STAATSKOERANT

VAN DIE REPUBLIEK VAN SUID-AFRIKA

REPUBLIC OF SOUTH AFRICA

GOVERNMENT GAZETTE

As 'n Nuusblad by die Poskantoor Geregistreer *Registered at the Post Office as a Newspaper*

Prys 20c Price
Oorsee 30c Overseas
POSVRY—POST FREE

VOL. 165] KAAPSTAD, 21 MAART 1979 CAPE TOWN, 21 MARCH 1979 [No. 6358

DEPARTEMENT VAN DIE EERSTE MINISTER

No. 583. 21 Maart 1979.

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

No. 17 van 1979: Wysigingswet op die Beheer van Medisyne en Verwante Stowwe, 1979.

DEPARTMENT OF THE PRIME MINISTER

No. 583. 21 March 1979.

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

No. 17 of 1979: Medicines and Related Substances Control Amendment Act, 1979.

Act No. 17, 1979 MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT, 1979.

GENERAL EXPLANATORY NOTE:

[ ] Words in bold type in square brackets indicate omissions from existing enactments.

Words underlined with solid line indicate insertions in existing enactments.

ACT

To amend the Medicines and Related Substances Control Act, 1965, so as to define or further define certain expressions; to further regulate the constitution of the Medicines Control Council and the Medicines Control Appeal Board; to extend the provisions of the said Act to medicines intended for animals; to make new provision in relation to the labelling and advertising of medicines; to further regulate the furnishing of information regarding the registration of medicines and the cancellation of such registration; to make further provision for the control of Scheduled substances and for the authorization of inspectors, analysts, pharmacologists and pathologists to act in terms of the said Act; to further regulate the taking of and dealing with samples of medicines and Scheduled substances; and to effect a change in relation to the power to make regulations; and to provide for matters connected therewith.

(Afrikaans text signed by the State President.)
(Assented to 13 March 1979.)

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

Amendment of section 1 of Act 101 of 1965, as substituted by section 1 of Act 65 of 1974.

1. Section 1 of the Medicines and Related Substances Control Act, 1965 (hereinafter referred to as the principal Act), is hereby amended—

(a) by the insertion in subsection (1) after the definition of "board" of the following definition:
"'export' includes deliver or supply within the Republic for dispatch to any destination outside the Republic;";

(b) by the insertion in subsection (1) after the definition of "hospital" of the following definition:
"'immediate container', in relation to a medicine or Scheduled substance, means a container which is in direct contact with the medicine or substance;";

(c) by the substitution in subsection (1) for the definition of "medical practitioner" of the following definition:
"'medical practitioner' means a person registered as such under the Medical Act, and includes an intern registered under that Act and, in relation to any medicine and any Schedule 1, Schedule 2, Schedule 3 and Schedule 4 substance, a student intern

registered under that Act who prescribes or provides the medicine or any such substance, as contemplated in section 36 (2) *(a*A*)* of the said Act;";

(d) by the substitution in subsection (1) for the definition of "medicine" of the following definition:

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

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in man,

and includes any veterinary medicine;";

(e) by the substitution in subsection (1) for the definition of "pharmacist" of the following definition:

"'pharmacist' means a person registered as such under the Pharmacy Act, 1974, and includes a trainee pharmacist, as defined in that Act, during the twelfth month of the period or periods of practical training referred to in section 20 (1) of that Act;";

(f) by the insertion in subsection (1) after the definition of "pharmacist" of the following definition:

"'pharmacist's assistant' means a person registered as such under the Pharmacy Act, 1974;";

(g) by the deletion in subsection (1) of the definition of "unqualified assistant";

(h) by the addition to subsection (1) of the following definition:

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

(i) by the substitution for subsection (2) of the following subsection:

"(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."; and

(j) by the substitution for subsection (3) of the following subsection:

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

Act No. 17, 1979

MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT ACT, 1979.

Amendment of section 3 of Act 101 of 1965, as amended by section 3 of Act 65 of 1974 and section 1 of Act 36 of 1977.

2. 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 **[fifteen]** sixteen members as may from time to time be determined by the State President."; and

(b) by the insertion in subsection (2) of the following paragraph after paragraph *(d)*:

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

Amendment of section 6 of Act 101 of 1965, as amended by section 5 of Act 65 of 1974.

3. 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 Veterinary Act, 1933, the Medical Act or the Pharmacy Act, 1974, from carrying on his profession, while so disqualified;"; and

(b) 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 or a veterinarian 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; or

(c) in the case of a veterinarian, he sells the medicine in question in the course of carrying on his professional activities as a veterinarian.".

