UNITED NATIONS

E/NL.1977/82-84
8 May 1979
ENGLISH ONLY

LAWS AND REGULATIONS

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

SOUTH AFRICA

Communicated by the Government of South Africa

NOTE BY THE SECRETARY GENERAL – In accordance with the relevant Articles of the International Treaties on Narcotic Drugs and Psychotropic Substances, the Secretary-General has the honour to communicate the following legislative texts.

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E/NL.1977/82

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965

ACT NO. 101, 1965

TO

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

ACT 1/

To amend the Drugs Control Act, 1965, so as to replace or define or further define certain expressions; to substitute the appellation "medicine" for the appellation "drug" in the English text, and to effect certain textual changes in that text arising out of such substitution; to further regulate the control of medicines; to further regulate the constitution of the Medicines Control Council and the remuneration of its members, of the members of its committees and of the members of the Medicines Control Appeal Board; to provide for the control of Scheduled substances; to make new provision for inspectors, analysts, pharmacologists and pathologists considered necessary for the proper enforcement of the said Act; and to effect a change in relation to the power to make regulations; and to provide for matters connected therewith.

(English text signed by the State President.)
(Assented to 23 October 1974.)

Be it enacted by the State President, the Senate and the House of Assembly of the Republic of South Africa, as follows:

"Definitions. 1. (1) In this Act, unless the context otherwise indicates:

(i) 'advertisement', in relation to any medicine or Scheduled substance, means any written, pictorial, visual or other descriptive matter or verbal statement or reference:

1/ Note by the Secretariat: This Act is a consolidated version of Act No. 101, 1965, as amended by Act 29 of 1968 and Act 65 of 1974.

(a) appearing in any newspaper or other publication; or

(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; (i)

(ii) 'analyst' means an analyst to whom authority has been granted under section 27; (xxix)

(iii) 'appeal board' means the Medicines Control Appeal Board established by section 10; (ii)

(iv) '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); (xxi)

(v) 'council' means the Medicines Control Council established by section 2; (xxxii)

(vi) 'dentist' means a person registered as such under the Medical Act; (xxxvii)

(vii) 'hospital' means any institution established as a hospital or a nursing home or registered as such in terms of any law; (xxiii)

(viii) 'inspector' means a person authorized as such under section 26; (xxiv)

(ix) '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; (xvi)

(x) 'Medical Act' means the Medical, Dental and Supplementary Health Service Professions Act, 1974; (xli)

(xi) 'medical practitioner' means a person registered as such under the Medical Act, and includes an intern registered under that Act; (xix)

(xii) 'medic
treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction or relief of a habit or craving for the substance used or for any other such substance except where the substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a Provincial Administration or the Administration of the territory, or approved for this purpose by the Minister; (v)

(xiii) '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; (xxvi)

(xiv) 'Minister' means the Minister of Health; (xxvii)

(xv) 'package' means anything in or by which any medicine or Scheduled substance is enclosed, covered, contained or packed; (xxx)

(xvi) 'pathologist' means a pathologist to whom authority has been granted under section 27; (xxxi)

(xvii) 'pharmacist' means a person registered as such under the Pharmacy Act, 1974; (iii)

(xviii) 'pharmacologist', except for the purposes of paragraph (c) of subsection (1) of section 10, means a pharmacologist to whom authority has been granted under section 27; (xvii)

(xix) 'pharmacy Board' means the South African Pharmacy Board referred to in section 2 of the Pharmacy Act, 1974; (iv)

(xx) 'prescribed' means prescribed by or under this Act; (xl)

(xxi) '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; (xxxiii)

(xxii) 'registered' means entered in the register; (xx)

(xxiii) 'registrar' means the Registrar of Medicines appointed under section 12; (xxxiv)

(xxiv) 'regulation' means a regulation made and in force under this Act; (xxxv)

(xxv) 'Scheduled substance' means any medicine or other substance included in any Schedule to this Act; (xviii)

(xxvi) 'Schedule 1 substance' means any medicine or other substance included in Schedule 1 to this Act; (vi)

(xxvii) 'Schedule 2 substance' means any medicine or other substance included in Schedule 2 to this Act; (vii)

(xxviii) 'Schedule 3 substance' means any medicine or other substance included in Schedule 3 to this Act; (viii)

(xxix) 'Schedule 4 substance' means any medicine or other substance included in Schedule 4 to this Act; (ix)

(xxx) 'Schedule 5 substance' means any medicine or other substance included in Schedule 5 to this Act; (x)

(xxxi) 'Schedule 6 substance' means any medicine or other substance included in Schedule 6 to this Act; (xi)

(xxxii) 'Schedule 7 substance' means any medicine or other substance included in Schedule 7 to this Act; (xii)

(xxxiii) 'Schedule 8 substance' means any medicine or other substance included in Schedule 8 to this Act; (xiii)

(xxxiv) 'Schedule 9 substance' means any medicine or other substance included in Schedule 9 to this Act; (xiv)

(xxxv) 'Secretary' means the Secretary for Health; (xxxvi)

(xxxvi) '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; (xxxix)

(xxxvii) 'this Act' includes any regulation; (xxii)

(xxxviii) 'the territory' means the territory of South-West Africa; (xv)

(xxxix) 'trainee pharmacist' means a trainee pharmacist as defined in the Pharmacy Act, 1974; (xxv)

(xl) 'unqualified assistant' means an unqualified assistant as defined in the Pharmacy Act, 1974; (xxviii)

(xli) 'veterinarian' means a person registered as such under the Veterinary Act, 1933 (Act No. 16 of 1933). (xxxviii)

(2) A medicine produced either within or outside the Republic 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 same applicant or if it is not presented in the same form as that other medicine.

(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.".

"Establishment, powers and functions of Medicines Control Council.

2. 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.".

Constitution of council

3. "(1) The Council shall consist of not less than seven or more than eleven members as may from time to time be determined by the State President.";

(2) The following persons shall be appointed by the State President 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;";

(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;

"(d) at least one person who shall be a pharmacist;"

(e) at least one person who shall be an officer of the Department of Health; and

(f) not more than two other persons.

(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.

Period of office and remuneration of members of the Council.

4. (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.".

Chairman and vice-chairman.

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

(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.

Disqualifications, vacation of office and filling of vacancies.

6. (1) No person shall be appointed as a member of the council:

(a) who is an unrehabilitated insolvent;

"(b) who is disqualified under the Medical Act or the Pharmacy Act, 1974, from carrying on his profession, while so disqualified;";

"(c) who has a direct or an indirect interest in the sale of any medicine; or";

(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);";

(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 State President 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.

"(4) For the purposes of paragraph (c) of subsection (1) a medical practitioner or a pharmacist shall not be deemed to have an interest in the sale of any medicine by reason only of the fact that:

(a) in the case of a medical practitioner, he sells the medicine in question in the course of carrying on his professional activities as a medical practitioner; or

(b) in the case of a pharmacist, he sells the medicine in question by retail in the course of carrying on his professional activities as a pharmacist.".

Meetings of the council.

7. (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.".

Quorum, majority decision and chairman's casting vote.

8. (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 set and act as members.

Appointment of executive committee and other committees.

9. (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.".

"Establishment of Medicines Control Appeal Board.

10. (1) There is hereby established a board to be known as the Medicines Control Appeal Board, which shall consist of three members to be appointed by the State President, of whom

(a) one shall be a retired judge or an advocate of the Supreme Court of South Africa, who shall be the chairman of the board;

(b) one shall be a medical practitioner who has a speciality in medicine entered in the appropriate register contemplated in section 19 of the Medical Act; and

(c) one shall be a pharmacologist.

(2) The provisions of section 4 shall "mutatis mutandis" apply in respect of a member of the appeal board."

Disqualifications, vacation of office and filling of vacancies on appeal board.

11. (1) No person shall be appointed as a member of the appeal board:

(a) if he is a member of the council;

(b) if he has at any time served as a member of a committee referred to in paragraph (b) of sub-section (1) of section nine;

(c) if he is in the full-time employment of the State;

(d) if he is an unrehabilitated insolvent;

(e) so long as he is disqualified under any law from carrying on his calling;

"(f) if he has a direct or an indirect interest in the sale of any medicine;

'(g) if he has been granted authority under section 27; or"

(h) if he is not a South African citizen permanently resident in the Republic or the territory.

(2) A member of the appeal board 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);"; and

(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 appeal board without the appeal board's leave.

(3) If the office of any member of the appeal board becomes vacant before the expiration of the period for which he was appointed, the State President may, subject to the applicable provisions of section ten, appoint another person to hold office for the unexpired portion of the period for which his predecessor was appointed.

(4) For the purposes of paragraph (f) of sub-section (1) a medical practitioner shall not be deemed to have an interest in the sale of any medicine by reason only of the fact that he sells the medicine in question in the course of carrying on his professional activities as a medical practitioner.

"Appointment of Registrar of Medicines.

12. (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 Secretary.

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

Medicines register.

13. 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 as are required by this Act to be entered therein.

"Prohibition on the sale of medicines which are subject to registration and are not registered.

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

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

(b) Any such resolution may also relate only to medicines which were available for sale in the Republic or the territory 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.

(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 or the territory immediately prior to the date of publication in the Gazette of the resolution by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) shall come into operation:

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

(b) if application for the registration of such medicine is made within the said period, on the date one month after the date on which a notice in respect of such medicine is published in the Gazette in terms of section 15 (10) or section 17 (a).

(4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine compounded in the course of carrying on his professional activities by a medical practitioner for a particular person in a quantity not greater than the quantity required for treatment as determined by the medical practitioner or compounded by a pharmacist for a particular person in a quantity not greater than that normally required for the purpose for which it is sold or in a quantity for a particular person as prescribed by a medical practitioner or a dentist, 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.

(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.".

(2) Any drug which prior to the commencement of subsection (1) was subject to registration by virtue of a resolution published in terms of subsection (2) of section 14 of the principal Act, shall be deemed to be a medicine subject to registration by virtue of a resolution published in terms of subsection (2) of section 14 of the principal Act as substituted by subsection (1) of this section.

"Registration of medicines.

