

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

NOTE: The whole of this Act, except sections 1, 15B, 18, 22B, 24, 34A and 40, has been repealed by section 50 of the South African Medicines and Medical Devices Regulatory Authority Act 132 of 1998 which will come into operation on a date to be fixed by the President by proclamation in the Gazette.

[ASSENTED TO 19 JUNE 1965] [DATE OF COMMENCEMENT: 1 APRIL 1966]
(Afrikaans text signed by the State President)

as amended by:

Drugs Control Amendment Act 29 of 1968
 Drugs Control Amendment Act 88 of 1970
 Drugs Laws Amendment Act 95 of 1971
 Drugs Control Amendment Act 65 of 1974
 Medicines and Related Substances Control Amendment Act 19 of 1976
 Health Laws Amendment Act 36 of 1977
 Medicines and Related Substances Control Amendment Act 17 of 1979
 Medicines and Related Substances Control Amendment Act 20 of 1981
 Transfer of Powers and Duties of the State President Act 97 of 1986
 Businesses Act 71 of 1991*
 Medicines and Related Substances Control Amendment Act 94 of 1991
 General Law Amendment Act 49 of 1996
 Abolition of Restrictions on the Jurisdiction of Courts Act 88 of 1996
 Medicines and Related Substances Control Amendment Act 90 of 1997
 Medicines and Related Substances Amendment Act 59 of 2002

ACT

To provide for the registration of medicines and related substances intended for human and for animal use; to provide for the establishment of a Medicines Control Council; to provide that such council shall be a juristic person; to make other provision for the constitution of the council; to provide that a member of the council or committee shall declare his or her commercial interest related to the pharmaceutical or health care industry; to provide that the appointment of members of the executive committee is subject to the approval of the Minister; to provide for the control of medicines and scheduled substances and medical devices; to make further provision for the prohibition on the sale of medicines which are subject to registration and are not registered; to provide for procedures that will expedite the registration of essential medicines, and for the re-evaluation of all medicines after five years; to provide for measures for the supply of more affordable medicines in certain circumstances; to provide that labels be approved by the council; to prohibit sampling and bonusing of medicines; to provide for the licensing of certain persons to compound, dispense or manufacture medicines and medical devices and also to act as wholesalers or distributors; to provide for the generic substitution of medicines; to provide for the establishment of a pricing committee; to regulate the purchase and sale of medicines by manufacturers, distributors, wholesalers, pharmacists and persons licensed to dispense medicines; to make new provisions for appeals against decisions of the Director-General or the council; to provide that the council may acquire and appropriate funds; to regulate the Minister's power to make regulations; to provide for the rationalization of certain laws relating to medicines and related substances that have remained in force in various territories on the national territory of the Republic of South Africa, 1996; and to provide for matters connected therewith.

1. Definitions

(1) In this Act, unless the context otherwise indicates-

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

- (a) appearing in any newspaper, magazine, pamphlet or other publication; or
- (b) distributed to members of the public; or
- (c) brought to the notice of members of the public in any manner whatsoever,

which is intended to promote the sale of that medicine or Scheduled substance; and 'advertise' has a corresponding meaning;

'analyst' means an analyst to whom authority has been granted under section 27;

'approved name', in relation to a medicine, means the international non proprietary name (INN) of such medicine or, where no such name exists, such other name as the council may determine, not being a brand name or trade name registered in terms of the Trade Marks Act, 1993 (Act 194 of 1993);

'certificate of registration' means a certificate of registration issued under section 15 (4), 15A (4) or 15 (B) (4);

'council' means the Medicines Control Council established by section 2;

'dentist' means a person registered as such under the Health Professions Act, 1974;

'Director-General' means the Director-General: Health;

'export' includes deliver or supply within the Republic for dispatch to any destination outside the Republic;

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

'immediate container', in relation to a medicine or Scheduled substance, means a container which is in direct contact with the medicine or substance;

'interchangeable multi-source medicine' means medicines that contain the same active substances which are identical in strength or concentration, dosage form and route of administration and meet the same or comparable standards, which comply with the requirements for therapeutic equivalence as prescribed;

'inspector' means a person authorized as such under section 26;

'label', when used as a verb, means brand, mark or otherwise designate or describe, and when used as a noun, means any brand or mark or any written, pictorial or other descriptive matter appearing on or attached to or packed with and referring to any article or the package containing any article;

'magistrate' means a magistrate as defined in section 1 of the Magistrates Act, 1993 (Act No.90 of 1993), and includes an additional magistrate and an assistant magistrate;

'medical device' means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent-

- (a) used or purporting to be suitable for use or manufactured or sold for use in-
 - (i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of disease, abnormal physical or mental states or the symptoms thereof; or
 - (ii) restoring, correcting or modifying any somatic or psychic or organic function; or
 - (iii) the diagnosis or prevention of pregnancy,
 and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the human body but which may be assisted in its function by such means; or
- (b) declared by the Minister by notice in the Gazette to be a medical device, and includes any part or an accessory of a medical device;

'medical practitioner' means a person registered as such under the Health Professions, 1974 and includes an intern registered under that Act;

'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;

'Minister' means the Minister of Health;

'nurse' means a person registered as such under the Nursing Act, 1978 (Act 50 of 1978);

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

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

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

'pharmacist intern' means a person registered as such under the Pharmacy Act, 1974;

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

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

'practitioner' means a person registered as such under the Allied Health Professions Act, 1982 (Act 63 of 1982);

'prescribed' means prescribed by or under this Act;

'public' includes a section of the public concerned with manufacturing, dispensing, selling or administering, or the issue of prescriptions for, medicines or a Scheduled substance;

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

'registered' means entered in the register;

'registrar' means the Registrar of Medicines appointed under section 12;

'regulation' means a regulation made and in force under this Act;

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

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

'this Act' includes any regulation;

'veterinarian' means a person registered as such under the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982);

'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 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.

