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GOVERNMENT GAZETTE

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DEPARTMENT OF THE PRIME MINISTER

No. 2000. 30 October 1974.

It is hereby notified that the State President has assented to the following Act which is hereby published for general information:—

No. 65 of 1974: Drugs Control Amendment Act, 1974.

DEPARTEMENT VAN DIE EERSTE MINISTER

No. 2000. 30 Oktober 1974.

Hierby word bekend gemaak dat die Staatspresident sy goedkeuring geheg het aan die onderstaande Wet wat hierby ter algemene inligting gepubliseer word:—

No. 65 van 1974: Wysigingswet op die Beheer van Medisyne, 1974.

ACT

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:—

1. (1) The following section is hereby substituted for section 1 of the Drugs Control Act, 1965 (hereinafter referred to as the principal Act): **Substitution of section 1 of Act 101 of 1965.**

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

(2) Any reference, in any law or elsewhere, to a drug as defined in section 1 of the principal Act prior to the substitution thereof by subsection (1) of this section, shall be deemed to be a reference to a medicine as defined in the said section 1 as so substituted.

Substitution of section 2 of Act 101 of 1965.

2. (1) The following section is hereby substituted for section 2 of the principal Act:

"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.".

(2) The Drugs Control Council established by section 2 of the principal Act prior to the substitution thereof by subsection (1) of this section, shall for all purposes be deemed to be and at all times to have been the Medicines Control Council referred to in the said section 2 as substituted by the said subsection (1), and any reference in any law or elsewhere to the Drugs Control Council shall be construed accordingly.

Amendment of section 3 of Act 101 of 1965.

3. Section 3 of the principal Act is hereby amended—

(*a*) by the substitution for subsection (1) of the following subsection:

"(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.";

(*b*) by the substitution for paragraph (*a*) of subsection (2) of the following paragraph:

"(*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;";

(*c*) by the substitution, in paragraph (*c*) of that subsection, for the word "drugs" of the word "medicines"; and

(*d*) by the substitution for paragraph (*d*) of that subsection of the following paragraph:

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

Amendment of section 4 of Act 101 of 1965.

4. (1) Section 4 of the principal Act is hereby amended by the substitution for subsection (4) of the following subsection:

"(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.".

(2) Notwithstanding the provisions of section 4 (1) of the principal Act, any person who is at the commencement of this Act a member of the council referred to in that section, shall vacate his office as such on a date fixed by the State President by proclamation in the *Gazette*.

Amendment of section 6 of Act 101 of 1965.

5. Section 6 of the principal Act is hereby amended—

(*a*) by the substitution for paragraph (*b*) of subsection (1) of the following paragraph:

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

(*b*) by the substitution for paragraph (*c*) of that subsection of the following paragraph:

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

(*c*) by the substitution for paragraph (*c*) of subsection (2) of the following paragraph:

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

(*d*) by the substitution for subsection (4) of the following subsection:

"(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.".

Amendment of section 7 of Act 101 of 1965.

6. Section 7 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

"(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.".

Amendment of section 9 of Act 101 of 1965.

7. Section 9 of the principal Act is hereby amended by the substitution for subsection (4) of the following subsection:

"(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.".

Substitution of section 10 of Act 101 of 1965.

8. (1) The following section is hereby substituted for section 10 of the principal Act:

"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."

(2) The Drugs Control Appeal Board established by section 10 of the principal Act prior to the substitution thereof by subsection (1) of this section, shall for all purposes be deemed to be and at all times to have been the Medicines Control Appeal Board referred to in the said section 10 as substituted by the said subsection (1), and any reference in any law or elsewhere to the said Drugs Control Appeal Board shall be construed accordingly.

Amendment of section 11 of Act 101 of 1965.

9. Section 11 of the principal Act is hereby amended—

(*a*) by the substitution for paragraph (*f*) of subsection (1) of the following paragraph:

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

(*b*) by the substitution for paragraph (*g*) of the said subsection (1) of the following paragraph:

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

(*c*) by the substitution for paragraph (*c*) of subsection (2) of the following paragraph:

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

(*d*) by the substitution, in subsection (4), for the word "drug", wherever it occurs, of the word "medicine".

Substitution of section 12 of Act 101 of 1965.

10. (1) The following section is hereby substituted for section 12 of the principal Act:

"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.".

(2) (*a*) Any reference in any other law to the Registrar of Drugs referred to in section 12 of the principal Act prior to the substitution thereof by subsection (1) of this section, shall be construed as a reference to the Registrar of Medicines referred to in the said section 12 as substituted by the said subsection (1).

(*b*) Anything done by the said Registrar of Drugs prior to the commencement of this section in the administration of any law, shall be deemed to have been done by the said Registrar of Medicines.

(*c*) The person who held office as the said Registrar of Drugs immediately prior to the commencement of this section, shall be deemed to have been appointed as the said Registrar of Medicines under section 12 of the principal Act as substituted by subsection (1) of this section.

Amendment of section 13 of Act 101 of 1965.

