparations and admixtures thereof, except guaiphenesin and chlorphenesin.

Propranolol and its salts; preparations and admixtures thereof.

Propylhexedrine and its salts; preparations and admixtures thereof, except when used as a vasoconstrictor and decongestant in nose drops and appliances for inhalation.

Protionamide; preparations and admixtures thereof.

Pyrazinamide; preparations and admixtures thereof.

Rauwolfia serpentina; preparations and admixtures containing 0,1 or more percent of its alkaloids or their derivatives.

Sodium nitroprusside; preparations and admixtures thereof.

Styramate; preparations and admixtures thereof.

Sulfonamides; substances, preparations and admixtures thereof, except those substances, preparations and admixtures intended for external use, and except those substances, preparations and admixtures registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

Tamoxifen and its salts; preparations and admixtures thereof.

Thiacetozone; preparations and admixtures thereof.

Tilidine and its salts; preparations and admixtures thereof.

Toxogonin and its salts; preparations and admixtures thereof.

Tranexamic acid; preparations and admixtures thereof.

Triamterene.

Verapamil (ipoveratril) and its salts; preparations and admixtures thereof.

Veratrum alkaloids; preparations and admixtures thereof.

[Schedule 4 added by section 36 of Act 65 of 1974]

Schedule 5

Amitryptiline and its derivatives and their salts; preparations and admixtures thereof.

Anaesthetic preparations containing preparations and admixtures.

Anticoagulants; preparations and admixtures thereof, except when used as rodenticides and vermicides, and except preparations for external application.

Aponal; preparations and admixtures thereof.

Apronalide; preparations and admixtures thereof.

L-Asparaginase; preparations and admixtures thereof.

Azacyclonol and its salts; preparations and admixtures thereof.

Barbituric acid, its derivatives and salts thereof; preparations and admixtures thereof, except when containing 15 or less milligrams per minimum recommended or prescribed dose of any of these in combination with other medicines and except admixtures containing not more than 30 milligrams per minimum recommended or prescribed dose where intended for continued use in asthma and epilepsy.

Benactyzine, its derivatives and their salts; preparations and admixtures thereof.

Benzoctamine and its salts; preparations and admixtures thereof.

Benzquinamide and its salts; preparations and admixtures thereof.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene, and 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 ring closure) and any salt or substance falling under the above and preparations and admixtures thereof (except preparations and admixtures of the above when used as vasoconstrictors and decongestants in anti-histamine nasal and eye drops, and except when contained in appliances for inhalation in which the substance is absorbed in solid material, and except ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylphedrine, phenylpropanolamine, prenylamine and preparations and admixtures thereof.)

Bromazepam; preparations and admixtures thereof.

Bromisovalum; preparations and admixtures thereof.

Busulphan and its salts; preparations and admixtures thereof.

Butriptyline and its salts; preparations and admixtures thereof.

Butyrophenones; preparations and admixtures thereof.

Carbamazepine; preparations and admixtures thereof.

Carbromal; preparations and admixtures thereof.

Chloral derivatives; preparations and admixtures thereof.

Chloramhucil and its salts; preparations and admixtures thereof.

Chlordiazepoxide and its salts; preparations and admixtures thereof.

Chlormezanone; preparations and admixtures thereof, except admixtures containing 100 or less milligrams of chlormezanone per minimum recommended or prescribed dose.

Clobenzazepam; preparations and admixtures thereof.

Clonazepam; preparations and admixtures thereof.

Clothiapine ; preparations and admixtures thereof.

Clozapine; preparations and admixtures thereof.

Deanol and its derivatives; preparations and admixtures thereof.

Dextropopoxyphene and its salts; preparations and admixtures thereof.

Diazepam; preparations and admixtures thereof.

Dibenzepin and its salts; preparations and admixtures thereof.

Diopotassium chlorazepate; preparations and admixtures thereof.

Dothiepin and its salts; preparations and admixtures thereof.

Doxepin and its salts; preparations and admixtures thereof.

Echothiopate ioidide; preparations and admixtures thereof.

Enflurane; preparations and admixtures thereof.

Ethinamate, its derivatives and their salts; preparations and admixtures thereof.

Ethchlorvynol and its salts; preparations and admixtures thereof.

Fencamfamine and its salts; preparations and admixtures thereof.

5-Fluorouracil; preparations and admixtures thereof.

Flurazepam and its salts; preparations and admixtures thereof.

Halothane.

Hedonal and its salts and esters; preparations and admixtures thereof.