15. (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 prescribed in section 24, as soon as possible after the expiration of that period; or

(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."

Cancellation of registration.

16. (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 person by whom or on whose behalf application for the registration of that medicine was made.

(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 connexion 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 by whom or on whose behalf application for the registration of a drug was made fails to pay the prescribed annual fee in respect of the retention of the registration of that drug 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 drug.".

"Notification of registration or cancellation of registration in Gazette

17. 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 person who applied for the registration of such medicine and the number which was allocated to it in terms of section 15.".

"Labels and advertisements.

18. (1) No person shall sell any medicine or Scheduled substance unless the package in which such medicine or Scheduled substance is sold bears a label stating

(a) the approved name of that medicine immediately followed, in the case of a registered medicine, by the number allocated thereto under section 15, which shall, if any trade name or brand name appears on the label, appear immediately above such trade name or brand name and shall be in letters not less than half the size of the letters in which such trade name or brand name appears and shall in all other respects be not less conspicuous than such trade name or brand name; and

(b) the active components of such medicine or Scheduled substance by mass or by volume or by unit immediately before or after the said approved name.

(2) No person shall in writing advertise any medicine for sale, unless:

(a) the approved name of such medicine, immediately followed, in the case of a registered medicine, by the number allocated thereto in terms of section 15, is stated in the advertisement, and (if the trade name or brand name, of the medicine is also stated in the advertisement) appears immediately above such trade name or brand name where it is used for the first time and is in letters not less than half the size of the letters in which such trade name or brand name appears and is in all other respects not less conspicuous than such trade name or brandname; and

(b) the names, as determined by the council, of the active components of the medicine and the mass or volume or number of units of such components are stated immediately before or after the approved name or after such number.

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

(a) sold by a medical practitioner for the treatment of a particular person and supplied by such medical practitioner to or on behalf of such person, if such medical practitioner considers that it would not be in the interest of such person for the prescribed particulars to appear on the label; or

(b) sold by a pharmacist for the treatment of a particular person and supplied to or on behalf of such person by such pharmacist in accordance with a prescription given by a medical practitioner if such medical practitioner has endorsed the prescription with the words "non nomen" and initialled such endorsement; or

(c) if such medicine forms a portion of the original contents of a package which is labelled in accordance with the provisions of this Act and such medicine is taken by a pharmacist or medical practitioner or dentist from such package and is sold by such pharmacist, medical practitioner or dentist or on behalf of a hospital for the treatment of a particular person and is supplied to or on behalf of such person in a package which bears a label stating

(i) the name and address of such pharmacist, medical practitioner, dentist or hospital;

(ii) in the case of a registered medicine, the number allocated to such medicine in terms of section 15;

(iii) the name of the medicine;

(iv) directions (if any) in regard to the manner in which such medicine should be used; and

(v) the name of the person for whose treatment such medicine is sold.".

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

19. (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 drug 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 subsection (2) is addressed, extend the period stipulated in such notice.

Publication or distribution of false advertisements concerning drugs.

20. (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 sub-paragraph (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.

Council may authorize sale of unregistered drug for certain purposes.

21. (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).

"Council to furnish certain information to medical practitioners, dentists and pharmacists

22. The Council shall, subject to the approval of the Secretary, in such manner as it considers most suitable:

(a) as soon as practicable after any medicine has been registered, inform medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine:

(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 has been cancelled in terms of section 16, inform medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine of the cancellation of such registration.".

"Control of medicines and Scheduled substances.

22A. (1) Subject to the provisions of this section, no person shall sell any medicine or Scheduled substance unless he is the holder of a licence issued in terms of an ordinance of a provincial council or the territory on the prescribed conditions, or he is employed by the holder of any such licence: Provided that nothing in this subsection contained shall be construed as requiring a medical practitioner, dentist, pharmacist or veterinarian to hold any such licence to sell any medicine or Scheduled substance in the course of lawfully carrying on his professional activities.

(2) The licensing authority may, and shall on the recommendation of the council, at any time withdraw, suspend or restrict any licence issued in terms of any such ordinance if any such condition on which such licence has been issued, is not complied with.

(3) Any Schedule 1 substance, not being any such substance prescribed for the purposes of this sub-section, shall not be sold by the holder of a licence referred to in sub-section (1): 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 unqualified 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 such order shall be retained by such seller for a period of not less than six months after the relevant sale.

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

(a) by any person other than a pharmacist or a trainee pharmacist or unqualified 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 unqualified 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 enters in a prescription book required to be kept in the prescribed manner, all the prescribed particulars of such sale.

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

(a) by any person other than a pharmacist or a trainee pharmacist or unqualified 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

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

(c) 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

(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 unqualified 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

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

(c) 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

(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 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.

(7) (a) Save as is permitted by the provisions of this sub-section, 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 unqualified assistant acting under the personal supervision of a pharmacist, upon a written prescription of a medical practitioner, dentist or veterinarian; or

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

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

(iv) in the case of a sale as provided in sub-paragraph (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 Scheduled 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 Secretary may, on the recommendation of the council, issue, subject to such conditions and requirements as the Secretary may on such recommendation 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 or for scientific, research, analytical or educational purposes.

(8) (a) Save as is permitted by the provisions of this sub-section, 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 practioner, 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 sub-paragraph (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 sub-paragraph (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 sub-section (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) No person shall manufacture, import or export any Schedule 6 substance unless:

(i) a permit for such manufacture, importation or exportation has been issued to him by the Secretary on the recommendation of the council and subject to the prescribed conditions; or

(ii) a permit has been issued to him by the Secretary on the recommendation of the council and 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.

(g) The Secretary may, on the recommendation of the council, issue, subject to such conditions and requirements as the Secretary may on such recommendation 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.

(9) (a) Save as is permitted by the provisions of this sub-section, 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 sub-paragraph (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) Subject, "mutatis mutandis", to the proviso to sub-section (7) (c), a Schedule 7 substance shall not be administered or used for other than medicinal purposes.

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

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

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

(i) a permit for such manufacture, importation or exportation has been issued to him by the Secretary on the recommendation of the council and subject to the prescribed conditions; or

(ii) a permit has been issued to him by the Secretary on the recommendation of the council and 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.

(g) The Secretary may, on the recommendation of the council, issue, subject to such conditions and requirements as the Secretary may on such recommendation 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.

(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 Secretary 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 Secretary on the recommendation of the council.

(11) A Schedule 9 substance shall not be acquired by any person other other than the Secretary 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 Secretary, on the recommendation of the council, may determine.

(12) Notwithstanding the other provisions of this section, the Secretary 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 Secretary may determine.

(13) Notwithstanding the other provisions of this section, the Minister may, on the recommendation of the council and after consultation with the Pharmacy Board, issue a permit to any person who is not registered as a pharmacist, to manufacture or pack and sell any medicine or Scheduled substance specified in the permit, and thereupon such person may, at the

place, in the manner and on the conditions specified in the permit, manufacture or pack and sell such medicine or substance.

(14) Notwithstanding the other provisions of this section, a pharmacist may sell a greater or a lesser quantity of a Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance than the quantity prescribed or ordered, according to the therapeutic pack in the original container of such substance as supplied to him: Provided that the quantity so sold shall not exceed or be less than, twenty-five per cent of the quantity specified in the prescription or order in question.

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

(a) any medical practitioner, dentist or veterinarian from selling any Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7 substance in the course of lawfully carrying on 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.".

Disposal of undesirable drugs

23. (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.

Appeals

24. '(1) Any person who is aggrieved by any decision of the council (not being any decision whatsoever contemplated in section 22A) may appeal against such decision to the appeal board.".

(2) (a) Any such appeal shall be lodged within one month after the date of the decision appealed against and shall be accompanied by written arguments and explanations of the grounds of appeal.

(b) The appellant may appear before the appeal board in person or through a representative and may tender evidence and submit any arguments or explanations in support of any written arguments or explanations submitted by him.

(3) The operation of any decision of the council which is the subject of an appeal under sub-section (1) (not being a decision contemplated in sub-section (1) of section twenty-three) shall be suspended pending a decision on the appeal.

(4) The decision of the appeal board on any appeal lodged with it under this section shall be final and shall be deemed to be a decision of the council.

Privileges of council and committees.

25. 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.

"Inspectors.

26. (1) The Secretary may, after consultation with the council, authorize such persons as inspectors, as he may consider necessary for the proper enforcement of this Act.

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

(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).".

Any person appointed, prior to the commencement of sub-section (1) of this section, as an inspector under section 26 (1) of the principal Act, whose appointment as such was in force immediately prior to such commencement, shall be deemed to have been authorized as an inspector under section 26 (1) of the principal Act as substituted by sub-section (1) of this section.

"Analysts, pharmacologists and pathologists.

27. The Secretary may, after consultation with the council, grant such authority to such analysts, pharmacologists and pathologists as he may consider necessary for the proper enforcement of this act."

Any analyst, pharmacologist or pathologist appointed, prior to the commencement of sub-section (1) of this section, under section 27 (1) of the principal Act, whose relevant appointment was in force immediately prior to such commencement, shall be deemed to have been granted authority under section 27 of the principal Act as substituted by sub-section (1) of this section.

Powers of inspectors.

28. (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/scheduled substance;

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

(c) seize any such medicine/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/scheduled substance as he may consider necessary for the purpose of testing, examination or analysis in terms of the provisions of this Act.

(2) Any sample taken in terms of paragraph (d) of sub-section (1) shall be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such medicine/scheduled substance, or if there is no such person or if he is absent for any reason, in the presence of any other witness, and shall in the presence of such person or such witness be divided into three parts, each of which shall forthwith be fastened up and sealed and suitably labelled or marked in such manner as its nature may permit. One part shall then be transmitted to an analyst, pharmacologist or pathologist together with a certificate in the prescribed form signed by such inspector. The second part, together with a copy of the aforesaid certificate, shall be handed or transmitted by registered post to the owner or seller of such medicine/scheduled substance or his agent. The third part shall be retained by the inspector.

(3) The analyst, pharmacologist or pathologist to whom one part of a sample has been transmitted in terms of the provisions of sub-section (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.

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

Offences.