11. (1) Section 13 of the principal Act is hereby amended by the substitution for the word "drugs", wherever it occurs, of the word "medicines".

(2) The drugs register referred to in section 13 of the principal Act prior to the commencement of subsection (1) of this section shall be deemed to be the medicines register referred to in section 13 of the principal Act as amended by subsection (1) of this section, and any drug registered in the said drugs register prior to such commencement shall be deemed to be a medicine registered in the said medicines register.

Substitution of section 14 of Act 101 of 1965, as substituted by section 1 of Act 29 of 1968.

12. (1) The following section is hereby substituted for section 14 of the principal Act:

"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.

13. The following section is hereby substituted for section 15 of the principal Act: Substitution of section 15 of Act 101 of 1965, as amended by section 2 of Act 29 of 1968.

"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.".

Amendment of section 16 of Act 101 of 1965, as amended by section 3 of Act 29 of 1968.

14. Section 16 of the principal Act is hereby amended by the substitution for the word "drug", wherever it occurs, of the word "medicine".

Substitution of section 17 of Act 101 of 1965, as amended by section 4 of Act 29 of 1968.

15. The following section is hereby substituted for section 17 of the principal Act:

"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.".

16. The following section is hereby substituted for section 18 of the principal Act: Substitution of section 18 of Act 101 of 1965.

"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 brand name; 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.".

Amendment of section 19 of Act 101 of 1965.

17. Section 19 of the principal Act is hereby amended by the substitution for the word "drug" wherever it occurs of the word "medicine".

Amendment of section 20 of Act 101 of 1965.

18. Section 20 of the principal Act is hereby amended by the substitution for the word "drug" wherever it occurs of the word "medicine".

Amendment of section 21 of Act 101 of 1965.

19. Section 21 of the principal Act is hereby amended by the substitution for the word "drug" wherever it occurs of the word "medicine".

Substitution section 22 of Act 101 of 1965.

20. The following section is hereby substituted for section 22 of the principal Act:

"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.".

21. The following section is hereby inserted in the principal Act after section 22: Insertion of section 22A in Act 101 of 1965.

"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 subsection, shall not be sold by thel hoder of a licence referred to in subsection (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 subsection, no person shall use or have in his possession or manufacture any Schedule 5 substance, or collect, cultivate or keep any plant or portion thereof from which any such substance can be extracted, derived, produced or manufactured.

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

(i) by any person other than a pharmacist or a trainee pharmacist or 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 subparagraph (i), in a quantity greater than that stated in the prescription: Provided that such sale may, if the person who issued the prescription indicated thereon the number of times and the intervals at which it may be dispensed, be repeated accordingly: Provided further that every seller shall endorse on the prescription the date of sale and the quantity of the said substance sold, and that the last seller shall retain the prescription for a period of not less than three years as from the date of the last sale.

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

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

(*e*) The 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 subsection, no person shall use or have in his possession or manufacture any Schedule 6 substance, or collect, cultivate or keep any plant or portion thereof from which any such substance can be extracted, derived, produced or manufactured.

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

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

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

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

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

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

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

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

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

(*f*) 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 subsection, no person shall use or have in his possession or manufacture any Schedule 7 substance, or collect, cultivate or keep any plant or portion thereof from which any such substance can be extracted, derived, produced or manufactured.

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

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

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

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

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

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

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

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

(*f*) 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 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.".

Amendment of section 23 of Act 101 of 1965.

22. Section 23 of the principal Act is hereby amended by the substitution for the word "drug" wherever it occurs of the word "medicine".

Amendment of section 24 of Act 101 of 1965.

23. Section 24 of the principal Act is hereby amended by the substitution for subsection (1) of the following subsection:

"(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.".

Substitution of section 26 of Act 101 of 1965.

24. (1) The following section is hereby substituted for section 26 of the principal 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).".

(2) Any person appointed, prior to the commencement of subsection (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 subsection (1) of this section.

Substitution of section 27 of Act 101 of 1965.

25. (1) The following section is hereby substituted for section 27 of the principal Act:

"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.".

(2) Any analyst, pharmacologist or pathologist appointed, prior to the commencement of subsection (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 subsection (1) of this section.

Amendment of section 28 of Act 101 of 1965.

26. Section 28 of the principal Act is hereby amended—

(*a*) by the substitution in subsections (1) and (2) for the word "drug", wherever it occurs, of the words "medicine or Scheduled substance"; and

(*b*) by the substitution for subsection (4) of the following subsection:

"(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.".

Amendment of section 29 of Act 101 of 1965.

27. Section 29 of the principal Act is hereby amended—

(*a*) by the substitution for paragraph (*h*) of the following paragraph:

"(*h*) makes any false or misleading statement in connection with any medicine or Scheduled substance—

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

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

(*b*) by the substitution for paragraph (*i*) of the following paragraph:

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

(*c*) by the addition of the word "or" at the end of paragraph (*j*); and

(*d*) by the addition of the following paragraph:

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

Amendment of section 30 of Act 101 of 1965.