Hydroxyurea; preparations and admixtures thereof.

Hydroxyzine and its salts; preparations and admixtures thereof.

Imipramine, its derivatives and their salts; preparations and admixtures thereof.

Iproniazid and its salts; preparations and admixtures thereof.

Ketamine and its salts; preparations and admixtures thereof.

Lithium salts; preparations and admixtures thereof, when intended for human use.

Lorazepam; preparations and admixtures thereof.

Maprotiline mesylate; preparations and admixtures thereof.

Mazindol; preparations and admixtures thereof.

Meclofenoxate and its salts; preparations and admixtures thereof.

Medazepam; preparations and admixtures thereof.

Melphalan, its derivatives and their salts; preparations and admixtures thereof.

Mephenoxalone; preparations and admixtures thereof.

Mephenternmine and its salts; preparations and admixtures thereof.

Meprobamate; preparations and admixtures thereof.

6-Mercaptopurine, its derivatives and their salts; preparations and admixtures thereof.

Methylphynidate and its salts; preparations and admixtures thereof.

Metoclopramide.

Molindone and its salts; preparations and admixtures thereof.

Nitrazepam; preparations and admixtures thereof.

Oxazepam; preparations and admixtures thereof.

Oxyperitine and its salts; preparations and admixtures thereof.

Paraldehyde; preparations and admixtures thereof.

Pargyline and its salts; preparations and admixtures thereof.

Pemoline and its complexes; preparations and admixtures thereof.

Phenethylbiguanide and its salts; preparations and admixtures thereof.

Phenothiazine, its derivatives and their salts; preparations and admixtures thereof except preparations containing promethazine or its salts when specially intended for the treatment of travel sickness or local

application to the epidermis, and except those registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).

Phentermine and its salts; preparations and admixtures thereof.

Piperadrol and its salts; preparations and admixtures thereof.

Pregnanedione.

Prolintane and its salts; preparations and admixtures thereof.

Sulfonmethane; preparations and admixtures thereof.

Sulpyride; preparations and admixtures thereof.

Temazepam; preparations and admixtures thereof.

Thiothixene and its salts; preparations and admixtures thereof.

Tranylcypromine and its salts; preparations and admixtures thereof.

Trazodone and its salts; preparations and admixtures thereof.

Trihexyphenidyl and its salts; preparations and admixtures thereof.

Urethan; preparations and admixtures thereof.

[Schedule 5 added by section 36 of Act 65 of 1974]

Schedule 6

Barbiturates, being amobarbital, cyclobarbital, pentobarbital, secobarbital and their salts; preparations and admixtures thereof.

Chlorphentermine and its salts; preparations and admixtures thereof.

Diethylpropion and its salts; preparations and admixtures thereof.

Glutethimide, preparations and admixtures thereof.

Methaqualone and its salts; preparations and admixtures thereof.

Pentazocine and its salts; preparations and admixtures thereof.

[Schedule 6 added by section 36 of Act 65 of 1974]

Schedule 7

All the substances mentioned in this Schedule include.—

(a) the isomers of the substances where the existence of such isomers is possible in the specific chemical compounds;

(b) the esters and ethers of the substances and the isomers thereof where the existence of such esters and ethers is possible;

(c) the salts of the substances or the isomers thereof or of the esters or ethers of the substances or the isomers thereof, where the existence of such salts is possible;

(d) all the preparations and admixtures of the substances where such preparations and admixtures are not expressly excluded.

Acetorphine.

Acetyldihidrocodeine, excluding admixtures containing not more than 2,5 per cent acetyldihydrocodeine.

Acetylmethadol.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmoephine.

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Chlorodyne (Tincture of Chloroform and Morphine B.P.C. 1963) or any preparation or admixture thereof described as chlorodyne and containing morphine in any proportion, except admixtures containing not more than 5,0 per cent chlorodyne in combination with other medicines in such a manner that it cannot be recovered by readily applicable means or cannot be recovered in a yield which would constitute a risk to public health.

Clonitazene.

Cocaine, excluding admixtures containing not more than 0,1 per cent cocaine, calculated as cocaine alkaloid.
Codeine (methylmorphine), excluding admixtures containing not more than2,5 per cent codeine.

Codoxime.

Concentrate of poppy straw.

Desomorphine.

Dextromoramide.

Diampromide.

Diethylthiambutene.

Difenoxine (or diphenoxylic acid); any preparation of difenoxine containing, per dosage unit, a maximum of 0,5 milligram of difenoxine, calculated as base, and a quantity of atropine sulphate equal to at least 5,0 per cent of the quantity of difenoxine, calculated as base, which is present in the mixture.