29. 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 connexion with any medicine or Scheduled substance:

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

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

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

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

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

shall be guilty of an offence.

Penalties.

30. (1) Any person who is convicted of an offence referred to in section twenty-nine shall be liable:

(a) on a first conviction, to a fine not exceeding five hundred rand or, in default of payment of such fine, to imprisonment for a period not exceeding six months; and

(b) on a second or subsequent conviction, to a fine not exceeding one thousand rand or to imprisonment for a period not exceeding twelve months or to both such fine and such imprisonment.

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

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

Procedure and evidence.

31. (1) In any criminal proceedings under this Act:

(a) any quantity of a medicine/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;

(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/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.

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

(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.

Special defences in case of prosecutions.

32. 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 drug complied with the prescribed requirements; and

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

Act or omission by manager, agent or employee.

33. (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.

Preservation of secrecy.

34. Any person who discloses, except to the Minister or to any other person for the purpose of the carrying out of his duties or the performance of his functions under this Act or when required to do so by any court or under any law, any information acquired by him in the carrying out of any duty or the performance of any function under this Act, in relation to the business or affairs of any other person, shall be guilty of an offence and liable on conviction to a fine not exceeding one thousand rand or to imprisonment for a period not exceeding twelve months.

"Regulations.

35. (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;

(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;

(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 particulars which shall be published in the Gazette in respect of any application for registration referred to in sub-section (11) of section 15;

(xii) prescribing the procedure at meetings of the council and of the appeal board and of any committee appointed under section 9 (including the quorum in the case of committees) and the manner in which meetings of the appeal board and of any such committee shall be called;

(xiii) prescribing the conditions on which any licence referred to in section 22A (1) may be issued, the forms which shall be used for an application for any such licence, the particulars which shall be furnished with any such application, the medicine or Scheduled substance which may be sold under any such licence and the returns and reports which shall be furnished to the council by the licensing authority;

(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 certain specified Schedule 1 substances may be sold by a person other than a medical practitioner, dentist, veterinarian or pharmacist, under a licence referred to in section 22A (1);

(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 connexion 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 the masters of ships or by the officer in charge of any aircraft;

(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;

(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;

(xxvii) as to the importation, conveyance, keeping, storage and packing of medicines and Scheduled substances, and the manner in which medicines and Scheduled substances shall be kept and controlled in hospitals;

(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 connexion with the testing, examination or analysis of samples taken under this Act;

(xxx) prescribing the fee (not exceeding one hundred rand) to be paid to the registrar in respect of the registration of a medicine, the fee (not exceeding thirty rand) to be paid annually to the registrar in respect of the retention of the registration of a medicine and the date on which the last-mentioned fee shall be so paid;

(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 sub-section.

(2) The Minister shall, not less than three months before any regulation is made under sub-section (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 sub-section (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 sub-section (1) except in consultation with the Minister of Finance.

(5) Regulations made under sub-section (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 five hundred rand or imprisonment for a period of six months.".

(2) Any regulation which was in force under section 35 of the principal Act immediately prior to the commencement of sub-section (1), shall remain in force until it is amended or withdrawn under the said section 35.

Exclusion of any drug from operation of Act.

36. 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.

Medicines manufactured for export.

37. 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 or the territory solely for the purpose of export from the Republic or the territory and is not used or disposed of for use in the Republic or the territory and in respect of which the council has granted a certificate that it is satisfied in regard to its quality, purity and safety.

Amendment of schedules.

37A. 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.

Operation of Act in relation to other laws.

38. 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.

Application of Act in South-West Africa.

39. This Act and any amendment thereof shall apply also in the territory (including the Eastern Caprivi Zipfel referred to in sub-section (3) of section three of the South-West Africa Affairs Amendment Act, 1951 (Act No. 55 of 1951)) and in relation to all persons in the portion of the territory known as the "Rehoboth Gebiet" and defined in the First Schedule to Proclamation No. 28 of 1923 of the territory.

'Short title.

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

Government Gazette, No. 4594
21 February 1975

E/NL.1977/83

No. R. 352

21 February 1975

MEDICINES AND RELATED SUBSTANCES
CONTROL ACT, 1965

The Minister of Health has, in terms of section 35 (1) and (3) (b) of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), 2/ made the following regulations:

Definitions

1. Unless the context otherwise indicates the expression "the Act" shall mean the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), and any expression which is defined in the Act shall have the same meaning as in the act, and further:

2/ Note by the Secretariat: E/NL.1977/82; see also foot-note 1/.

"applicant" means the person by or on whose behalf application for registration of a medicine is made;

"manufacture" means make, compound, process and, except in regulation 7 (g) and the application form provided for in regulation 15 and the annexures thereto, also pack, and "manufacturer" and "manufacturing process" have corresponding meanings;

"batch", in relation to any medicine, means a particular quantity of the medicine which has homogeneous properties;

"batch number" means the number or other cypher allocated to a medicine by the manufacturer thereof from which it is possible to determine the complete manufacturing process of the medicine and the origin of all the raw materials used in the manufacture of any specific package of such medicine;

"expiry date", in relation to any batch of a medicine, means the date up to which a medicine in that batch will retain the strength and other properties which are mentioned on the label and which must be stated on the label by the applicant in relation to every package containing medicines of that batch of which the strength or any other property can change after lapse of time and the date after which the medicine shall not be sold to the public;

"outer label", in relation to any medicine, means a label as prescribed by the Act which is affixed to a carton, wrapper or package in which the immediate container of a medicine is packed;

"package insert" means a pamphlet on which is printed the particulars as prescribed in regulation 10;

"business address", in relation to a business which is carried on in the Republic or in the Territory, means the full address of the premises where that business is carried on; and

"country of origin", in relation to a medicine, means the country where the basic research in connexion with the manufacture of the particular drug was undertaken.

Application for registration of a medicine

2. Application for registration of a medicine may be made by

(a) a pharmacist; or

(b) a body corporate which carries on business as a pharmacist in terms of section 22 of the Pharmacy Act, 1974 (Act 53 of 1974), or a person authorized by such body corporate to apply on its behalf; or

(c) in the case of a medicine which is manufactured by a person who is the holder of a permit issued under the provisions of section 22A (13) of the Act, that person.

3. Every application for the registration of a medicine which was available for sale in the Republic or the Territory immediately prior to 5 July 1968 shall be submitted in single copy and 40 copies of every application for the registration of a medicine which was not available for sale in the Republic or the Territory immediately prior to 5 July 1968 shall be submitted on the form prescribed by regulation 15, together with the prescribed registration fee, to the Registrar of Medicines, Private Bag X88, Pretoria, 0001.

The classification of medicines

4. For the purpose of registration all medicines shall be divided into the following two basic categories:

(a) Category A. Medicines which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine or medicines.

(b) Category B. Medicines which cannot normally be administered without further manipulation.

5. Both Categories A and B shall for the same purpose be further subdivided into the following classification based on their principal pharmacological purpose or therapeutic effect:

Pharmacological classification

1. Central nervous system stimulants

1.1 Central analeptics
1.2 Psychoanaleptics (antidepressants)
1.3 Special antidepressant combinations
1.4 Respiratory stimulants
1.5 Hallucinogenic medicines

2. Central nervous system depressants

2.1 Anaesthetics
2.2 Sedatives, hypnotics
2.3 Barbiturates
2.4 Non-barbiturates
2.5 Anticonvulsants, including anti-epileptics
2.6 Tranquillizers
2.6.1 Phenothiazines and derivatives
2.6.2 Rauwolfia: Alkaloids and combinations
2.6.3 Diphenylmethane and its derivatives
2.6.4 Alkyldiols and their derivatives
2.6.5 Miscellaneous structures
2.7 Narcotic analgesics
2.8 Non-narcotic analgesics, antipyretics
2.9 Special analgesic combinations
2.10 Centrally active muscle relaxants

..... 3/

Samples with application for registration

6. An application for registration of a medicine shall, if so requested by the Council, be accompanied by:

(a) a sample of the final product in the smallest of each of the package forms available for sale to the public or if such product be not yet so available, a sample in a container in which the applicant intends to make it available on the market;

(b) samples of all advertising material and package inserts which may be in draft form listing the basic information which the applicant intends to use and samples of the raw materials used in the manufacture of the product.

Information which shall appear in the medicines register

7. When a medicine is registered the following information shall be written in the medicines register which shall be kept in terms of section 13 of the Act:

(a) The name of the medicine approved by the Council in terms of section 15 (5);

(b) the trade name of the medicine, if any;

(c) the registration number of the medicine;

(d) the name and quantity of each active ingredient of the medicine, per unit;

(e) the form of preparation of the medicine;

(f) the conditions of registration, if any;

(g) the name and business address of the manufacturer;

(h) the name and business address of the applicant; and

(i) the date of registration of the medicine.

3/ Note by the Secretary-General: Those sections not directly relevant to narcotics or psychotropic substances have been omitted.

Form of certificate of registration

8. The following certificate of registration shall be issued after a medicine has been registered in terms of section 15 (4) of the Act:

MBR 13

MEDICINES AND RELATED SUBSTANCES CONTROL
ACT, 1965 (Act 101 of 1965)

MEDICINE REGISTRATION CERTIFICATE

It is hereby certified that the medicine as described hereunder has been registered in terms of section 15 (4), subject to the conditions indicated:

1. Approved name .....
2. Trade name under which marketed .....
3. Registration number .....
4. Active ingredients and quantities per unit .....
.....
5. Form of preparation .....
6. Conditions under which medicine is registered .....
.....
7. Name and business address of manufacturer .....
.....
8. Registered in the name of .....
.....
Business address .....
.....
9. Date of registration .....

.....
Registrar of Medicines

Pretoria,

..... 19 ..