28. Section 30 of the principal Act is hereby amended—

(*a*) by the substitution in subsection (2) for the word "drug" of the word "medicine or Scheduled substance"; and

(*b*) by the substitution for subsection (3) of the following subsection:

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

Amendment of section 31 of Act 101 of 1965.

29. Section 31 of the principal Act is hereby amended by the substitution in paragraphs (*a*) and (*d*) of subsection (1) for the word "drug" of the words "medicine or Scheduled substance".

Amendment of section 32 of Act 101 of 1965.

30. Section 32 of the principal Act is hereby amended by the substitution for the word "drug", wherever it occurs, of the word "medicine".

Substitution of section 35 of Act 101 of 1965, as amended by section 5 of Act 29 of 1968, section 1 of Act 88 of 1970 and section 7 of Act 95 of 1971.

31. (1) The following section is hereby substituted for section 35 of the principal Act:

"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 subsection (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 connection with the treatment of eye injuries or for other essential purposes;

(xxiii) authorizing and regulating the purchase, acquisition, keeping or use of Scheduled substances by 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 connection 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 subsection.

(2) The Minister shall, not less than three months before any regulation is made under subsection (1), cause the text of such regulation to be published in the *Gazette* together with a notice declaring his intention to make that regulation and inviting interested persons to furnish him with any comments

thereon or any representations they may wish to make in regard thereto.

(3) The provisions of subsection (2) shall not apply in respect of—

(*a*) any regulation which, after the provisions of that subsection have been complied with, has been amended by the Minister in consequence of comments or representations received by him in pursuance of the notice issued thereunder; or

(*b*) any regulation in respect of which the Minister is, after consultation with the council, of the opinion that the public interest requires it to be made without delay.

(4) No regulation shall be made under paragraph (xxx) of subsection (1) except in consultation with the Minister of Finance.

(5) Regulations made under subsection (1) (x) may prescribe that any medicine or any component thereof shall comply with the requirements set out in any publication which in the opinion of the council is generally recognized as authoritative.

(6) Regulations may be made under this section in respect of particular medicines or Scheduled substances or classes or categories of medicines or Scheduled substances or in respect of medicines or Scheduled substances other than particular classes or categories of medicines or Scheduled substances, and different regulations may be so made in respect of different medicines or Scheduled substances or different classes or categories of medicines or Scheduled substances.

(7) Any regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith, not exceeding a fine of 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 subsection (1), shall remain in force until it is amended or withdrawn under the said section 35.

Amendment of section 36 of Act 101 of 1965.

32. Section 36 of the principal Act is hereby amended by the substitution for the word "drug" of the word "medicine".

Substitution of section 37 of Act 101 of 1965.

33. The following section is hereby substituted for section 37 of the principal Act:

"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.".

Insertion of section 37A in Act 101 of 1965.

34. The following section is hereby inserted in the principal Act after section 37:

"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.".

Substitution of section 40 of Act 101 of 1965.

35. The following section is hereby substituted for section 40 of the principal Act:

"Short title.

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

Addition of Schedules to Act 101 of 1965.

36. Schedules A, B, C, D, E, F, G, H and I to this Act are hereby added to the principal Act as Schedules 1, 2, 3, 4, 5, 6, 7, 8 and 9, respectively, thereto.

Substitution of long title of Act 101 of 1965.

37. The following long title is hereby substituted for the long title of the principal Act:

"ACT

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.".

Repeal of certain provisions of Act 13 of 1928.

38. (1) Sections 48 to 72 of and the Fourth and Sixth Schedules to the Medical, Dental and Pharmacy Act, 1928, are hereby repealed.

(2) Anything done in terms of a provision repealed by subsection (1) shall, if it could be done in terms of a provision of the principal Act as amended by this Act, be deemed to have been done in terms of such last-mentioned provision.

Short title and commencement.

39. This Act shall be called the Drugs Control Amendment Act, 1974, and shall come into operation on a date fixed by the State President by proclamation in the *Gazette*.

Schedule A

(SCHEDULE 1 TO ACT NO. 101 OF 1965.)

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

Acetanilide and alkyl acetanilides.

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

Alclofenac.

All preparations for injection, unless otherwise scheduled.

Amyl nitrite.

Anethole trithione.

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

Anticoagulants; preparations and admixtures thereof intended for external use.

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

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

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

Camylofin and its salts.