- (2) Subject to section 15C, a medicine shall, notwithstanding the fact that its components are identical to those of any other medicine as to physical characteristics, quantity and quality, for the purpose of this Act not be regarded as being the same medicine as that other medicine if registration thereof is not applied for by the holder of the certificate of registration issued in respect of that other medicine.
- (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.
- (4) International tendering for medicines shall be allowed in the prescribed manner and on the prescribed conditions.

2. Establishment, powers and functions of Medicines Control Council

- (1) There is hereby established a council to be known as the Medicines Control Council, which may exercise the powers and shall perform the functions conferred upon or assigned to the council by this Act.
- (2) The Council may advise the Minister or furnish a report to the Minister on any matter referred to the council by the Minister for consideration and arising from the application of this Act.
- (3) The council shall be a juristic person.

3. Constitution of council

The council shall consist of so many members, but not more than 24, as the Minister may from time to time determine and appoint.

4. Period of office and remuneration of members of the council

- (1) A member of the council shall, subject to the provisions of section 6 (3), be appointed for a period of five years but a new council shall be appointed within six months after the date of commencement of the Medicines and Related Substances Control Amendment Act, 1997.
- (2) Any person whose period of office as a member of the council has expired, shall be eligible for reappointment: Provided that no person who has served two periods of five years as a member shall be so eligible.
- (3) The Minister shall give notice in the Gazette of the appointment of any member of the council and the date from which his membership commences and, in the case of a member appointed to fill a casual vacancy on the council, the period for which he is appointed.
- (4) A member of the council (other than a person who is in the full-time employment of the State) shall receive such remuneration and such allowances in respect of his services as a member of the council or of any committee thereof, as the Minister in consultation with the Minister of Finance may determine.

5. Chairman and vice-chairman

- (1) One of the members of the council shall be designated by the Minister as chairman of the council and another member shall be designated by the Minister as vice-chairman to act as chairman during the absence of the chairman.
- (2) The vice-chairman, when acting as chairman as provided in subsection (1), shall have all the powers and discharge all the duties of the chairman.

6. Disqualifications, vacation of office, filling of vacancies and declaration of interest

- (1) No person shall be appointed as a member of the council-
 - (a) who is an unrehabilitated insolvent;
 - (b) who is disqualified under the Veterinary and Para-Veterinary Professions Act, 1982, the Chiropractors, Homeopaths and Allied Health Service Professions Act, 1982, the Health Professions Act, 1974, or the Pharmacy Act, 1974, from carrying on his or her profession, while so disqualified;
 - (c) who is not a South African citizen permanently resident in the Republic; or
 - (d) who is employed in the pharmaceutical industry.
- (2) A member of the council shall vacate his or her office-
 - (a) if he or she is or becomes subject to any disqualification referred to in subsection (1);
 - (b) if he or she becomes mentally ill, as defined in the Mental Health Act, 1973 (Act 18 of 1973);
 - (c) if he or she is convicted of an offence and is sentenced to imprisonment without the option of a fine;
 - (d) if he or she has been absent from more than two consecutive meetings of the council without the council's leave; or

- (e) if the Minister is satisfied that the member has violated the internal rules of conduct as determined by the council and published by notice in the Gazette.
- (3) If the office of any member becomes vacant before the expiration of the period for which he or she was appointed, the Minister may appoint another person to hold office for the unexpired portion of the period for which his or her predecessor was appointed.
- (4) A member of the council or of a committee appointed in terms of section 9 shall declare his or her commercial interests related to the pharmaceutical or health care industry, which interests shall include, but shall not be limited to, any consultancy, paid or unpaid, any research grant from which the member directly or indirectly benefits, or any equity holding or any executive or non-executive directorship or any other payment or benefit in kind, and shall recuse himself or herself from any discussion or decision-making to which the said interests relate or may relate.

7. Meetings of the council

- (1) The first meeting of the council shall be held at a time and place to be fixed by the Minister, and all subsequent meetings shall, subject to the provisions of sub-section (2), be held at such times and places as may be fixed by the council: Provided that the council shall hold at least one meeting in any period of three months and, if at the close of any meeting the council has not fixed the time and place for its next meeting, such time and place shall be fixed by the chairman.
- (2) The chairman of the council may at any time call a special meeting of the council to be held at such time and place as he may determine, and shall, upon a written request by the Minister or a written request signed by not less than three members of the council, call a special meeting thereof to be held within thirty days after the date of receipt of such request, at such time and place as he may determine.