The labelling of medicines and scheduled substances

9. (1) The package in which a medicine or scheduled substance is sold shall bear a label on which is stated in clear and indelible letters and in both official languages the following information:

(a) The name and business address of the applicant in whose name the medicine is registered or in whose name the application for registration was made;

(b) the requirements, if any, for the method of storage or other necessary precautions for the preservation of the medicine or scheduled substance;

(c) the particulars determined by the Council in terms of section 15 (7) of the Act;

(d) the name and percentage of any bacteriostatic or bactericidal agent which is added to the medicine or scheduled substance as a preservative;

(e) the batch number of the medicine or scheduled substance;

(f) the expiry date of the medicine or scheduled substance, where applicable;

(g) where practicable, the dosage of the medicine or scheduled substance;

(h) in the case of scheduled substances, the letter "S" followed by the number of the schedule in which the substance is listed, in a prominent type size and surrounded by a border;

(i) in the case of a medicine which contains phenacetin, aspirin or paracetamol, the warning: Do not use continuously for more than 10 days without consulting your doctor;

(j) in the case of a preparation intended for oral use containing an antihistaminic substance, the warning: The use of this medicine leads to drowsiness which is aggravated by the simultaneous intake of alcohol.

(2) In the case of a package of a medicine or scheduled substance of 10 ml or less, it will be adequate to record the information required by subregulation (1) (a), (b), (c), (d), (g), (h), (i) and (j) on the outer label.

(3) In the case of the sale of a medicine in terms of the provisions of section 18 (3) (a) and (b) of the Act, the package in which such medicine is sold shall bear a label on which the following details appear:

(a) The name and address of the pharmacist or medical practitioner by whom the medicine is sold: Provided that if such sale is effected by a pharmacist or medical practitioner in the service of a hospital, the name and address of such hospital shall appear on the label:

(b) directions (if any) regarding the manner in which such medicine should be used;

(c) the name of the person for the treatment of whom the medicine is sold; and

(d) the reference number referred to in regulation 28 (1) (e);

(4) the provisions of subregulation (1) shall not apply in the case of the sale on prescription of a medicine by a medical practitioner, dentist, veterinarian or pharmacist for the treatment of a specified person or animal: Provided that subject to the provisions of section 18 (1) of the Act, such medicine shall bear a label stating

(a) the name and address of the seller;

(b) the directions (if any) regarding the manner in which the medicine should be used; and

(c) the name of the person for the treatment of whom the medicine is sold, or in the case of a prescription issued by a veterinarian, the name of the person to whom the medicine should be sold.

(5) The Council may authorize, at the request of and after consideration of the reasons submitted by the applicant, any deviation from the regulations with regard to labelling.

Package inserts

10. (1) Each package of a medicine shall contain a package insert on which is printed in prominent type in both official languages:

(a) All the information which shall in terms of section 18 (1) of the Act and regulation 9 (1) appear on labels;

(b) directions for use;

(c) any necessary warning concerning the unsafe use of the medicine by children, old people and pregnant women and the possible dangers that may arise from the prolonged use of the medicine or in connexion with the administration of the medicine;

(d) a summary of relevant information concerning the purpose and the beneficial, detrimental, injurious or other effects of the medicine; and

(e) all relevant information, including particulars in regard to a specific medicine as an antidote (if known), concerning the treatment of a patient in cases where an overdose of the medicine has been administered.

(2) The information shall be printed on the package insert under the headings and in the order indicated hereunder:

(a) Registration number (to be allocated by the Council).

(b) Pharmacological classification.

(c) Scheduling category (to be allocated by the Council).

(d) Approved name (where applicable).

(e) Trade name.

(f) Composition (including preservatives, if present).

(g) Identification (physical appearance).

(h) Pharmacological action.

(i) Indications.

(j) Contra-indications.

(k) Dosage and directions for use.

(l) Side effects and special precautions.

(m) Known symptons of overdosage and particulars of its treatment (where practicable to include).

(n) Conditions of registration of the medicine (if any) imposed by the Council.

(o) Presentation.

(p) Storage directions.

(q) Name of application.

(3) The provisions of subregulation (1) shall not be applicable in those cases to which section 18 (3) (a), (b) and (c) of the Act and regulation 9 (3) and (4) apply.

(4) The Council may, on the request of an applicant, and after consideration of the reasons submitted by the applicant, approve any deviation from the regulations relative to package inserts.

Advertisements

11. When a medicine is advertised orally for the first time by or on behalf of the applicant to any member of the medical or dental profession or the pharmaceutical profession, written information, which shall include at least the information called for in terms of regulation 10, shall simultaneously be given to the person to whom the oral advertisement is directed and when the medicine is advertised orally on subsequent occasions such information shall be available on request.

Standards for composition, therapeutic suitability and effect, purity, etc., with which a medicine shall comply

12. (a) All medicines shall comply with the standard, if any, laid down in the most recent edition of the British Pharmacopoeia or the British Pharmaceutical Codex or the European Pharmacopoeia or the Pharmacopeia of the United States, as the case may be, or with standards which satisfy the Council.

(b) Every applicant shall, without delay, inform the Council of any departure from the particulars furnished by him with any application for the registration of a medicine, irrespective of whether such alteration is made before or after such medicine was registered.

Particulars which shall be published in the Government Gazette in terms of section 15 (11) of the Act

13. The following particulars shall be published in the Government Gazette in terms of section 15 (11) of the Act:

(a) The trade name of the medicine, if any;

(b) the name and quantity of each active ingredient of the medicine;

(c) the name and business address of the applicant; and

(d) the form of preparation of the medicine

Rules relating to the conduct of business of the Medicines Control Council

..... 3/

15. The following form shall be used for application for the registration of a medicine:

MBR 1

CONFIDENTIAL

APPLICATION FOR REGISTRATION OF A MEDICINE

[Section 15 of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965)]

N.B. - Please study the directions on the reverse side carefully before completing the form.

PARTICULARS OF APPLICANT

Name (1*) .....
Business address .....
.....
Postal address .....
.....
Telephone No. .....

PARTICULARS OF MEDICINE

Proposed approved name (2*) .....
Trade mark (trade name, if any) (3*) .....
.....
Form of preparation (4*) .....
.....
Country of origin (country in which the basic research was conducted) .....
Name and business address of manufacturer of the preparation .....
.....
.....
Classification (5*) .....

The medicine was available in this formulation before 5 July 1968. ☐

The medicine was not available in this formulation before 5 July 1968. ☐

(Indicate with an X)

The undersigned hereby declares that all the information contained herein and in the Annexures hereto is correct and true (6*).

.....
Signature of applicant

Date of application .....

.....
Designation

/ (1), (2*), etc. refer to directions on reverse side.

GENERAL INFORMATION

1. Application for the registration of a medicine may be made by:

(a) a pharmacist; or

(b) a body corporate which carries on business as a pharmacist in terms of section 22 of the Pharmacy Act, 1974 (Act 53 of 1974), or a person authorized by such body corporate to apply on its behalf; or

(c) in the case of a medicine which is manufactured by a person who is the holder of a permit issued under the provisions of section 22A (13) of the Act, that person.

2. If no approved name has been given to the medicine by an acceptable international body, the name which was, or will be, submitted for approval should be mentioned here.

3. Attention is drawn to section 1 (2) of the Act. Furthermore, it should be noted that medicines which are not identical in composition or strength are not regarded as the same medicine. Applications for the registration of medicines of which only the strength varies may be made on the same form. However, registration fees in respect of each strength are payable.

4. The form of preparation, e.g. solutions, suspensions, eye drops, ear drops, emulsions, ointments, suppositories, tablets, capsules, injections, should be mentioned here.

5. The classification of the medicine as described in regulations 4 and 5 should be mentioned here.

6. Any person who makes any false or misleading statement in connexion with any medicine:

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

(ii) in the course of the sale thereof;

is guilty of an offence (section 29).

7. The registration procedure can be commenced only if Form MBR 1 and its Annexures have been properly completed. Only the information required in the Annexures should be furnished.

8. References to literature should be furnished in the appropriate Annexure.

9. All documents shall be submitted in either of the official languages.

10. A sample of the smallest available pack of the medicine must be submitted if requested by the Council.

MBR 1

ANNEXURE 1

Name of applicant .....
Name of medicine .....
Form of preparation .....

The text of the package insert shall be submitted, and must be in the following order:

1. Registration number (to be allocated by the Council).
2. Pharmacological classification.
3. Scheduling category (to be allocated by the Council).
4. Approved name (where applicable).
5. Trade name.
6. Composition (including preservatives, if present).
7. Identification (physical appearance).
8. Pharmacological action.
9. Indications.
10. Contra-indication.
11. Dosage and directions for use.
12. Side effects and special precautions.
13. Known symptoms of overdosage and particulars of its specific treatment (where practicable to include).
14. Conditions of registration of the medicine (if any) imposed by the Council.
15. Presentation.
16. Storage directions.
17. Name of applicant.

MBR 1

ANNEXURE 2

Name of applicant .....
Name of medicine .....
Form of preparation .....
Dosage unit .....

The following is a schedule of the names and quantities of each active and non-active ingredient contained in a dosage unit or other suitable mass or volume unit of the medicine and must conform with the relevant particulars in the package insert and on the label with regard to the active ingredients.

Particulars with regard to averages in the formulation should be given separately.

Constituent		Quantity	Active or non-active
Chemical name	Approved name (if any)		
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....

1. Approved and chemical names should, where possible, be given in terms of the published list of an acceptable international body, e.g. I.N.N.

2. Where the stated amount of active ingredient differs from that on the label of the medicine, this difference should be explained.

MBR 1

ANNEXURE 3

Name of applicant .....
Name of medicine .....
Form of preparation .....

The names and structural formulae of the active ingredients are as follows:

Approved or chemical name	Structural formula
.....	.....
.....	.....
.....	.....

1. Approved and chemical names should, where possible, be given in terms of a published list of an acceptable international body, e.g. I.N.N.

2. Reference to the following publications will, where applicable, be acceptable:

British Pharmacopoeia, British Pharmaceutical Codex, Pharmacopeia of the United States, European Pharmacopoeia, Pharmacopeia Internationalis, Merck Index, Remington's Pharmaceutical Sciences, or such other works of reference as will be acceptable to the Council.

MBR 1

ANNEXURE 4

Name of applicant .....
Name of medicine .....
Form of preparation .....

Specifications for all the active and non-active raw materials used in the manufacturing process of the medicines are as follows:

.....
.....
.....