Chlormezanone; admixtures thereof containing 100 milligrams or less per minimum recommended or prescribed dose.
Chloroform; all substances, preparations and admixtures containing more than 20 per cent.
Clonidine and its salts; preparations and admixtures thereof when intended for the treatment of migraine.
Cocaine; preparations containing 0,1 per cent or less cocaine, calculated as cocaine alkaloid.
Codeine (methylmorphine); admixtures containing 2,5 per cent or less codeine.
Cresol and phenol; all preparations and admixtures containing 3,0 per cent or more of any one of these substances.
Dicyclomine and its salts.
Diphenoxylate; admixtures containing 2,5 milligrams or less of diphenoxylate, calculated as base, per dosage unit.
Epinephrine and its salts.
Escin (aescin) and its salts; preparations and admixtures thereof intended for external use and containing 1,0 per cent or less escin.
Ethacridine and its salts.
Ether (diethyl ether).
Ethylmorphine; admixtures containing 2,5 per cent or less ethylmorphine.
Ethylphenylephrine.
Fenoterol and its salts.
Flufenamic acid and its salts; preparations and admixtures thereof intended for external use.
Hexamine.
Hexoprenaline and its salts.
Hormones (natural or synthetic); such preparations thereof intended solely for topical application to the epidermis or for vaginal use.
Isoproterenol and its salts.
Ketoprofen.
Lead acetate.
Lead plaster and its combinations.
Local anaesthetics; preparations for topical application to the skin or mucous membranes.
Mercuric iodide.
Mercuric oxides; substances, preparations and admixtures thereof *except* those containing less than 3,0 per cent of mercury.
Mercuric ammonium chloride.
Metaproterenol and its salts.
Methylacetanilide.
Morphine; admixtures containing 0,2 per cent or less morphine calculated as anhydrous morphine.
Naproxen.
Nonoxynol.
Oral antidiabetic preparations.
Phenacetin.
Phenylephrine and its salts; preparations and admixtures thereof, *except* eye drops containing 0,2 per cent or less phenylephrine or its salts.
Pholcodine; admixtures containing 2,5 per cent or less pholcodine.
Piracetam.
Potassium dichromate.
Propylhexedrine and its salts; nose drops and preparations for inhalation containing the above substances.
Pyridoxilate; preparations and admixtures thereof.
Quinine and its salts; preparations and admixtures thereof containing more than 1,0 per cent.
Sodium cromoglycate.
Sulfonamides; preparations and admixtures thereof intended for external use.
Terbutaline and its salts.
Tretinoin.

Schedule B

(SCHEDULE 2 TO ACT NO. 101 OF 1965.)

Aconite alkaloids; substances, preparations and admixtures containing 0,02 per cent or more.
Alkaloids and glycosides; all poisonous alkaloids and glycosides, and their salts, not specifically named in any Schedule; substances, preparations and admixtures containing in each single dose more than one-half of the maximum dose of the poison shown in any recognized formulary declared to be such by the Minister by notice in the *Gazette*.
Antihistaminics, *except* when intended specifically for the treatment of travel sickness or topical application.
Antimony potassium tartrate and antimony sodium tartrate; substances, preparations and admixtures containing 1,0 per cent or more thereof.
Antipyrine (phenazone) and its salts; preparations and admixtures thereof, *except* preparations and admixtures intended for external use.
Apomorphine; substances, preparations and admixtures containing 0,2 per cent or more.
Aptocaine and its salts; preparations and admixtures thereof.
Arsenic; substances, preparations and admixtures containing 0,01 per cent or more of the equivalent of arsenic trioxide.
"AS XVII" (Spasmo-urgenin).
Atropine; substances, preparations and admixtures containing 0,1 per cent or more.
Belladonna alkaloids; substances, preparations and admixtures containing 0,1 per cent or more, *except* belladonna plasters.
Calabar bean alkaloids and their salts; substances, preparations and admixtures containing 0,2 per cent or more.
Calcium dobesilate.
Camphorated Opium Tincture B.P.

Cantharidin; substances, preparations and admixtures containig 0,01 per cent or more
Chloroform.
Cyclandelate.
Cyclopentolate.
Dextromethorphan and its salts.
Dimenhydrinate; preparations and admixtures thereof.
Dipyridamole.
Dithiazanine and its salts; preparations and admixtures thereof.
Emepronium bromide.
Ephedra alkaloids (natural or synthetic) and their salts; substances, preparations and admixtures thereof, *except* preparations and admixtures for external use containing not more than one per cent, and other preparations and admixtures containing not more than 30 milligrams per dose of ephedrine or ephedra alkaloids.
Epinephrine (adrenaline) and its salts; preparations and admixtures thereof.
Ergot alkaloids (natural or synthetic) and their salts; preparations and admixtures thereof.
Fenoterol and its salts; preparations and admixtures thereof.
Flavoxate hydrochloride.
Flucytosine; preparations and admixtures thereof when intended for external use.
Furazolidone and its salts; preparations and admixtures thereof.
Gelsenium alkaloids; substances, preparations and admixtures containing 0,1 per cent or more.
Glycopyrronium bromide.
Hexoprenaline and its salts; preparations and admixtures thereof.
Hyoscine; substances, preparations and admixtures containing 0,1 per cent or more.
Inhalants containing epinephrine, fenoterol, hexoprenaline, isoproterenol, metaproterenol, salbutamol or the salts of the above substances in any amount.
Isoprenaline (isoproterenol) and its salts; preparations and admixtures thereof.
Lobelia alkaloids; substances, preparations and admixtures containing 0,5 per cent or more.
Metaproterenol (Orciprenaline) and its salts; preparations and admixtures thereof.
Mercuric chloride; substances, preparations and admixtures containing one per cent or more.
Mercuric organic compounds; preparations and admixtures thereof, *except* substances, preparations and admixtures not being in the form of aerosols intended for topical application to the skin or mucous membranes and containing less than the equivalent of 0,6 per cent of mercury.
Naloxone hydrochloride.
Nitrofurazone and its salts; preparations and admixtures thereof.
Nux vomica; substances, preparations and admixtures containing 0,2 per cent or more of strychnine.
Oleoresin of Aspidium (Filix Mas); preparations and admixtures thereof.
Papaverine; substances, preparations and admixtures containing 0,2 per cent or more.
Phenylephrine and its salts; preparations and admixtures of the above substances, *except* eye drops containing 0,2 per cent or less thereof.
Phenylpropanolamine; preparations and admixtures thereof.
Pilocarpine; substances, preparations and admixtures containing 0,5 per cent or more.
Pimethixene.
Procaine and its salts when used internally.
Procyclidine and its salts; preparations and admixtures thereof.
Propyphenazone; preparations and admixtures thereof.
Pyrodifenium bromide.
Sabadilla alkaloids; substances, preparations and admixtures containing 1,0 per cent or more.
Strychnine; substances, preparations and admixtures containing 0,2 per cent or more.