8. Quorum, majority decision and chairman's casting vote

- (1) A majority of all the members of the council shall form a quorum for any meeting of the council.
- (2) At all meetings of the council the chairman, or in his absence the vice-chairman, or in the absence of both the chairman and the vice-chairman, some other member of the council chosen by the members present, shall preside.
- (3) Save as provided in section thirty-six, the decision of a majority of the members of the council present at any meeting thereof shall constitute a decision of the council, and in the event of an equality of votes in regard to any matter, the person presiding at the meeting in question shall have a casting vote in addition to his deliberative vote.
- (4) No decision or act done under the authority of the council shall be invalid by reason only of an interim vacancy on the council or of the fact that a person who is disqualified from being a member of the council, or with respect to whose appointment the provisions of this Act have not been observed, sat or acted as a member at the time when the decision was taken or the act was performed or authorized, if the decision was taken or the act was performed or authorized by the requisite majority of the members of the council present at the time who were entitled to sit and act as members.

9. Appointment of executive committee and other committees

- (1) The council may appoint-
 - (a) subject to the approval of the Minister, from among its members an executive committee; and

- (b) subject to the approval of the Minister, such other committees as it may deem necessary, to investigate and report to it on any matter within the purview of the council in terms of this Act.
- (2) The executive committee may, subject to the directions of the council, exercise all the powers and perform all the functions of the council during periods between meetings of the council, but shall not have the power, save in so far as the council otherwise directs, to set aside or vary any decision of the council, and any action taken or decision made by the executive committee shall be subject to review at the first ensuing meeting of the council.
- (3) The council may appoint such persons, including persons other than members of the council, as it may deem fit, to be members of any committee appointed in terms of paragraph (b) of sub-section (1).
- (4) There shall be payable to a member of a committee of the council (other than a member of the council or a person who is in the full-time employment of the State) such remuneration and such allowances, while he is engaged in the carrying out of his duties as a member of such committee, as the Minister may, in consultation with the Minister of Finance, determine.

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12. **Appointment of Registrar and Deputy Registrar of Medicines**

- (1) The Minister may, after consultation with the council, appoint a Registrar and one or more Deputy Registrars or revoke such an appointment.
- (2) The Registrar shall exercise the powers and perform the duties assigned to, or imposed upon, him or her in terms of this Act and such other powers and duties as may from time to time be assigned to or imposed upon him or her by the council, Minister or Director-General.
- (3) A Deputy Registrar shall assist the Registrar in the exercise of his or her powers and the performance of his or her duties and may, subject to the approval of the Registrar, exercise any power conferred upon the Registrar.

13. **Medicines register**

The registrar shall keep in the prescribed form a register, to be known as the medicines register, in which he shall register all medicines the registration of which has been approved by the council, and in which he shall enter all such particulars in regard to such medicines and the holder of the certificate of registration in respect of such medicines as are required by this Act to be entered therein.

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

- (1) Save as provided in this section or sections 21 and 22A, no person shall sell any medicine which is subject to registration by virtue of a resolution published in terms of subsection (2) unless it is registered.
- (2) (a) The council may from time to time by resolution approved by the Minister, determine that a medicine or class or category of medicines or part of any class or category of medicines mentioned in the resolution shall be subject to registration in terms of this Act.
- (b) Any such resolution may also relate only to medicines which were available for sale in the Republic immediately prior to the date on which it comes into operation in terms of paragraph (c) or only to medicines which were not then so available.
- (c) Any such resolution shall be published in the Gazette by the registrar and shall come into operation on the date on which it is so published.

- (3) In the case of a medicine which was available for sale in the Republic immediately prior to the date of publication in the Gazette of the resolution by virtue of which it is subject to registration in terms of this Act, the provisions of subsection (1) shall come into operation-
- (a) if no application for the registration of such medicine is made within the period of six months immediately succeeding that date, on the expiration of that period; or
 - (b) if application for the registration of such medicine is made within the said period, on the date one month after the date on which a notice in respect of such medicine is published in the Gazette in terms of section 15 (10) or section 17 (a).
- (4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine-
- (a) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a license contemplated in section 22C (1) (a), for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or
 - (b) compounded by a pharmacist in a quantity not greater than that prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Health Professions Act, 1974, and referred to in section 22A, 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 or has not been advertised: Provided that the active components of such medicine appear in another medicine which has been registered under this Act.

15. Registration of medicines

- (1) Every application for the registration of a medicine shall be submitted to the registrar in the prescribed form and shall be accompanied by the prescribed particulars and samples of the relevant medicine and by the prescribed registration fee.
- (2) The registrar
- (a) as soon as possible after receipt by him or her 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;
 - (b) ensure that such an application in respect of medicine which appears on the latest Essential Drug List or medicine which does not appear thereon but which, in the opinion of the Minister, is essential for national health is subject to such procedures as may be prescribed in order to expedite the registration.
- (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 or she may within a period of one month after the date of the notification furnish the registrar with his or her 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, including the registration of medicines already registered, shall be valid for a period of five years and may be made subject to such conditions as may with 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 or her 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 medicine concerned subject to the said condition.
 - (10) Notice of the rejection of an application under this section in respect of a medicine referred to in subsection (3) of section 14 shall be given in the Gazette by the registrar-
 - (a) if no appeal is lodged against the rejection within the period referred to in section 24, as soon as possible after the expiration of that period; or
 - (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 section 14(3) publish in the Gazette the prescribed particulars in respect of all applications for registration received by him or her prior to such date.
 - (12) For the purposes of this section, 'Essential Drug List' means the list of essential drugs included in the latest edition of the official publication relating to guidelines for standard treatment which is compiled by the Department of Health.