Reference to publications mentioned in footnote 2 of Annexure 3 will, where applicable, be acceptable. Where reference is made to other sources, the information must accompany the application.

MBR 1

ANNEXURE 5

Name of applicant .....
Name of medicine .....
Form of preparation .....

The analytical control procedures which are performed on all active and non-active raw materials before they are used in the manufacturing process are as follows:
.....
.....
.....

Specify in each case in which laboratory the said analytical control procedures are carried out.

If the above corresponds to Annexure 4, reference thereto will suffice.

MBR 1

ANNEXURE 6

Name of applicant .....
Name of medicine .....
Form of preparation .....

The analytical control procedures and the frequency with which they are performed during the manufacturing process are as follows:
.....
.....
.....

See footnote to Annexure 5.

MBR 1

ANNEXURE 7

Name of applicant .....
Name of medicine .....
Form of preparation .....

Full specifications of the final manufactured product are as follows:
.....
.....
.....

MBR 1

ANNEXURE 8

Name of applicant .....
Name of medicine .....
Form of preparation .....

The nature, and the specifications, where applicable, of the packaging materials in immediate contact with the dosage form, are as follows:
.....
.....
.....

MBR 1

ANNEXURE 9

Name of applicant .....
Name of medicine .....
Form of preparation .....

The analytical control procedures which are performed on the final manufactured product are as follows:
.....
.....
.....

1. Reference to the publications mentioned in footnote 2 to Annexure 3 will, where applicable, be acceptable.

2. Mention should be made of the laboratory where the above analytical control procedures are carried out.

MBR 1

ANNEXURE 10

Name of applicant .....
Name of medicine .....
Form of preparation .....

The following is a description of:

(a) the experimental details and results of stability tests performed on the final manufactured product;

(b) the interpretation of the above results; and

(c) the inferred shelf life.

.....
.....

MBR 1

ANNEXURE 11

Name of applicant .....
Name of medicine .....
Form of preparation .....

Summaries of the methods of manufacture and packaging are as follows:

.....
.....

Should any of the manufacturing or packaging procedures be carried out at an address other than that of the manufacturer, full particulars of such procedures must be furnished.

MBR 1

ANNEXURE 12

Name of applicant .....
Name of medicine .....
Form of preparation .....

The following reports with regard to registration were issued by the statutory licensing or registering authority in the country of origin or any other country. (If no such report is available, all relevant particulars with regard to the progress already made concerning the registration of the medicine must be furnished).

MBR 1

ANNEXURE 13

Name of applicant .....
Name of medicine .....
Form of preparation .....

N.B. - In the following instances the particulars below should be furnished only if called for by the Council:

(i) Medicines which were available for sale in the Republic or the Territory prior to the promulgation of the regulations.

(ii) Where details and results as described in item B of Annexure 15 are submitted.

Experimental details and results of the tests performed on the medicine to confirm its physiological availability:

.....
.....
.....

MBR 1

ANNEXURE 14

Name of applicant .....
Name of medicine .....
Form of preparation .....

N.B. With regard to medicines which were available for sale in the Republic or the Territory prior to the promulgation of the regulations, the particulars below should be furnished only if called for by the Council.

A. Summaries* of, and conclusions derived from, tests performed on animals to demonstrate all aspects of the toxicity of the medicine, and to substantiate the safety of its use, with special reference to:

(i) LD 50 determinations;
(ii) teratogenicity studies;
(iii) carcinogenicity studies;
(iv) other tests to substantiate the safety of the medicine:
.....
.....

In certain cases where well-known active constituents are concerned the Council may grant exemption from the submission of the above information.

B. Summaries* of methods of, experimental results of, and conclusions drawn from, tests performed on animals with reference to the efficacy of the medicine, with special emphasis on the relationship between the tests performed and the purpose for which the medicine is, or will be, propagated, and further with regard to the dosage and method of administration of the medicine, with special reference to pharmacokinetic tests on experimental animals:
.....
.....

---

* Full particulars will be requested by the Council, if required.

MBR 1

ANNEXURE 15

Name of applicant .....
Name of medicine .....
Form of preparation .....

N.B. With regard to medicines which are available for sale in the Republic or the Territory prior to the promulgation of the regulations, the particulars below should be furnished only if called for by the Council:
.....
.....

A. Summaries* of the tests performed on human beings in regard to the safety of the use of the medicine, with special reference to the particular dosage, routes of administration used and the side effects observed:
.....
.....
.....

B. Particulars of clinical tests conducted with reference to the efficacy of the use of the medicine, with a summary* of the nature of the tests, by whom conducted and where, results, etc., with special reference to comparative or controlled clinical tests, double blind tests, etc.:
.....
.....
.....

C. Experimental details and results of the tests performed to establish the blood or other suitable physiological levels associated with the action claimed for the medicine:
.....
.....
.....

---

* If required, full particulars will be requested by the Council.

MBR 1

ANNEXURE 16

PARTICULARS OF THE APPLICATION FOR PUBLICATION
IN THE GOVERNMENT GAZETTE

(Must be completed in duplicate in both official languages)

Naam en sakeadres van applikant
Name and business address of applicant .....

Naam en sakeadres van vervaardiger (volledige adres)
Name and business address of manufacturer (full address) .....

Voorgestelde goedgekeurde naam van medisyne
Proposed approved name of medicine .....
.....

Bereidingsvorm
Form of preparation .....
.....

Aktiewe bestanddele (hoeveelheid per doseringseenheid)
Active ingredients (quantity per dosage unit) .....
.....

16. The following form shall be issued by inspectors in respect of samples taken in terms of the Act:

29 (a)

MEDICINES CONTROL COUNCIL

CERTIFICATE BY INSPECTOR

A COPY OF THIS CERTIFICATE SHALL BE HANDED OR FORWARDED BY REGISTERED POST TO THE OWNER OR SELLER OF THE MEDICINE OR SCHEDULED SUBSTANCE OR TO HIS AGENT

I hereby certify that the accompanying is (are) a sample/samples of a medicine or scheduled substance taken on .....
at * .....
from stock in charge of ** .....
in the presence of *** .....

The following are particulars in connexion with the sample(s) of the medicine or scheduled substance:

1. Approved name .....
2. Trade name (if any) .....
3. Registration number .....
4. Estimated quantity .....
5. Name and business address:
   (a) Manufacturer .....
   .....
   (b) Seller .....
6. Batch number on label .....
7. Expiry date on label .....
8. Other particulars on label .....
9. Particulars on package insert .....
10. Any other appropriate particulars .....
    .....

Witness ..... Inspector .....
Date .....

---

* Full address.
** Name and full address.
*** Name and full address of witness.

17. The following form shall be issued with regard to the testing, examination or analysis of samples taken under the act:

MEDICINES CONTROL COUNCIL

CERTIFICATE BY ANALYST, PHARMACOLOGIST OR PATHOLOGIST OF RESULTS OF ANALYSIS OR TESTING OR EXAMINATION OF SAMPLE OF A MEDICINE OR SCHEDULED SUBSTANCE

I, (full name) .....
a duly appointed: (i) analyst; (ii) pharmacologist; or (iii) pathologist in terms of section 27 of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), hereby declare that on (date) ..... I received a sample of * .....
from ** ..... for: (i) analysis; (ii) testing; (iii) examination;
that the sample was marked as follows *** .....
.....
that I have analysed and/or tested the sample and found the results which are subjoined .....
.....

Remarks with regard to results .....
.....

.....
Analyst, Pharmacologist, Pathologist

---

* Name of contents as described on the label.
** Name of person from whom sample was received.
*** Name of manufacturer, batch number and any other particulars on the label.

(i))
(ii)) Delete whichever is not applicable.
(iii))

Sale of medicines and substances not contained in the Schedules by persons other than pharmacists, medical practitioners, dentists and veterinarians

18. (1) A licence for the sale of a medicine or substance not contained in the Schedules to the Act may, subject to the provisions of the appropriate provincial ordinance or of the ordinance of the territory, be issued to a person on condition that:

(a) such person applies for such licence to the authority specified in the ordinance;

(b) the medicine is sold only from the premises stated in the licence;

(c) the licence is at all times available for inspection on the premises mentioned therein.

(2) The form to be used for application for a licence shall conform to the requirements of the licensing authority.

(3) The licensing authority shall, when a licence is issued, furnish the Council with a copy thereof.

Prescription for a medicine or scheduled substance

19. Every prescription shall be written and signed by a medical practitioner, dentist or veterinarian and shall state:

(a) the date of issue of the prescription;

(b) the name and quantity of the medicine or scheduled substance to be supplied thereunder: Provided that in the case of Schedule 6 and Schedule 7 substances the quantity to be supplied shall be expressed in figures as well as in words: Provided further that where the prescriber has failed to express the quantity in figures as well as in words, the medical practitioner, dentist, veterinarian or pharmacist dispensing the prescription may, after obtaining confirmation from the prescriber, insert the words or figures that have been omitted;

(c) the name and address of the patient or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the medicine or scheduled substance shall be sold: Provided that where the medical practitioner, dentist or veterinarian who issued the prescription has omitted to insert thereon the address of the patient or person as aforesaid, such address may be inserted by the person by whom the prescription is dispensed; and

(d) the name, qualifications and address of the medical practitioner, dentist or veterinarian by whom the prescription was issued: Provided that such particulars may be printed on the prescription.

Orders for Schedule 6 and Schedule 7 substances by pharmacists, medical practitioners, dentists and veterinarians

20. Every order for a Schedule 6 or Schedule 7 substance, issued by a pharmacist, medical practitioner, dentist or veterinarian, shall state:

(a) the name and quantity of the substance to be supplied thereon: Provided that the quantity to be supplied shall be expressed in figures as well as in words;

(b) the name, business address and qualifications of the particular pharmacist, medical practitioner, dentist or veterinarian ordering the Schedule 6 or Schedule 7 substance; and

(c) the date of the order.