Schedule C

(SCHEDULE 3 TO ACT NO. 101 OF 1965.)

Allopurinol; preparations and admixtures thereof.
Chromonar and its salts; preparations and admixtures thereof.
Clofibrate; preparations and admixtures thereof.
Digitalis, its glycosides and other active principles thereof unless diluted below one unit (B.P.) in each two grams.
Insulin; preparations and admixtures thereof.
Isoniazid and its derivatives; preparations and admixtures thereof.
Para-aminosalicylic acid and its salts and esters; preparations and admixtures thereof.
Phenytoin and its salts; preparations and admixtures thereof.
Strophanthus, its glycosides and their hydrolysis products, their salts and derivatives; preparations and admixtures thereof.
Thyroid gland and its active principles and derivatives; preparations and admixtures thereof.
Trimethadione; preparations and admixtures thereof.

Schedule D

(SCHEDULE 4 TO ACT NO. 101 OF 1965.)

Acetazolamide and its salts; preparations and admixtures thereof.
Alprenalol and its salts; preparations and admixtures thereof.
Amantadine and its salts; preparations and admixtures thereof.
Aminopyrine (amidopyrine) and its salts; preparations and admixtures thereof.
Antihemophilic Factor; preparations and admixtures thereof.
Antimalarials; preparations thereof *except* the 4-aminoquinoline, 8-aminoquinoline, diguanide and diaminopyridine groups of compounds and preparations thereof when these are intended specifically for malaria prophylaxis.

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

bacitracin
tyrothricin
nystatin
polymixin B
framycetin
neomycin
natamycin
gramicidin

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

Azapropazone; preparations and admixtures thereof.
Baclofen; preparations and admixtures thereof.
Bee venom; preparations and admixtures thereof, *except* preparations for external application.
Benzbromarone; preparations and admixtures thereof.
Bufenoide; preparations and admixtures thereof.
Carbidopa; preparations and admixtures thereof.
Chlorothiazide and other derivatives of benzo-1, 2, 4-thiadiazine-7-sulfonamide-1, 1-dioxide, whether or not hydrogenated, including hydrochlorothiazide, bendrofluazide, benzthiazide, cyclopenthiazide, hydroflumethiazide, methchlorothiazide; preparations and admixtures thereof.
Chlorthalidone and its salts; preparations and admixtures thereof.
Cholestyramine resin; preparations and admixtures thereof.
Clofazimine; preparations and admixtures thereof.
Chlonidine and its salts; preparations and admixtures thereof, *except* preparations and admixtures intended for the treatment of migraine.
Corticosteroids (natural or synthetic); preparations and admixtures thereof.
Cyclofenil; preparations and admixtures thereof.
Dapsone and its derivatives; preparations and admixtures thereof, *except* preparations intended specifically for malaria prophylaxis and *except* products which are registered under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).
Debrisoquine and its salts; preparations and admixtures thereof.
Diazoxide; preparations and admixtures thereof.
Di-isopropyl fluorophosphate; preparations and admixtures thereof.
Dimethyl sulfoxide; preparations and admixtures thereof.
Dinitrophenol and its salts; preparations and admixtures thereof.
Diphemethoxidine and its salts; preparations and admixtures thereof.
Diphenidol and its salts; preparations and admixtures thereof.
Dipyridamole; preparations and admixtures thereof.
Disopyramide; preparations and admixtures thereof.
Disulfiram; preparations and admixtures thereof.
Dopa; preparations and admixtures thereof.
Emetine and its salts; preparations and admixtures thereof.
Escin (aescin) and its salts; preparations and admixtures thereof, *except* preparations and admixtures for external use containing 1,0 or less percent escin.
Ethacrynic acid and its salts; preparations and admixtures thereof.
Ethambutol and its salts; preparations and admixtures thereof.
Ethionamide; preparations and admixtures thereof.
Eyedrops containing local anaesthetics.
Flucytosine; preparations and admixtures thereof, *except* preparations and admixtures intended for external use.
Flufenamic acid and its salts; preparations and admixtures thereof, *except* preparations and admixtures intended for external use.
Furosemide; preparations and admixtures thereof.
Glaphenine; preparations and admixtures thereof.
Guanacline and its salts; preparations and admixtures thereof.
Halofenate; preparations and admixtures thereof.
Hormones (natural or synthetic); preparations and admixtures thereof, *except* those preparations and admixtures intended solely for topical application to the epidermis, and *except* preparations for vaginal use, and *except* those registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), and *except* insulin and epinephrine (adrenaline).
Indapamide; preparations and admixtures thereof.
Indomethacin and its salts; preparations and admixtures thereof.
Local anaesthetics; preparations and admixtures thereof, *except* preparations for external application to the skin and mucous membranes.
Mefenamic acid and its salts; preparations and admixtures thereof.
Mephentermine and its salts; preparations and admixtures thereof.
2-Mercaptonylpropionylglycine; preparations and admixtures thereof.
Methampyrone; preparations and admixtures thereof.
Methyldopa and its salts and esters; preparations and admixtures thereof.
Methysergide and its salts; preparations and admixtures thereof.
Morphazinamide and its salts; preparations and admixtures thereof.
Morphethylbutyne hydrochloride; preparations and admixtures thereof.
Nalidixic acid; preparations and admixtures thereof.
Nalorphine hydrobromide; preparations and admixtures thereof.
Niflumic acid; preparations and admixtures thereof.