15A Amendment of entries in register

- (1) The entry made in the register with respect to any medicine may on application by the holder of the certificate of registration issued in respect of such medicine be amended by the registrar with the approval of the council.
- (2) Application for the amendment of an entry in the register shall be made to the registrar on the prescribed form and shall be accompanied by the prescribed application fees.
- (3) The registrar shall as soon as possible after the receipt of any such application submit the application to the council for consideration.
- (4) If the council grants its approval in respect of any application submitted to it in terms of subsection (3) the registrar shall make the required amendments in the register and, if necessary, cancel the existing certificate of registration in respect of such medicine and issue a new certificate of registration on the prescribed form to the applicant in respect of such medicine.

15B Transfer of certificates of registration

- (1) A certificate of registration may with the approval of the council be transferred by the holder thereof to any other person.
- (2) Application for approval of the transfer of a certificate of registration shall be made to the registrar on the prescribed form and shall be accompanied by the certificate of registration in question and the prescribed application fees.
- (3) The registrar shall as soon as practicable after the receipt of any such application submit the application to the council for consideration.
- (4) If the council grants any application submitted to it in terms of subsection (3) the registrar shall make the necessary entries in the register relating to the person to whom the certificate of registration is transferred, cancel the existing certificate of registration and issue a new certificate of registration on the prescribed form to such person in respect of the relevant medicine.

15C - Measures to ensure supply of more affordable medicines

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

- (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

16. Cancellation of registration

- (1) If the council-
- (a) is of the opinion that any person has failed to comply with any condition subject to which any medicine has been registered; or
 - (b) is of the opinion that any medicine does not comply with any prescribed requirement; or
 - (c) is of the opinion that it is not in the public interest that any medicine shall be available to the public,

the council shall cause notice in writing to be given accordingly by the registrar to the holder of the certificate of registration issued in respect of that medicine.

- (2) Any such notice shall specify the grounds on which the council's opinion is based, and shall indicate that the person to whom it is directed may within one month after receipt thereof submit to the registrar any comments he may wish to put forward in connection with the matter.
- (3) If no such comments are so submitted, or if after consideration of any comments so submitted the council is of the opinion that the registration of the medicine in question should be cancelled, the council may direct the registrar to cancel the registration thereof.
- (4) If the person who is the holder of the certificate of registration issued in respect of any medicine fails to pay the prescribed annual fee in respect of the retention of the registration of that medicine before or on the prescribed date or such later date as the registrar may with the approval of the council determine on application by that person, the registrar shall cancel the registration of that medicine.

17. Notification of registration or cancellation of registration in Gazette

The registrar shall give notice in the Gazette of the registration or cancellation of the registration of any medicine in terms of this Act, and shall in such notice specify-

- (a) in the case of a registration of any medicine, the name under which such medicine is registered, the active components of such medicine, the name of the person who applied for the registration of such medicine, the number allocated to it in terms of section 15 and the conditions (if any) subject to which it is registered;
- (b) in the case of a cancellation of the registration of any medicine, the name under which such medicine was registered, the name of the holder of the certificate of registration issued in respect of such medicine and the number which was allocated to it in terms of section 15.

18. Labels and advertisements

- (1) No person shall sell any medicine or Scheduled substance unless the immediate container or the package in which that medicine or Scheduled substance is sold bears a label stating the prescribed particulars.
- (2) No person shall advertise any medicine or Scheduled substance for sale unless such advertisement complies with the prescribed requirements.
- (3) The label referred to in subsection (1) shall be approved by the council.
- (4) The council may authorise a deviation from the prescribed format and contents of any label.

- (5) The Minister may prescribe additional requirements for the labelling of medicines.

18A. Bonusing

No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme.

18B. Sampling of medicines

- (1) No person shall sample any medicine.
- (2) For the purposes of this section 'sample' means the free supply of medicines by a manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, but does not include the free supply of medicines for the purposes of clinical trials, donations of medicines to the State, tendering to the State and quality control by inspectors.
- (3) The use of medicines or Scheduled substances for exhibition purposes shall be as prescribed.

18C. Marketing of medicines

The Minister shall, after consultation with the pharmaceutical industry and other stakeholders, make regulations relating to the marketing of medicines, and such regulations shall also provide for an enforceable Code of Practice.

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

- (1) No person shall sell any medicine unless it complies with the prescribed requirements.
- (2) The council may by notice in writing require any person who manufactures or sells or administers or prescribes any medicine or on whose direction any medicine is administered to furnish it, within a period stipulated in such notice, with any information which such person has in his possession or which such person is in a position to obtain regarding such medicine.
- (3) The council may, if so requested by any person to whom a notice under subsection (2) is addressed, extend the period stipulated in such notice.

20. Publication or distribution of false advertisements concerning medicines

- (1) No person shall-
- (a) publish or distribute or in any other manner whatsoever bring to the notice of the public or cause or permit to be published or distributed or to be so brought to the notice of the public any false or misleading advertisement concerning any medicine; or
 - (b) in any advertisement make any claim to the effect that the therapeutic efficacy and effect of any medicine is other than that stated by the council in terms of sub-paragraph (ii) of paragraph (a) of section twenty-two or state or suggest that any medicine should be used for a purpose or under circumstances or in a manner other than that stated by the council in terms of sub-paragraph (iii) or paragraph (a) of that section.
- (2) It shall be a sufficient defence in any prosecution for an offence under paragraph (a) of sub-section (1) if it is proved to the satisfaction of the court that the accused, not being a person selling the medicine to which

the false or misleading advertisement which is the subject of the prosecution relates, did not know, and could not reasonably be expected to have known, that the advertisement was in any respect false or misleading, unless it is proved that the accused failed on demand by the registrar or an inspector or a member of the South African Police to furnish the name and address of the person at whose instance the advertisement was published, distributed or so brought to the notice of the public.