Keeping and sale of Schedule 1, Schedule 2, Schedule 3 and Schedule 4 substances by persons in the service of a manufacturer of or a wholesale dealer in pharmaceutical products

21. A person who is in the service of a manufacturer of or wholesale dealer in pharmaceutical products and who has been authorized thereto by such manufacturer or wholesale dealer may keep and sell Schedule 1, Schedule 2, Schedule 3 and Schedule 4 substances: Provided that:

(a) such person shall be in possession of a document of authorization on which appear his name and address and signature and the name, business address and signature of the manufacturer or wholesale dealer concerned, as well as the name and quantity of each scheduled substance which he may keep at any given time and the period for which he is so authorized. Provided further that such document of authorization shall be produced, on request, to any person to whom such substances are sold;

(b) such person shall keep a register in which the quantities of all receipts and sales of the scheduled substances concerned have been entered, and shall balance such register so as to show clearly the quantity of every scheduled substance remaining in stock as on the last day of March, June, September and December of each year, the balancing to be completed within 14 days of the aforementioned dates, and the balances so shown shall be inspected and certified as correct by the manufacturer or wholesale dealer concerned; and

(c) the sale of such scheduled substances shall take place only on an order issued and signed by a pharmacist, medical practitioner, dentist or veterinarian, on which shall appear the name and quantity of the substances which may be sold thereon, the name and business address and qualifications of the pharmacist, medical practitioner, dentist or veterinarian to whom the substances were sold and the date on which such order was executed: Provided further that not more than one issue of such substances shall be made on such order and that such order shall be retained for one year.

Schedule 5 substances record for use by manufacturer, wholesaledealer, importer or exporter

22. (1) A Schedule 5 substances record shall be kept and shall contain the following information:

(a) The name and business address of the person from whom each substance has been received or to whom such substance has been sold;

(b) the date on which such substance was received or sold;

(c) the quantity of such substance received or sold;

(2) A Schedule 5 substances record shall be retained for a period of not less than three years.

Schedule 6 substances register for use by manufacturer, wholesaledealer, importer or exporter

23. (1) The Schedule 6 substances register should be in the form indicated hereunder and the undermentioned details must be entered therein:

(a) the name and business address of the person from whom each such substance was received or to whom it was sold;

(b) the date on which such substance was received or sold;

(c) the quantity of such substance received or sold; and

(d) the quantity in stock on the last day of March, June, September and December of each year.

(2) The Schedule 6 substances register also serves as an order book as required in terms of section 22A (8) (b) (iii) of the Act and the details contained in subregulation (1) shall be entered therein.

(3) The Schedule 6 substances register shall be retained at the business address of the seller for a period of not less than three years after the date of the last entry therein.

SCHEDULE 6 SUBSTANCES REGISTER

Name of Schedule 6 substance .....

Receipts			Issues		
Date	Name and address of supplier	Quantity	Date	Name and address of purchaser	Quantity

Record of receipt of Schedule 5 and Schedule 6 substances to be kept by pharmacists who sell by retail, and medical practitioners, dentists and veterinarians

24. (1) Every pharmacist who sells by retail, and every medical practitioner, dentist or veterinarian shall keep a record of all receipts of Schedule 5 and Schedule 6 substances, and shall retain such record for a period of not less than three years.

(2) The record referred to in subregulation (1) shall consist of the invoices of purchase or a separate register of such substances.

Schedule 7 substances register

25. (1) The Schedule 7 substances register should be in the form indicated hereunder and the undermentioned details must be entered therein:

(a) The name and business address of the person from whom each such substance or to whom it was sold was received;

(b) the date on which such substance was received or sold;

(c) the quantity of such substance received or sold;

(d) the quantity in stock on the last day of March, June, September and December of each year; and

(e) in the case of a prescription issued by a medical practitioner, dentist or veterinarian, also the name and business address of such person.

(2) The Schedule 7 substances register shall be retained at the business address of the seller for a period of not less than three years after the date of the last entry therein.

SCHEDULE 7 SUBSTANCES REGISTER

Name of Schedule 7 substance .....

Receipts			Issues				
Date	Name and address of supplier	Quantity	Date	Name and address of purchaser or patient	Name and address of prescriber	Quantity	Prescription No.

Importation, exportation and manufacture of Schedule 6 and Schedule 7 substances

26. (1) A permit for the importation or exportation through an approved post office or port of entry or exit or the manufacture of a Schedule 6 or Schedule 7 substance may be issued after the submission to the Registrar of Drugs, Private Bag X88, Pretoria 0001, of an application for such permit, signed by a medical practitioner, dentist, veterinarian or a pharmacist and containing the following particulars:

(a) The name and quantity of the Schedule 6 or Schedule 7 substance concerned:

(b) the form of preparation of the substance;

(c) the name and business address of the person to whom the substance is to be exported or from whom the substance is to be imported, as well as the country of origin or destination of the substance;

(d) the purpose for which the substance is required;

(e) in the case of an application for an export permit, a certificate issued by a duly authorized officer of the government or administration of the importing country to the effect that such government or administration is satisfied that the medicine will be used exclusively for medicinal, scientific or educational purposes, and that it approves its importation; and

(f) any further particulars required by the Secretary or the Council.

(2) A permit for the importation or exportation of a Schedule 6 or Schedule 7 substance issued in terms of subregulation (1) shall contain the following information:

(a) The name and business address of the applicant;

(b) the name and business address of the person to whom the substance is to be exported or from whom the substance is to be imported, as well as the country of origin or destination of the substance;

(c) the name and quantity of each substance which may be imported or exported under the permit;

(d) the period of validity of the permit;

(e) in the case of an import permit, the place where the substance is to be stored or processed;

(f) the conditions under which the permit is issued;

(g) instructions regarding the reports and returns to be submitted by the applicant; and

(h) any other particulars determined by the Secretary.

(3) A permit issued in terms of subregulation (1) shall be subject to the conditions set out therein and may be amended or withdrawn.

Cultivation or collection of plants from which Schedule 6 and Schedule 7 substances can be extracted, derived, produced or manufactured

27. (1) A permit for the cultivation or collection of plants or portions thereof from which Schedule 6 or Schedule 7 substances can be extracted, derived, produced or manufactured may be issued after the submission to the Registrar of Drugs, Private Bag X88, Pretoria 0001, of a written application for such permit, containing such particulars as may be required by the Secretary or the Council.

(2) A permit issued in terms of subregulation (1) shall contain the following particulars:

(a) The name and business address of the person to whom the permit has been issued;

(b) the names of the plants or portions thereof to be cultivated or collected;

(c) the names of the Schedule 6 or Schedule 7 substances to be extracted, derived, produced or manufactured and the purpose for which they will be used;

(d) the period of validity of the permit;

(e) the place where the cultivation or collection will take place;

(f) the conditions under which the permit has been issued; and

(g) any other particulars determined by the Secretary.

(3) A permit issued in terms of subregulation (1) may be amended or withdrawn if the conditions contained therein are not complied with or at the discretion of the Secretary on the recommendation of the Council.

Prescription books

28. (1) A prescription book or other permanent record shall be kept on every premises where prescriptions are dispensed and shall be in the form of a record in which the following details relating to every sale of a medicine or scheduled substance are entered for easy reference:

(a) The date on which the prescription was dispensed;

(b) the form of preparation and quantity of the medicine or scheduled substance sold;

(c) the name and address of the patient, or, in the case of a prescription issued by a veterinarian, the name and address of the person to whom the medicine or scheduled substance was sold;

(d) where applicable the name of the medical practitioner, dentist or veterinarian by whom the prescription was issued, or in the case of a Schedule 2 substance sold without a prescription in terms of section 22A (4) of the Act, the name of the pharmacist or trainee pharmacist or unqualified assistant by whom the Schedule 2 substance was sold; and

(e) in the case of the sale of a medicine or scheduled substance in terms of the provisions of sections 18 (3) (a) and (b) of the Act, the reference number allocated to the sale by the seller.

(2) A prescription book or such other record shall be retained at the business address of the seller for a period of at least three years after the date of the last entry made therein.

Ports of entry for Schedule 6 and Schedule 7 substances

29. No person shall import any Schedule 6 or Schedule 7 substance into the Republic or the Territory except through one of the following "ports of entry": Cape Town, Mossel Bay, Port Elizabeth, East London, Durban, Johannesburg, Kempton Park, Blomfontein, Kimberley, Pietermaritzburg, Pretoria, Germiston, Walvis Bay, Windhoek, Lüderitz, and in addition Queenstown, Grahamstown and King William's Town for imports by parcel post only.

Transmission of Schedule 6 and Schedule 7 substances by post

30. No Schedule 6 or Schedule 7 substance shall be conveyed into the Republic or the Territory by letter post, and no person shall despatch or transmit any such medicine in the Republic or the Territory by Letter post. Where any such medicine is conveyed into or within the Republic or the Territory by post it shall be sent or conveyed by certified parcel post.

The purchase, acquisition, keeping or use of scheduled substances by the master of a ship or by the officer in charge of any aircraft

31. The Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, or a medical practitioner designated by him may, notwithstanding the provisions of section 22A of the Act and the provisions of the regulations, on the written request of the master of a ship or the officer in charge of an aircraft, authorize the purchase, acquisition, keeping or use of a Schedule 3, Schedule 4, Schedule 5, Schedule 6 or Schedule 7 substance: Provided that the quantity shall be within reasonable limits and subject to the condition that such substance is intended for medicinal use.

Obtaining of pethidine or preparations or admixtures thereof by registered midwives

32. (1) Every person registered as a midwife in terms of the Nursing Act, 1957 (Act 69 of 1957), who wishes to obtain a supply of a combination of pethidine hydrochloride 50 mg/ml with levallorphan tartrate 0.625 mg/ml (hereinafter referred to as "the medicine") for administration to a midwifery case in an emergency, shall apply, in writing, to the Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, for a permit therefor, stating

(a) the exact nature and quantity of the medicine; and

(b) the name and address of the pharmacist from whom it is proposed to obtain the medicine.

(2) The Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, may, upon receipt of such application and after making such enquiries as he may deem necessary, issue at his discretion a permit authorizing the (midwife) applicant to purchase or obtain as frequently as may be necessary during the period of validity of the permit not more than 600 mg of the medicine at any one time, at that pharmacy except in special cases when the Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, may authorize the supply of a larger quantity not exceeding 1,200 mg.