Amendment of section 10 of Act 101 of 1965, as substituted by section 8 of Act 65 of 1974.

4. Section 10 of the principal Act is hereby amended—

(a) by the substitution in subsection (1) for the words preceding paragraph *(a)* of the following words:

"(1) There is hereby established a board to be known as the Medicines Appeal Board, which shall consist of **[three]** four members to be appointed by the State President, of whom—";

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

"*(b)* one shall be a medical practitioner who has a speciality in medicine entered in the appropriate register contemplated in section **[19]** 18 of the Medical Act; **[and]**";

(c) by the insertion after paragraph *(b)* of the said subsection (1) of the following paragraph:

"*(b*A) one shall be a veterinarian; and"; and

(d) by the addition of the following subsection:

"(3) The member of the appeal board—

(a) referred to in subsection (1) *(b)*, shall not participate in any proceedings of the appeal board relating to any medicine which is a veterinary medicine; and

(b) referred to in subsection (1) *(b*A), shall not participate in any proceedings of the appeal board relating to any medicine other than a veterinary medicine.".

Amendment of section 11 of Act 101 of 1965, as amended by section 9 of Act 65 of 1974.

5. Section 11 of the principal Act is hereby amended by the substitution for subsection (4) of the following subsection:

"(4) For the purposes of paragraph *(f)* of subsection (1) a medical practitioner or a veterinarian shall not be deemed to have an interest in the sale of any medicine by reason only of

the fact that he sells the medicine in question in the course of carrying on his professional activities as a medical practitioner or a veterinarian.".

Amendment of section 14 of Act 101 of 1965, as substituted by section 12 of Act 65 of 1974.

6. Section 14 of the principal Act is hereby amended by the substitution for subsection (4) of the following subsection:

"(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 or a veterinarian for a particular person or animal, as the case may be, in a quantity not greater than the quantity required for treatment as determined by the medical practitioner or veterinarian or compounded by a pharmacist for a particular person or animal 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 or animal as prescribed by a medical practitioner or a dentist or a veterinarian, as the case may be, if such medicine does not contain any component the sale of which is prohibited by this Act or any component in respect of which an application for registration has been rejected, and is not and has not been advertised.".

Substitution of section 18 of Act 101 of 1965, as substituted by section 16 of Act 65 of 1974.

7. The following section is hereby substituted for section 18 of the principal Act:

"Labels and advertisements.

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

(2) No person shall advertise any medicine or Scheduled substance for sale unless such advertisement complies with the prescribed requirements.".

Substitution of section 22 of Act 101 of 1965, as amended by section 20 of Act 65 of 1974.

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

"Secretary to cause certain information to be furnished.

22. (1) The **[council shall, subject to the approval of the Secretary, in such manner as it]** Secretary shall, after consultation with the council, cause, in such manner as the Secretary considers most suitable—

(a) as soon as practicable after any medicine, other than a veterinary medicine, has been registered, **[inform]** medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine to be informed—

(i) of the name and number under which such medicine is registered and the conditions, if any, subject to which such medicine is registered;

(ii) of the therapeutic efficacy and effect of such medicine;

(iii) of the purpose for which, the circumstances under which and the manner in which such medicine should be used; and

(iv) regarding any other matter concerning such medicine which, in the opinion of the council, may be of value to them;

(b) as soon as practicable after the registration of any medicine, other than a veterinary medicine, has been cancelled in terms of section 16, **[inform]** medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine to be informed of the cancellation of such registration.

(2) The provisions of subsection (1) shall apply *mutatis mutandis* in respect of any veterinary medicine, and for the purposes of such application the reference in that subsection to medical practitioners and dentists shall be deemed to be a reference to veterinarians.".

Amendment of section 22A of Act 101 of 1965, as inserted by section 21 of Act 65 of 1974.