21. Council may authorize sale of unregistered medicine for certain purposes

- (1) The council may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine which is not registered.
- (2) Any medicine sold in pursuance of any authority granted under sub-section (1) may be used for such purposes and in such manner and during such period as the council may in writing determine.
- (3) The council may at any time by notice in writing withdraw any authority granted in terms of sub-section (1) if effect is not given to any determination made in terms of sub-section (2).

22. Director-General to cause certain information to be furnished

- (1) The Director-General shall after consultation with the council, cause, in such manner as the Director-General considers most suitable-
 - (a) as soon as practicable after any medicine, other than a veterinary medicine, has been registered, medical practitioners, dentists, pharmacists and the person who applied for the registration of such medicine to be informed-
 - (i) of the name and number under which such medicine is registered and the conditions, if any, subject to which such medicine is registered;
 - (ii) of the therapeutic efficacy and effect of such medicine;
 - (iii) of the purpose for which, the circumstances under which and the manner in which such medicine should be used; and
 - (iv) regarding any other matter concerning such medicine which, in the opinion of the council, may be of value to them;
 - (b) as soon as practicable after the registration of any medicine, other than a veterinary medicine, has been cancelled in terms of section 16, medical practitioners, dentists, pharmacists and the holder of the certificate of registration issued in respect of such medicine to be informed of the cancellation of such registration.
- (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.

22A Control of medicines and Scheduled substances

- (1) Subject to this section, no person shall sell, have in his or her possession or manufacture any medicine or Scheduled substance, except in accordance with the prescribed conditions.
- (2) The Minister may, on the recommendation of the council, prescribe the Scheduled substances referred to in this section.
- (3) Any Schedule 0 substance may be sold in an open shop.

- (4) Any Schedule 1 substance shall not be sold-
- (a) by any person other than-
 - (i) a pharmacist, or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist;
 - (ii) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
 - (iii) a medical practitioner or dentist, who may-
 - (aa) prescribe such substance;
 - (bb) compound and dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
 - (iv) a veterinarian who may prescribe, compound or dispense such substance;
 - (v) a practitioner, nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may-
 - (aa) prescribe only the Scheduled substances identified in the Schedule for that purpose;
 - (bb) compound and dispense the Scheduled substances referred to in item (aa) only if he or she is the holder of a licence contemplated in section 22C (1) (a);
 - (b) to any person apparently under the age of 14 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C (1) (a), or on a written order disclosing 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 14 years;
 - (c) unless the seller, other than a manufacturer or wholesale dealer in pharmaceutical products, enters in a prescription book required to be kept in the prescribed manner, the prescribed particulars of such sale.
- (5) Any Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance shall not be sold by any person other than-
- (a) a pharmacist, pharmacist intern or a pharmacist's assistant acting under the personal supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription;
 - (b) a pharmacist or a pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, upon a written prescription issued by an authorised prescriber or on the verbal instructions of an authorised prescriber who is known to such pharmacist;
 - (c) a manufacturer of or wholesale dealer in pharmaceutical products for sale to any person who may lawfully possess such substance;
 - (d) a medical practitioner or dentist, who may-
 - (i) prescribe such substance;

- (ii) compound or dispense such substance only if he or she is the holder of a licence as contemplated in section 22C (1) (a);
- (e) a veterinarian who may prescribe, compound or dispense such substance;
- (f) a practitioner, a nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, who may-
 - (i) prescribe only the Scheduled substances identified in the Schedule for that purpose;
 - (ii) compound and dispense the Scheduled substances referred to in subparagraph (i) only if he or she is the holder of a licence contemplated in section 22C (1) (a):
- (6) Any sale under subsection (5) shall only take place on condition that-
 - (a) all the prescribed particulars of every sale shall be recorded in the prescribed manner in a prescription book or other permanent record required to be kept in the prescribed manner;
 - (b) the authorised prescriber who has given verbal instructions to a pharmacist to dispense a prescription shall within seven days after giving such instructions furnish such pharmacist with a prescription confirming such instructions;
 - (c) in the case of verbal instructions the treatment period shall not exceed seven days;
 - (d) if a prescription is not presented for dispensing within 30 days of issue it shall not be dispensed;
 - (e) in the case of a Schedule 2 substance, such substance may not be supplied to any person apparently under the age of 14 years except upon a prescription issued by an authorised prescriber and dispensed by a pharmacist, pharmacist intern or pharmacist's assistant or by a veterinarian or a person who is the holder of a licence as contemplated in section 22C (1) (a), or on a written order disclosing 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 14 years;
 - (f) in the case of a Schedule 2, Schedule 3 or Schedule 4 substance, such sale may be repeated if the person who issued the prescription has indicated thereon the number of times it may be dispensed, but not for longer than six months;
 - (g) in the case of a Schedule 5 substance, such sale shall not be repeated for longer than six months, and then only if the authorised prescriber has indicated on the prescription the number of times and the intervals at which it may be dispensed;
 - (h) where a Schedule 5 substance is used for-
 - (i) its anxiolytic, antidepressant or tranquillising properties it shall not be prescribed for longer than six months unless the authorised prescriber has consulted a registered psychiatrist, or, in the case of a psychiatrist, another psychiatrist before issuing a new prescription;
 - (ii) its analgesic properties it shall not be prescribed for longer than six months unless the authorised prescriber has consulted another medical practitioner, before issuing a new prescription;
 - (i) in the case of a Schedule 6 substance, it shall not be repeated without a new prescription being issued;