(3) All permits described in paragraph (2) above shall be issued subject to the following conditions:

(a) The permit shall be in the form as set out hereunder.

(b) The pharmacist supplying the medicines shall, upon production of a permit, in addition to entering the particulars in his Schedule 7 substances register, enter in the space provided on the permit the date of supply, the nature, strength and quantity of medicines supplied and his signature.

(c) The permit shall be of force and effect for a period of six months from the date of issue thereof unless cancelled or withdrawn as provided in paragraph (d) hereof.

(d) The Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, may cancel or withdraw any permit at any time and on being notified of such cancellation or withdrawal, the holder thereof shall forthwith return such permit, together with any quantity of the medicine still in her possession, to the Regional Director, State Health Services, or, in the case of South-West Africa, the Director of Health Services, for disposal as directed by him.

(e) On the request of any person authorized thereto, in writing, by the Secretary for Health, or, in the case of South-West Africa, the Director of Health Services, the holder of a permit shall produce the same for inspection, together with any quantity of the medicine in her possession.

(4) The medicines purchased or obtained by virtue of a permit shall be kept under lock and key by the midwife, who shall at no time have in her possession more than a total quantity of 1,200 mg of the medicine specified in such permit.

(5) (a) The holder of a permit may administer the medicine to a midwifery case, in emergencies only, when a medical practitioner is not available or pending the arrival of a medical practitioner.

(b) The holder of a permit shall not administer to a midwifery case more than 100 mg of the medicine.

(c) The administration of the medicine may be repeated once only and then only after the lapse of at least four hours and only if a medical practitioner is still not available.

(6) The holder of a permit shall, after the administration of the medicine, enter the particulars of such administration in the space provided on the reverse side of the permit.

(7) If the medicine is administered to a midwifery case on the authority of a medical practitioner, his signature shall appear in the space provided therefor on the reverse side of the permit.

(8) An application for the renewal of a permit shall reach the Regional Director, State Health Services, of the area concerned, or, in the case of South-West Africa, the Director of Health Services, at least 14 days before the expiration of such permit and shall be accompanied by such permit on which shall be entered the quantity of medicines in the possession of the holder at the time of the application for renewal.

PERMIT FOR SCHEDULE 7 SUBSTANCE FOR USE BY MIDWIVES

Schedule 7 substance Permit No. .....
Issued in terms of Government Notice R .....
Date .....
Permission is hereby granted to .....
of .....
a midwife registered in terms of the provisions of the Nursing Act, 1957 (Act 69 of 1957), to purchase or obtain, as often as may be necessary, from ..... at .....
the undermentioned Schedule 7 substance for the purpose of administration in emergency midwifery cases.

This permit will expire on .....

.....
Regional Director: State Health Services/
Director of Health Services

Official date stamp.

Quantity of Schedule 7 substances in possession of midwife on date of application for this permit.

To be completed by the officer issuing the permit:

Date	Medicine	Strength	Quantity
.....	.....	.....	.....
.....	.....	.....	.....
.....	.....	.....	.....

Note: A midwife shall at no time have in her possession more than 1,200 mg of the medicine referred to in the above-mentioned Government Notice.

Particulars to be furnished by pharmacist supplying the Schedule 7 substances:

Date	Description of Schedule 7 substances	Strength	Quantity	Signature
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....

Record of administration of Schedule 7 substances:

Date	Hour	To whom administered (Name and address)	Medicine Name, strength and quantity	Reason why midwife administered medicine, or medical practitioner's signature [Subregulation (7)]
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....
.....	.....	.....	.....	.....

Particulars to be furnished by the midwife on application for renewal of this permit: Name, strength and quantity of medicines on hand on date of application for renewal .....
.....
.....

.....
Applicant's signature

Date .....

Possession of certain scheduled substances by persons entering or departing from the Republic or the Territory

33. Any person entering or departing from the Republic or the Territory may, notwithstanding anything to the contrary in the Act or the regulations, be in possession for personal medicinal use of a quantity of a Schedule 5, Schedule 6, Schedule 7 or Schedule 9 substance, which shall not exceed a reasonable quantity required for use for a period of not more than one month: Provided that such person is in possession of:

(a) a prescription for such substance; or

(b) a certificate by a pharmacist to the effect that the substance concerned was prescribed by a medical practitioner for such person.

Importation of medicines

34. No person except a pharmacist, medical practitioner, dentist, veterinarian or other person authorized by the Secretary may import any medicine or scheduled substance into the Republic or the Territory.

Registration fees

35. The following fees shall be payable to the Registrar:

(a) In respect of the registration of a medicine: R60.

(b) Annually, in respect of the retention of the registration of a medicine for which a registration certificate has been issued in terms of section 15 (4) of the Act: R20.

The first payment of the prescribed fee referred to in paragraph (b) shall be made after a medicine has been registered for a period of one year, and annually thereafter within 30 days of such date.

E/NL.1977/84

Republic of South Africa
Regulation Gazette No. 2449, Vol. 142, No. 5476
1 April 1977

Department of Health

GOVERNMENT NOTICE NO. R.437

1 April 1977

AMENDMENT OF SCHEDULES 1 TO 9 TO THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965) 2/

The Minister of Health has, by virtue of the powers vested in him by section 37A of the Medicines and Related Substances Control Act, 1965 (Act 101 of 1965), and on the recommendation of the Medicines Control Council, amended Schedules 1 to 9 to the said Act, as indicated hereunder. This amendment shall come into effect on a date three months after the date of the publication of this notice.

SCHEDULE 1

All preparations and admixtures which are not included in Schedule 2 and contain a substance listed in Schedule 1 or 2, except substances, preparations and admixtures excluded specifically from this Schedule.

All preparations for injection unless otherwise scheduled, except preparations registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Acetanilide and alkyl acetanilides.

Acetyldihydrocodeine; preparations containing 2.5 per cent or less of acetyldihydrocodeine.

..... 3/

Barbituric acid, its derivatives and salts thereof, excluding amobarbital, cyclobarbital, pentobarbital, secobarbital and their salts; preparations and admixtures containing not more than 30 milligrams per minimum recommended or prescribed dose when intended for continued use in asthma and not more than 50 milligrams per minimum recommended or prescribed dose when intended for continued use in epilepsy.

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Beta-aminopropylbenzene and beta-aminoisopropylbenzene; such preparations and admixtures thereof as are exempted from the conditions of Schedule 5.

.....

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

Chlorprenaline and its salts; preparations and admixtures thereof, except inhalants.

Chlorodyne (Tincture of Chloroform and Morphine B.P.C. 1963); preparations and admixtures containing not more than 5.0 per cent of chlorodyne in combination with other medicinal ingredients in such a manner that it cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health.

.....

Cocaine; preparations containing 0.1 per cent or less of cocaine, calculated as cocaine alkaloid.

Codeine (methylmorphine); admixtures containing 2.5 per cent or less of codeine.

DEXTROMETHORPHAN AND ITS SALTS

Difenoxin (or diphenoxylic acid); admixtures containing, per dosage unit, 0.5 milligram or less of difenoxine, calculated as base, and a quantity of atrophine sulphate equal to at least 5.0 per cent of the quantity of difenoxine, calculated as base, which is present in the mixture.

Dihydrocodeine; admixtures containing not more than 2.5 per cent of dihydrocodeine.

Diphenoxylate; preparations containing not more than 2.5 milligrams of diphenoxylate, calculated as base, and not less than 25 micrograms of atropine sulphate per dosage unit.

.....

Ethylmorphine; admixtures containing 2.5 per cent or less of ethylmorphine.

Ethylphenylephrine.

.....

Ipecacuanha alkaloids; substances, preparations and admixtures thereof containing more than 0.01 or less than 0.2 per cent of alkaloids, calculated as emetine.

Morphine; admixtures containing 0.2 per cent or less of morphine calculated as anhydrous morphine.

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Norcodeine; admixtures containing not more than 2.5 per cent of norcodeine.

Opium; admixtures containing not more than 0.2 per cent of morphine, calculated as anhydrous morphine.

.....

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

.....

Pholcodine; admixtures containing 2.5 per cent or less of pholcodine.

Procaine and its salts; preparations and admixtures thereof when intended for internal use, except preparations and admixtures registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Propylhexedrine and its salts; nose drops and inhalants containing the above substances.

Pyridoxilate; preparations and admixtures thereof.

.....

Radix Valerianae and its extracts; preparations and admixtures containing more than 10 per cent thereof.

.....

SCHEDULE 2

Amobarbital, cyclobarbital, pentobarbital, secobarbital and their salts; preparations and admixtures thereof containing not more than 30 milligrams per minimum recommended or prescribed dose, when intended for continued use in asthma and epilepsy.

.....

4/ Note by the Secretariat: International non-proprietary names are underlined.

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 thereof.

Aptocaine and its salts; preparations and admixtures thereof.

.....

Belladonna alkaloids; substances, preparations and mixtures containing 0.1 per cent or more thereof, excluding belladonna plasters.

.....

Camphorated Opium Tincture BP.

.....

Ephedra alkaloids (natural or synthetic) and their salts; substances, preparations and admixtures thereof, except preparations and admixtures for external use containing not more than 1.0 per cent and other preparations and admixtures containing not more than 30 milligrams per dose of ephedrine or ephedra alkaloids.

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

Gelsenium alkaloids; substances, preparations and admixtures containing 0.1 per cent or more thereof.

.....

Hyoscine; substances, preparations and admixtures containing 0.1 per cent or more thereof.

Procyclidine and its salts; preparations and admixtures thereof.

Propyphenazone; preparations and admixtures thereof.

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SCHEDULE 3

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*Benzydamine and its salts; preparations and admixtures thereof.

.....

SCHEDULE 4

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

Amiphenazole and its salts; preparations and admixtures thereof.

.....

Dimethyl sulfoxide; preparations and admixtures thereof.

.....

Disulfiram; preparations and admixtures thereof.

.....

Doxapram and its salts; preparation and admixtures thereof.

.....

Hydralazine and its salts; preparations and admixtures thereof.

.....

Isoprenaline (isoproterenol) and its salts; preparations thereof for injection.