9. Section 22A of the principal Act is hereby amended—

(a) by the substitution for the proviso to subsection (3) of the following proviso:

"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]** pharmacist's assistant or by a medical practitioner or dentist or veterinarian or on a written order which discloses the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of sixteen years **[and such order shall be retained by the seller for a period of not less than six months after the relevant sale]**.";

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

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

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

(b) to any person apparently under the age of sixteen years except upon a prescription issued by a medical practitioner, dentist or veterinarian and dispensed by a pharmacist, trainee pharmacist or **[unqualified]** pharmacist's assistant or by a medical practitioner or dentist or veterinarian or on a written order which discloses the purpose for which such substance is to be used and bears a signature known to the seller as the signature of a person known to such seller and who is apparently over the age of sixteen years; and

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

(c) by the substitution for paragraph *(a)* of subsection (5) of the following paragraph:

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

(d) by the substitution for paragraph *(c)* of subsection (5) of the following paragraph:

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

(e) by the substitution in paragraph *(a)* of subsection (6) for the words preceding the proviso of the following words:

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

(f) by the substitution for paragraph *(c)* of subsection (6) of the following paragraph:

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

(g) by the substitution for the first proviso to paragraph *(d)* of subsection (6) of the following proviso:

"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:";

(h) by the substitution for subparagraph (i) of paragraph *(b)* of subsection (7) of the following subparagraph:

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

(i) by the substitution for paragraph *(e)* of subsection (7) of the following paragraph:

"*(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.";

(j) by the substitution for paragraph *(f)* of subsection (8) of the following paragraph:

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

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

[(ii)] *(bb)* 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.

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

(k) by the substitution for paragraph *(g)* of subsection (8) of the following paragraph:

"*(g)* The Secretary may **[on the recommendation of the council]** issue, subject to such conditions and

requirements as the Secretary may on [such] the recommendation of the council determine, a permit to any person to acquire, possess or use any Schedule 6 substance, or to collect, cultivate or keep, for scientific, research or educational purposes, any plant or any portion thereof from which any such substance can be extracted, derived, produced or manufactured.";

(l) by the insertion after paragraph *(b)* of subsection (9) of the following paragraph:

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

(m) by the substitution for paragraph *(f)* of subsection (9) of the following paragraph:

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

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

[(ii)] *(bb)* 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.

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

(n) by the substitution for paragraph *(g)* of subsection (9) of the following paragraph:

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

(o) by the deletion of subsection (13); and

(p) by the addition to subsection (15) of the following paragraphs:

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

(d) any veterinary assistant or veterinary nurse within the meaning of the Veterinary Act, 1933 (Act No.

16 of 1933), from selling, upon a written prescription issued by a veterinarian or on the verbal instructions of a veterinarian, any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal.".

Amendment of section 26 of Act 101 of 1965, as amended by section 24 of Act 65 of 1974 and section 1 of Act 19 of 1976.

10. Section 26 of the principal Act is hereby amended by the substitution for subsection (1) of the following subsection:

"(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.".

Substitution of section 27 of Act 101 of 1965, as substituted by section 25 of Act 65 of 1974.

11. 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.".

Amendment of section 28 of Act 101 of 1965, as amended by section 26 of Act 65 of 1974.

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

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

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

and

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

"(3) The analyst, pharmacologist or pathologist to whom **[one part of]** a sample has been transmitted in terms of the provisions of subsection (2) shall with all convenient speed test, examine or analyse the sample delivered to him, and the result of the test, examination or analysis shall be stated in a certificate in the prescribed form.".

Amendment of section 31 of Act 101 of 1965, as amended by section 29 of Act 65 of 1974.

13. Section 31 of the principal Act is hereby amended by the substitution for subsection (2) of the following subsection:

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

Amendment of section 35 of Act 101 of 1965, as substituted by section 31 of Act 65 of 1974 and amended by section 3 of Act 19 of 1976.

14. Section 35 of the principal Act is hereby amended—

(a) by the insertion in subsection (1) after paragraph (xxv) of the following paragraph:

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

(b) by the substitution in subsection (1) for paragraph (xxviA) of the following paragraph:

"(xxviA) as to the **[procedure to be followed if]** disposal or destruction of a Scheduled substance which has become unfit for use, and the report to be furnished in respect thereof;";

(c) by the substitution in subsection (1) for paragraph (xxvii) of the following paragraph:

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

(d) by the substitution in subsection (1) for paragraph (xxx) of the following paragraph:

"(xxx) prescribing the fee **[(not exceeding one hundred rand)]** to be paid to the registrar in respect of the application for the registration, and in respect of the registration, of a medicine, the fee **[(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 lastmentioned fee shall be so paid;".

Substitution of long title of Act 101 of 1965, as substituted by section 37 of Act 65 of 1974.

15. 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 and for animal use, for the establishment of a Medicines Control Council, for the control of medicines and Scheduled substances and for matters incidental thereto.".

Short title.

16. This Act shall be called the Medicines and Related Substances Control Amendment Act, 1979.