Niridazole; preparations and admixtures thereof.
Nitrofurantoin and its salts; preparations and admixtures thereof.
Nitroxoline and its salts; preparations and admixtures thereof.
Oxolinic acid; preparations and admixtures thereof.
Oxprenalol and its salts; preparations and admixtures thereof.
Pancuronium and its salts; preparations and admixtures thereof.
Penicillamine; preparations and admixtures thereof.
Pentoxifylline; preparations and admixtures thereof.
Perhexiline maleate; preparations and admixtures thereof.
Phentolamine and its salts; preparations and admixtures thereof.
Phenylbutazone and its salts; preparations and admixtures thereof, *except* preparations for topical application to the epidermis.
Picrotoxin; preparations and admixtures thereof.
Polyglycerylene-dextran and its salts; preparations and admixtures thereof.
Potassium canrenoate; preparations and admixtures thereof.
Practolol and its salts; preparations and admixtures thereof.
Prazosin and its salts; preparations and admixtures thereof.
Prindolol; preparations and admixtures thereof.
Procaine amide; preparations and admixtures thereof.
Propanediol derivatives and their salts; preparations and admixtures thereof, *except* guaiphenesin and chlorphenesin.
Propranolol and its salts; preparations and admixtures thereof.
Propylhexedrine and its salts; preparations and admixtures thereof, *except* when used as a vasoconstrictor and decongestant in nose drops and appliances for inhalation.
Protionamide; preparations and admixtures thereof.
Pyrazinamide; preparations and admixtures thereof.
Rauwolfia serpentina; preparations and admixtures containing 0,1 or more percent of its alkaloids or their derivatives.
Sodium nitroprusside; preparations and admixtures thereof.
Styramate; preparations and admixtures thereof.
Sulfonamides; substances, preparations and admixtures thereof, *except* those substances, preparations and admixtures intended for external use, and *except* those substances, preparations and admixtures registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).
Tamoxifen and its salts; preparations and admixtures thereof.
Thiacetazone; preparations and admixtures thereof.
Tilidine and its salts; preparations and admixtures thereof.
Toxogonin and its salts; preparations and admixtures thereof.
Tranexamic acid; preparations and admixtures thereof.
Triamterene.
Verapamil (iproveratril) and its salts; preparations and admixtures thereof.
Veratrum alkaloids; preparations and admixtures thereof.

Schedule E

(SCHEDULE 5 TO ACT NO. 101 OF 1965.)