- (j) in an emergency in which the health or life of a patient is at stake, a pharmacist engaged in wholesale practice may, on receipt of a telephonic or telefaxed or other electronic request, supply a Schedule 6 substance to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, without a written order:
Provided that-
- (i) it shall be the responsibility of such pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person to ensure that such pharmacist receives a written order within seven days.
 - (ii) the Schedule 6 substance shall be supplied in the smallest unit sales pack available;
 - (iii) a permanent record is made and kept of such supply.
- (k) in an emergency a pharmacist may sell any Schedule 5 or Schedule 6 substance in a quantity not greater than that required for continuous use for a period of 48 hours, on the verbal instructions of a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, who is known to such pharmacist, but the prescriber who has given such verbal instructions shall within 72 hours after giving such instructions furnish to such pharmacist a written prescription confirming the instructions;
- (l) in an emergency a pharmacist may sell a Schedule 2, Schedule 3 or Schedule 4 substance on a non-recurring basis for a period not exceeding 30 days in accordance with the original prescription in order to ensure that therapy is not disrupted if he or she is satisfied that an authorised prescriber initiated the therapy, with the intention that the therapy be continued, and that the particulars of such sale are recorded in a prescription book or other prescribed permanent record;
- (m) 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 or her, but the quantity so sold shall not exceed or be less than, 25 per cent of the quantity specified in the prescription or order in question;
- (n) any seller referred to in this subsection shall retain the prescription or order concerned for a period of not less than five years as from the date of such sale;
- (o) a Schedule 6 substance may only be sold if the course of treatment does not exceed 30 consecutive days;
- (p) the sale of a specified Schedule 5 or Schedule 6 substance by a manufacturer of or wholesale dealer in pharmaceutical products shall be recorded in a register which shall be kept in the prescribed manner, and shall be balanced so as to show clearly the quantity of every specified Schedule 5 or Schedule 6 substance remaining in stock as on the last day of March, June, September and December of each year, and such balancing shall be completed within the 14 days following each of the said dates;
- (q) a pharmacist shall endorse on the prescription the date of sale and the quantity of the substance sold, and when it is repeated, the date of sale and the quantity of the said substance sold, and the last seller shall retain the prescription for a period of not less than five years as from the date of the last sale;
- (r) any Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substance for the treatment of any animal may be supplied by any person practising a para-veterinary profession within the meaning of the Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982), upon a written prescription issued by a veterinarian or on the verbal instructions of a veterinarian.

- (7) (a) No person, other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, shall sell or export a Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit, issued in accordance with the prescribed conditions has, subject to paragraph (b), been obtained from the Director-General for such purpose.
- (b) The Director-General may revoke any permit referred to in paragraph (a) if the conditions on which such permit was issued, are not complied with or if it is not in the public interest that the particular action be continued.
- (8) Subject to subsection (9), a Schedule 8 substance shall not be acquired by any person other than the Director-General for the purpose of providing a medical practitioner therewith, on the prescribed conditions, for the treatment of a particular patient of that medical practitioner upon such conditions as the Director-General, on the recommendation of the council, may determine.
- (9) (a) No person shall-
- (i) acquire, use, possess, manufacture, or supply any Schedule 7 or Schedule 8 substance, or manufacture any specified Schedule 5 or Schedule 6 substance unless he or she has been issued with a permit by the Director-General for such acquisition, use, possession, manufacture, or supply: Provided that the Director-General may, subject to such conditions as he or she may determine, acquire or authorise the use of any Schedule 7 or Schedule 8 substance in order to provide a medical practitioner, analyst, researcher or veterinarian therewith on the prescribed conditions for the treatment or prevention of a medical condition in a particular patient, or for the purposes of education, analysis or research;
- (ii) manufacture, use or supply any Schedule 5 or Schedule 6 substance for other than medicinal purposes, unless he or she has been issued by the Director-General with a permit for such manufacture, use or supply upon the prescribed conditions.
- (b) Notwithstanding paragraph (a), the Director-General may at any time revoke any permit issued in terms of that paragraph if any condition on which the permit was issued is not being complied with.
- (c) A permit issued in terms of this subsection shall be valid for a period of 12 calendar months after the date of issue thereof.
- (10) Notwithstanding anything to the contrary contained in this section, no person shall sell or administer any Scheduled substance or medicine for other than medicinal purposes: Provided that the Minister may, subject to the conditions or requirements stated in such authority, authorise the administration outside any hospital of any Scheduled substance or medicine for the satisfaction or relief of a habit or craving to the person referred to in such authority.
- (11) (a) No person shall import or export any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance or other substance or medicine prescribed for that purpose unless a permit has been issued to him or her by the Director-General in the prescribed manner and subject to such conditions as may be determined by the Director-General.
- (b) A permit referred to in paragraph (a) may be issued for any purpose other than the satisfaction or relief of a habit or craving in respect of such substance or medicine.
- (c) The issue of a permit referred to in paragraph (a) may be refused if-