Dihydrocodeine, excluding admixtures containing not more than 2,5 per cent dihydrocodeine.

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene.

Dioxaphetylbutyrate.

Diphenoxylate, excluding admixtures containing not more than 2,5 milligrams of diphenoxylate calculated as base.

Dipipanone.

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

Ethylmethylthiambutene.

Ethylmorphine, excluding admixtures containing mot more than 2,5 per cent ethylmorphine.

Etonitazene.

Etorphine.

Etoxeridine.

Fentanyl.

Furethidine.

Hydrocodone (dihydrocodeinone).

Hydromorphinol (14-hydroxydihydromoephine).

Hydromorphone (dihydromorphinone).

Hydroxypethidine.

lsomethadone.

Ketobemidone.

Levomoramide.

Levophenacylmorphan.

Levorphanol.

Mefenorex.

Metazocine.

Methadone.

Methadone—intermediate.

Methorphan, including levomethorphan and racemethorphan, but excluding dextromethorphan.

Methyldesorphine.

Methyldihydromorphine.

Methylphenidate and its derivatives.

Metopon.

Morarnide-intermediate.

Morpheridine.

Morphine, excluding preparations and admixtures of morphine containing not more than 0,2 per cent morphine, calculated as anhydrous morphine, and except admixtures from which morphine cannot be recovered by readily applicable means or cannot be recovered in such a quantity that it would constitute a risk to public health. (See also Chlorodyne.)

Morphine methobromide and other pentavalent nitrogen morphine derivatives.

Morphine-N-oxide and its derivatives.

Myrophine (myristylbenzylmorphine).

Nicocodine.

Nicodicodine.

Nicomorphine.

Noracymethadol.

Norcodeine, excluding admixtures containing not more than 2,5 per cent norcodeine.

Norlevorphanol.

Normethadone.

Normorphine (demethylmorphine or N-demethylated morphine).

Norpipanone.

Opium, excluding admixtures containing not more than 0,2 per cent morphine calculated as anhydrous morphine. (See also Chlorodyne.)

Nicocodine.

Nicodicodine.

Nicomorphine.

Noracymethadol.

Norcodeine, excluding admixtures containing not more than 2,5 per cent norcodeine.

Norlevorphanol.

Normethadone.

Normorphine (demethylmorphine or N-demethylated morphine).

Norpipanone.

Opium, excluding admixtures containing not more than 0,2 per cent morphine calculated as anhydrous morphine. (See also Chlorodyne.)

Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).

Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).

Pethidine, pethidine-intermediate-A, pethidine-intermediate-B and pethidine-intermediate-C

Phenadoxone.

Phenampromide.

Phenazocine.

Phencyclidine.

Phendimetrazine.

Phenomorphan.

Phenoperidine.

Pholcodine, excluding admixtures containing not more than 2,5 per cent pholcodine.

Piminodine.

Piritramide.

Proheptazine.

Properidine.

Propiram.

Racemoramide.

Racemorphan.

Thebacon.

Thebaine.

Trimeperidine.

[Schedule 7 added by section 36 of Act 65 of 1974]

Schedule 8

All the substances mentioned in this schedule include—

(a) the isomers of the substances where the existence of such isomers is possible in the specific chemical compounds ;

(b) the esters and ethers of the substances and the isomers thereof where the existence of such esters and ethers is possible;

(c) the salts of the substances or the isomers thereof or of the esters or ethers of the substances or the isomers thereof, where the existence of such salts is possible;

(d) all the preparations and admixtures of the substances where such preparations and admixtures are not expressly excluded.

Bufotenine (N,N-dimethylserotonin).

Cannabis and the whole plant or any portion or product thereof.

Coca leaf.

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

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

Harmaline (3, 4-dihydroharmine).

Harmine [7-methoxy-1-methyl-9-pyrid (3, 4-6)-indole].

Heroin (diacetylmorphine).

Lysergide (lysergic acid diethylamide).

Mescaline (3, 4, 5-trimethoxyphenethylamine).

Prepared Opium. Psilocin (4-hydroxydimethyltryptamine).

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

Tetrahydrocannabinol.

[Schedule 8 added by section 36 of Act 65 of 1974]

Schedule 9 (Schedule 9 to Act No. 101 of 1965)

Amphetamine.

Dexainphetamine.

[Schedule 9 added by section 36 of Act 65 of 1974]