Levallorphan and its salts; preparations and admixtures thereof.

.....

Mephentermine and its salts; preparations and admixtures thereof.

.....

Nalidixic acid; preparations and admixtures thereof.

Nalorphine hydrobromide; preparations and admixtures thereof.

Naloxone and its salts; preparations and admixtures thereof.

.....

Nikethamide; preparations and admixtures thereof.

.....

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

.....

Picrotoxin; preparations and admixtures thereof.

.....

Propanediol, its derivatives and its salts; preparations and admixtures thereof excluding guaiphenesin and chlorphenesin.

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

Rauwolfia serpentina; preparations and admixtures containing 0.1 per cent or more of its alkaloids or their derivatives.

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SCHEDULE 5

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

Aponal; preparations and admixtures thereof.

Apronalide; preparations and admixtures thereof.

.....

Azacyclonol and its salts; preparations and admixtures thereof.

.....

Barbituric acid, its derivatives and its salts, excluding amobarbital, cyclobarbital, pentobarbital, secobarbital and their salts; preparations and admixtures thereof, except preparations and admixtures containing not more than 30 milligrams per minimum recommended or prescribed dose, when intended for continued use in asthma and not more than 50 milligrams per minimum recommended or prescribed dose, when intended for continued use in epilepsy.

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

.....

Benzoctamine and its salts; preparations and admixtures thereof.

Beta-aminopropylbenzene and beta-aminoisopropylbenzene, any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and ring closure) and any salt or substance falling under the above; preparations and admixtures thereof (except preparations and admixtures of the above when used as vasoconstrictors and decongestants in antihistamine nose and eye-drops, and except when contained in appliances for inhalation in which the substance is absorbed in solid material, and excluding ephedrine, etafedrine, N-methylephedrine, N-diethylamino-ethylephedrine, phenylpropanolamine, prenylamine and preparations and admixtures thereof) and except substances listed in Schedules 8 and 9.

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Bromazepam; preparations and admixtures thereof.

Bromisoval preparations and admixtures thereof.

Butriptyline and its salts; preparations and admixtures thereof.

Carbromal; preparations and admixtures thereof.

Chloral derivatives; preparations and admixtures thereof.

Chlordiazepoxide and its salts; preparations and admixtures thereof.

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

Chlorprothixene; preparations and admixtures thereof.

Clomacran and its salts; preparations and admixtures thereof.

Clomethiazole and its salts; preparations and admixtures thereof.

Clonazepam; preparations and admixtures thereof.

.....

Cyclophosphamide, its salts and its derivatives; preparations and admixtures thereof.

Deanol and its derivatives; preparations and admixtures thereof.

Dextropropoxyphene and its salts; preparations and admixtures thereof.

Diazepam; preparations and admixtures thereof.

Dibenzepin and its salts; preparations and admixtures thereof.

Dipotassium chlorazepate; preparations and admixtures thereof.

Dothiepin and its salts; preparations and admixtures thereof.

Doxepin and its salts; preparations and admixtures thereof.

.....

Emylcamate; preparations and admixtures thereof.

Enflurane; preparations and admixtures thereof.

Ethclorvynol; preparations and admixtures thereof.

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

Etodroxizine; preparations and admixtures thereof, except preparations and admixtures thereof when used solely as an antihistaminic.

Fencamfamin and its salts; preparations and admixtures thereof.

Fenfluramine and its salts; preparations and admixtures thereof.

Flunitrazepam; preparations and admixtures thereof.

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Flurazepam and its salts; preparations and admixtures thereof.

Fluspirilene; preparations and admixtures thereof.

Halothane.

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

Heminevrin; preparations and admixtures thereof.

Hydroxyurea; preparations and admixtures thereof.

Hydroxyzine and its salts; preparations and admixtures thereof.

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

Iproniazid and its salts; preparations and admixtures thereof.

Isoflurane; 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.

Loxapine and its salts; preparations and admixtures thereof.

Maprotiline and its salts; preparations and admixtures thereof.

Mazindol; preparations and admixtures thereof.

Mechlorethamine and its derivatives; preparations and admixtures thereof.

Meclofenoxate and its salts; preparations and admixtures thereof.

Medazepam; preparations and admixtures thereof.

Melitracen and its salts; preparations and admixtures thereof.

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

Mephenoxalone; preparations and admixtures thereof.

Meprobamate; preparations and admixtures thereof.

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

Methotrexate and its salts; preparations and admixtures thereof.

Methoxyflurane; preparations and admixtures thereof.

Methyprylon and its salts; preparations and admixtures thereof.

Mianserin and its salts; preparations and admixtures thereof.

Molindone and its salts; preparations and admixtures thereof.

Nitrazepam; preparations and admixtures thereof.

NOMIFENSINE AND ITS SALTS; PREPARATIONS AND ADMIXTURES THEREOF

Oxazepam; preparations and admixtures thereof.

Oxypertine 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.

Phenethylhydrazine and its salts; preparations and admixtures thereof.

Phenothiazine, its derivatives and their salts; preparations and admixtures thereof, except preparations containing promethazine or dimethothiazine or their salts when used solely as an antihistaminic, and except preparations containing promethazine or its salts when specially intended for the treatment of travel sickness or local application to the epidermis, and except preparations registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947).

Phentermine and its salts; preparations and admixtures thereof.

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Pipradol and its salts; preparations and admixtures thereof.

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Prazepam; preparations and admixtures thereof.

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Prolintane and its salts; preparations and admixtures thereof.

Propanidid; preparations and admixtures thereof.

Sulfonmethane; preparations and admixtures thereof.

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Temazepam; preparations and admixtures thereof.

Tiothixene and its salts; preparations and admixtures thereof.

Tranylcypromine and its salts; preparations and admixtures thereof.

Trazodone and its salts; preparations and admixtures thereof.

TRIAZOLAM; PREPARATIONS AND ADMIXTURES THEREOF

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Urethane; preparations and admixtures thereof.

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SCHEDULE 6

Amobarbital, cyclobarbital, pentobarbital, secobarbital and their salts; preparations and admixtures thereof, except preparations and admixtures containing not more than 30 milligrams per minimum recommended or prescribed dose when intended for continued use in asthma and epilepsy.

Chlorphentermine and its salts; preparations and admixtures thereof.

Diethylpropion and its salts; preparations and admixtures thereof.

Glutethimide; preparations and admixtures thereof.

Pentazocine and its salts; preparations and admixtures thereof.

Phencyclidine and its salts; preparations and admixtures thereof.

Tilidine and its salts; preparations and admixtures thereof.

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 compound;

(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 the esters or ethers of the said 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.

Acetyldihydrocodeine; except admixtures containing not more than 2.5 per cent of acetyldihydrocodeine.

Acetylmethadol.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

Chlorodyne (Tincture of Chloroform and Morphine BPC 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 of chlorodyne in combination with other medicines in such manner that it cannot be recovered by readily applicable means or in a yield which would constitute a risk to public health.

Clonitazene.

Cocaine; except admixtures containing not more than 0.1 per cent of cocaine, calculated as cocaine alkaloid.

Codeine (methylmorphine); except admixtures containing not more than 2.5 per cent of codeine.

Codoxime.

Concentrate of poppy straw.

Desomorphine.

Dextromoramide.

Diampromide.

Diethylthiambutene.

Difenoxin (or diphenoxylic acid); any preparation of difenoxine, except admixtures containing, per dosage unit, 0.5 milligram or less 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; except admixtures containing not more than 2.5 per cent of dihydrocodeine.

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene.

Dioxaphetylbutyrate.

Diphenoxylate; except preparations containing not more than 2.5 milligrams of diphenoxylate, calculated as base, and not less than 25 micrograms of atropine sulphate per dosage unit.

Dipipanone.

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

Ethylmethylthiambutene.

Ethylmorphine; except admixtures containing not more than 2.5 per cent of ethylmorphine.

Etonitazene.

Etorphine.

Etoxeridine.

Fenproporex.

Fentanyl.

Furethidine.

Hydrocodone (dihydrocodeinone).

Hydromorphinol (14-hydroxydihydromorphine).

Hydromorphone (dihydromorphinone).

Hydroxypethidine.

Isomethadone.

Ketobemidone.

Levomoramide.

Levophenacylmorphan.

Levorphanol.

Mefenorex.

Metazocine.

Methadone.

Methadone-intermediate.

Methaqualone.

Methorphan, including levomethorphan and racemethorphan, but excluding dextromethorphan.

Methyldesorphine.

Methyldihydromorphine.

Methylphenidate and its derivatives.

Metopon.

Moramide-intermediate.

Morpheridine.

Morphine; except preparations and admixtures of morphine containing not more than 0.2 per cent of morphine, calculated as anhydrous morphine, and except admixtures from which morphine cannot be recovered by readily applicable means or in a yield which 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.

Noracemethadol.

Norcodeine; except admixtures containing not more than 2.5 per cent of norcodeine.

Norlevorphanol.

Normethadone.

Normorphine (demethylmorphine or N-demethylated morphine).

Norpipanone.

Opium; except admixtures containing not more than 0.2 per cent of 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.

Phendimetrazine.

Phenomorphan.

Phenoperidine.

Pholcodine; except admixtures containing not more than 2.5 per cent of pholcodine.

Piminodine.

Piritramide.

Proheptazine.

Properidine.

Propiram.

Racemoramide.

Racemorphan.

Thebacon.

Thebaine.

Trimeperidine.

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 compound;

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

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

Amphetamine

Bufotenine (N,N-dimethylserotonin).

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

Coca Leaf.

Dexamphetamine.

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). [LSD][5/]

Mescaline (3,4,5-trimethoxyphenethylamine).

Methamphetamine.

Phenmetrazine.

Prepared opium.

Psilocine (4-hydroxydimethyltryptamine).

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

Tetrahydrocannabinols.

SCHEDULE 9

Amphetamine.

Dexamphetamine.

Note:

(a) The Scheduling status of substances referred to in entries marked * have been amended in this notice.

(b) The entries in capital letters indicate substances which have been included in the Schedules for the first time.

5/ Note by the Secretariat: The words in square brackets have been inserted by the Secretariat.