Amitryptiline and its derivatives and their salts; preparations and admixtures thereof.
Anaesthetic preparations containing pregnanedione derivatives.
Anticoagulants; preparations and admixtures thereof, *except* when used as rodenticides and vermicides, and *except* preparations for external application.
Aponal; preparations and admixtures thereof.
Apronalide; preparations and admixtures thereof.
L-Asparaginase; preparations and admixtures thereof.
Azacyclonol and its salts; preparations and admixtures thereof.
Barbituric acid, its derivatives and salts thereof; preparations and admixtures thereof, *except* when containing 15 or less milligrams per minimum recommended or prescribed dose of any of these in combination with other medicines and *except* admixtures containing not more than 30 milligrams per minimum recommended or prescribed dose where intended for continued use in asthma and epilepsy.
Benactyzine, its derivatives and their salts; preparations and admixtures thereof.
Benzoctamine and its salts; preparations and admixtures thereof.
Benzquinamide and its salts; preparations and admixtures thereof.
Beta-aminopropylbenzene and beta-aminoisopropylbenzene, and any compound structurally derived from either of these substances by substitution in the side chain or by ring closure therein (or by both such substitution and ring closure) and any salt or substance falling under the above and preparations and admixtures thereof (*except* preparations and admixtures of the above when used as vasoconstrictors and decongestants in antihistamine nasal and eye drops, and *except* when contained in appliances for inhalation in which the substance is absorbed in solid material, and *except* ephedrine, etafedrine, N-methylephedrine, N-diethylaminoethylephedrine, phenylpropanolamine, prenylamine and preparations and admixtures thereof.)
Bromazepam; preparations and admixtures thereof.
Bromisovalum; preparations and admixtures thereof.
Busulphan and its salts; preparations and admixtures thereof.
Butriptyline and its salts; preparations and admixtures thereof.
Butyrophenones; preparations and admixtures thereof.
Carbamazepine; preparations and admixtures thereof.
Carbromal; preparations and admixtures thereof.
Chloral derivatives; preparations and admixtures thereof.
Chlorambucil and its salts; preparations and admixtures thereof.
Chlordiazepoxide and its salts; preparations and admixtures thereof.
Chlormezanone; preparations and admixtures thereof, *except* admixtures containing 100 or less milligrams of chlormezanone per minimum recommended or prescribed dose.

Clobenzazepam; preparations and admixtures thereof.
Clonazepam; preparations and admixtures thereof.
Clothiapine; preparations and admixtures thereof.
Clozapine; preparations and admixtures thereof.
Deanol and its derivatives; preparations and admixtures thereof.
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.
Echothiopate iodide; preparations and admixtures thereof.
Enflurane; preparations and admixtures thereof.
Ethchlorvynol; preparations and admixtures thereof.
Ethinamate, its derivatives and their salts; preparations and admixtures thereof.
Fencamfamine and its salts; preparations and admixtures thereof.
Fenfluramine and its salts; preparations and admixtures thereof.
5-Fluorouracil; preparations and admixtures thereof.
Flurazepam and its salts; preparations and admixtures thereof.
Halothane.
Hedonal and its salts and esters; preparations and admixtures thereof.
Hydroxyurea; preparations and admixtures thereof.
Hydroxyzine and its salts; preparations and admixtures thereof.
Imipramine, its derivatives and their salts; preparations and admixtures thereof.
Iproniazid and its salts; preparations and admixtures thereof.
Ketamine and its salts; preparations and admixtures thereof.
Lithium salts; preparations and admixtures thereof, when intended for human use.
Lorazepam; preparations and admixtures thereof.
Maprotiline mesylate; preparations and admixtures thereof.
Mazindol; preparations and admixtures thereof.
Meclofenoxate and its salts; preparations and admixtures thereof.
Medazepam; preparations and admixtures thereof.
Melphalan, its derivatives and their salts; preparations and admixtures thereof.
Mephenoxalone; preparations and admixtures thereof.
Mephentermine and its salts; preparations and admixtures thereof.
Meprobamate; preparations and admixtures thereof.
6-Mercaptopurine, its derivatives and their salts; preparations and admixtures thereof.
Methyprylone and its salts; preparations and admixtures thereof.
Metoclopramide.
Molindone and its salts; preparations and admixtures thereof.
Nitrazepam; preparations and admixtures thereof.
Oxazepam; preparations and admixtures thereof.
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 its salts when specially intended for the treatment of travel sickness or local application to the epidermis, and *except* those registered and sold under the provisions of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947).
Phentermine and its salts; preparations and admixtures thereof.
Pipradrol and its salts; preparations and admixtures thereof.
Pregnanedione.
Prolintane and its salts; preparations and admixtures thereof.
Sulfonmethane; preparations and admixtures thereof.
Sulpyride; preparations and admixtures thereof.
Temazepam; preparations and admixtures thereof.
Thiothixene and its salts; preparations and admixtures thereof.
Tranylcypromine and its salts; preparations and admixtures thereof.
Trazodone and its salts; preparations and admixtures thereof.
Trihexyphenidyl and its salts; preparations and admixtures thereof.
Urethan; preparations and admixtures thereof.

Schedule F

(SCHEDULE 6 TO ACT NO. 101 OF 1965.)

Barbiturates, being amobarbital, cyclobarbital, pentobarbital, secobarbital and their salts; preparations and admixtures thereof.
Chlorphentermine and its salts; preparations and admixtures thereof.
Diethylpropion and its salts; preparations and admixtures thereof.
Glutethimide, preparations and admixtures thereof.
Methaqualone and its salts; preparations and admixtures thereof.
Pentazocine and its salts; preparations and admixtures thereof.