- (i) the Director-General is not convinced that the applicant is capable of keeping or storing the substance or medicine in a satisfactory manner in order to prevent the loss thereof;
 - (ii) the use of such substance or medicine has not been authorised in terms of this Act;
 - (iii) the Director-General is of the opinion that the annual importation quota for such substance has been exceeded or will be exceeded;
 - (iv) the Director-General is of the opinion that such substance or medicine, of an acceptable quality, is already available in the Republic; or
 - (v) the applicant did not comply with the conditions under which a previous permit was issued to him or her.
- (d) If an application is refused, the applicant shall be furnished with the reasons for such refusal.
- (e) A permit issued in terms of this subsection shall be valid for a period of six months from the date of issue thereof.
- (12) (a) The control on the importation of Scheduled substances shall relate to-
- (i) any specified Schedule 5, Schedule 6, Schedule 7 or Schedule 8 substance;
 - (ii) such substances irrespective of the scheduling status allocated thereto, as the Minister may prescribe;
 - (iii) any other substance which becomes subject to international control in terms of the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances entered into by the Republic.
- (b) The obtaining of import or export permits as required in terms of subsection (11) shall not apply to any preparation which contains a substance as prescribed which is specifically exempted from all control measures for the obtaining of such import or export permits by the 1961 Single Convention on Narcotic Drugs referred to in paragraph (a).
- (c) Notwithstanding paragraph (b), no such importation or exportation shall take place unless authorised by the Director-General.
- (13) Any permit issued under subsection (11) shall be subject-
- (a) to the applicant's furnishing the registrar annually with the prescribed information;
 - (b) to the requirement that there shall be no deviation from the particulars reflected on the permit: Provided that if the quantity of such substance or medicine to be imported is less than that provided for in the permit, the Director-General shall be informed in writing thereof within 10 days after the importation of such substance or medicine; and
 - (c) to the conditions, as detailed on the permit, having been complied with, the triplicate copy of the permit having been certified by a customs officer or an employee of the S.A. Post Office Limited.
- (14) Notwithstanding anything to the contrary contained in this section-
- (a) a pharmacist's assistant shall not handle any specified Schedule 5 or Schedule 6 substance except as contemplated in subsection (5) (a) and (b); and

- (b) no nurse or a person registered under the Health Professions Act, 1974, other than a medical practitioner or dentist, may prescribe a medicine or Scheduled substance unless he or she has been authorised to do so by his or her professional council concerned.
- (15) Notwithstanding anything to the contrary contained in this section, the Director-General may, after consultation with the Interim Pharmacy Council of South Africa as referred to in section 2 of the Pharmacy Act, 1974 (Act 53 of 1974), issue a permit to any person or organisation performing a health service, authorising such person or organisation to acquire, possess, use or supply any specified Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance, and such permit shall be subject to such conditions as the Director-General may determine.
- (16) Notwithstanding anything to the contrary contained in this section-
- (a) any person may possess a Schedule 0, Schedule 1 or Schedule 2 substance for medicinal purposes;
 - (b) any person may possess a Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance if he or she is in possession of a prescription issued by an authorised prescriber;
 - (c) any medicine or scheduled substance may be possessed by a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974, or under the Veterinary and Para-Veterinary Professions Act, 1982, for the purposes of administering it in accordance with his or her scope of practice;
 - (d) any medicine or scheduled substance may be possessed for sale by a pharmacist, a person licenced to own a pharmacy in terms of the Pharmacy Act, 1974, or a person who is the holder of a licence as contemplated in section 22C.
- (17) For the purposes of this section-
- (a) 'authorised prescriber' means a medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974; and
 - (b) 'medicinal purpose' means for the purposes of 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 government or approved for such purpose by the Minister.

22B Publication of information relating to medicine, Scheduled substance or medical device

- (1) Notwithstanding the provisions of section 34 the council may, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, Scheduled substance or medical device.
- (2) The Director-General may publish the information referred to in subsection (1) or release it to the public in a manner which he thinks fit.

22C. Licensing

- (1) Subject to the provisions of this section-
 - (a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions;

- (b) the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine.
- (2) A licence referred to in subsection (1) (a) shall not be issued unless the applicant has successfully completed a supplementary course determined by the South African Pharmacy Council after consultation with the Health Professions Council of South Africa, the Allied Health Professions Council of South Africa and the South African Nursing Council.
 - (3) The Director-General or the council, as the case may be, may require an applicant contemplated in subsection (1) to furnish such information, in addition to any information furnished by the applicant in terms of the said subsection, as the Director-General or the council may deem necessary.
 - (4) When the Director-General or the council, as the case may be, grants or refuses an application for a licence-
 - (a) written notice shall be given of that fact to the applicant; and
 - (b) in the event of the refusal of an application, the applicant shall be furnished with the reasons for such refusal.
 - (5) No person shall compound or dispense a medicine unless he or she is authorised thereto in terms of the Pharmacy Act, 1974, is a veterinarian or is the holder of a licence as contemplated in subsection (1) (a).
 - (6) No manufacturer, wholesaler or distributor referred to in subsection (1) (b) shall manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any medicine unless he or she is the holder of a licence contemplated in the said subsection.
 - (7) Subsections (5) and (6) shall come into operation twelve months from the date of commencement of this section.

22D Period of validity and renewal of licence

A licence issued under section 22C shall be valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Director-General or the council, as the case may be, may allow and on payment of the prescribed fee.