Schedule G

(SCHEDULE 7 TO ACT No. 101 OF 1965.)

All the substances mentioned in this Schedule include—

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

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

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

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

Acetorphine.

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

Acetylmethadol.

Allylprodine.

Alphacetylmethadol.

Alphameprodine.

Alphamethadol.

Alphaprodine.

Anileridine.

Benzethidine.

Benzphetamine.

Benzylmorphine.

Betacetylmethadol.

Betameprodine.

Betamethadol.

Betaprodine.

Bezitramide.

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

Clonitazene.

Cocaine, *excluding* admixtures containing not more than 0,1 per cent cocaine, calculated as cocaine alkaloid.

Codeine (methylmorphine), *excluding* admixtures containing not more than 2,5 per cent codeine.

Codoxime.

Concentrate of poppy straw.

Desomorphine.

Dextromoramide.

Diampromide.

Diethylthiambutene.

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

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

Dihydromorphine.

Dimenoxadol.

Dimepheptanol.

Dimethylthiambutene.

Dioxaphetylbutyrate.

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

Dipipanone.

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

Ethylmethylthiambutene.

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

Etonitazene.

Etorphine.

Etoxeridine.

Fentanyl.

Furethidine.

Hydrocodone (dihydrocodeinone).

Hydromorphinol (14-hydroxydihydromorphine).

Hydromorphone (dihydromorphinone).

Hydroxypethidine.

Isomethadone.

Ketobemidone.

Levomoramide.

Levophenacylmorphan.

Levorphanol.

Mefenorex.

Metazocine.

Methadone.

Methadone—intermediate.

Methorphan, including levomethorphan and racemethorphan, but *excluding* dextromethorphan.

Methyldesorphine.
Methyldihydromorphine.
Methylphenidate and its derivatives.
Metopon.
Moramide—intermediate.
Morpheridine.
Morphine, *excluding* preparations and admixtures of morphine containing not more than 0,2 per cent morphine, calculated as anhydrous morphine, and *except* admixtures from which morphine cannot be recovered by readily applicable means or cannot be recovered in such a quantity that it would constitute a risk to public health. (See also Chlorodyne.)
Morphine methobromide and other pentavalent nitrogen morphine derivatives.
Morphine-N-oxide and its derivatives.
Myrophine (myristylbenzylmorphine).
Nicocodine.
Nicodicodine.
Nicomorphine.
Noracymethadol.
Norcodeine, *excluding* admixtures containing not more than 2,5 per cent norcodeine.
Norlevorphanol.
Normethadone.
Normorphine (demethylmorphine or N-demethylated morphine).
Norpipanone.
Opium, *excluding* admixtures containing not more than 0,2 per cent morphine calculated as anhydrous morphine. (See also Chlorodyne.)
Oxycodone (14-hydroxydihydrocodeinone or dihydrohydroxycodeinone).
Oxymorphone (14-hydroxydihydromorphinone or dihydrohydroxymorphinone).
Pethidine, pethidine-intermediate-A, pethidine-intermediate-B and pethidine-intermediate-C
Phenadoxone.
Phenampromide.
Phenazocine.
Phencyclidine.
Phendimetrazine.
Phenomorphan.
Phenoperidine.
Pholcodine, *excluding* admixtures containing not more than 2,5 per cent pholcodine.
Piminodine.
Piritramide.
Proheptazine.
Properidine.
Propiram.
Racemoramide.
Racemorphan.
Thebacon.
Thebaine.
Trimeperidine.

Schedule H

(SCHEDULE 8 TO ACT NO. 101 OF 1965.)

All the substances mentioned in this schedule include—

(*a*) the isomers of the substances where the existence of such isomers is possible in the specific chemical compounds;
(*b*) the esters and ethers of the substances and the isomers thereof where the existence of such esters and ethers is possible;
(*c*) the salts of the substances or the isomers thereof or of the esters or ethers of the substances or the isomers thereof, where the existence of such salts is possible;
(*d*) all the preparations and admixtures of the substances where such preparations and admixtures are not expressly excluded.

Bufotenine (N,N-dimethylserotonin).
Cannabis and the whole plant or any portion or product thereof.
Coca leaf.
Diethyltryptamine [3-(2-(diethylamino)-ethyl)-indole].
Dimethyltryptamine [3-(2-(dimethylamino)-ethyl)-indole].
Harmaline (3, 4-dihydroharmine).
Harmine [7-methoxy-1-methyl-9-pyrid (3, 4-6)-indole].
Heroin (diacetylmorphine).
Lysergide (lysergic acid diethylamide).
Mescaline (3, 4, 5-trimethoxyphenethylamine).
Prepared Opium.
Psilocin (4-hydroxydimethyltryptamine).
Psilocybin (4-phosphoryloxy-N, N-dimethyltryptamine).
Tetrahydrocannabinol.

Schedule I

(SCHEDULE 9 TO ACT NO. 101 OF 1965.)

Amphetamine.
Dexamphetamine.