22E Suspension and cancellation of licence

- (1) If the holder of a licence under section 22C-
 - (a) has in or in connection with an application for a licence or renewal of a licence furnished the Director-General or the council, as the case may be, with any information which to the knowledge of such holder is untrue or misleading in any material respect;
 - (b) has contravened or failed to comply with a condition upon which the licence was issued;
 - (c) has contravened or failed to comply with a provision of this Act;

- (d) has, in the case of a licence issued in terms of section 22C (1) (a), at any time been convicted of an offence which is of such a nature that, in the opinion of the Director-General, it renders him or her unsuitable to compound or dispense medicines,

the Director-General or the council, as the case may be, may by way of a notice in writing call upon him or her to show cause within the period specified in the notice, which period shall not be less than 20 days as from the date of the notice, why the licence in question should not be suspended or revoked.

- (2) The Director-General or the council, as the case may be, may after considering the reasons furnished to him or her in terms of subsection (1)-
- (a) suspend the licence in question for such period as he or she or the council may determine; or
- (b) revoke the licence in question.
- (3) No person shall be entitled to the repayment of any prescribed fee in respect of any application for the granting or renewal of a licence if such application has been refused or if the licence has been suspended or revoked.

22F Generic substitution

- (1) Subject to subsections (2), (3) and (4), a pharmacist or a person licensed in terms of section 22C(1)(a) shall-
- (a) inform all members of the public who visit the pharmacy or any other place where dispensing takes place, as the case may be, with a prescription for dispensing, of the benefits of the substitution for a branded medicine by an interchangeable multi-source medicine, and shall, in the case of a substitution, take reasonable steps to inform the person who prescribed the medicine of such substitution; and
- (b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.
- (2) If a pharmacist is forbidden as contemplated in subsection (1) (b), that fact shall be noted by the pharmacist on the prescription.
- (3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.
- (4) A pharmacist shall not sell an interchangeable multi-source medicine-
- (a) if the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed;
- (b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or
- (c) where the product has been declared not substitutable by the council.

22G Pricing committee

- (1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.

- (2) The Minister may, on the recommendation of the pricing committee, make regulations-
- (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
 - (b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C (1) (a).
 - (c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule O medicines.
- (3)
- (a) The transparent pricing system contemplated in subsection (2) (a) shall include a single exit price which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
 - (b) No pharmacist or person licensed in terms of section 22C (1) (a) or wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).
 - (c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2) (b).
- (4) To the members of the pricing committee who are not in the full-time employment of the State may be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine.

22H Purchase and sale of medicines by wholesalers

- (1)
 - (a) No wholesaler shall purchase medicines from any source other than from the original manufacturer or from the primary importer of the finished product.
 - (b) A wholesaler shall sell medicines only into the retail sector.
- (2) Subsection (1) shall not be construed as preventing the return of medicines for credit purposes only, to the manufacturer or wholesaler from which that medicine was initially obtained.
- (3) Any wholesaler may in the prescribed manner and on the prescribed conditions be exempted by the Director-General from the provisions of subsection (1).

23. Disposal of undesirable medicines

- (1) If the council is of the opinion that it is not in the public interest that any medicine shall be made available to the public, it may-
 - (a) by notice in writing transmitted by registered post to any person direct that person; or
 - (b) by notice in the Gazette direct any person,

to return any quantity of such medicine which he has in his possession to the manufacturer thereof or (in the case of any imported medicine) to the importer concerned or to deliver or send it to any other person designated by the council.
- (2) The council may by notice in writing direct any manufacturer or importer of any such medicine who has in his possession any quantity thereof (including any quantity returned, delivered or sent to him in pursuance of a direction under sub-section (1)), or any other person to whom any quantity of such

medicine has been so returned, delivered or sent, to deal with or dispose of that quantity in such manner as the council may determine.

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

24. Appeal against decision of council or Director-General

- (1) Any person aggrieved by a decision of the council may, within the prescribed period, in the prescribed manner and upon payment of the prescribed fee, appeal against such decision to an appeal committee appointed by the Minister for the purposes of the appeal concerned.
- (2) An appeal committee contemplated in subsection (1) shall consist of no fewer than three persons: Provided that-
- (a) the chairperson shall be appointed on account of his or her knowledge of the law;
 - (b) the skills of the other two members shall be relevant to the case concerned;
 - (c) no member shall have a direct or indirect interest in the affairs of the appellant or respondent.
- (3) The appeal committee may after hearing the appeal-
- (a) confirm, set aside or vary the relevant decision of the council; and
 - (b) direct the council to execute the decision of the appeal committee.
- (4) The decision of the appeal committee shall be in writing and a copy thereof shall be furnished to the appellant as well as to the council.
- (5) To the members of the appeal committee who are not in the full-time employment of the State shall be paid such remuneration and allowances as the Minister, with the concurrence of the Minister of Finance, may determine.
- (6) Any person aggrieved by the decision of the Director-General may within the prescribed period and in the prescribed manner, make written representations with regard to such decision to the Minister.
- (7) The Minister shall, after considering representations made in terms of subsection (6), confirm, set aside or vary the decision of the Director-General.

25. Privileges of council and committees

The council or a committee appointed under section 9(1), 22G(1) or 24(1) or any member of the council or of any such committee shall not be liable in respect of anything done in good faith under this Act.

26. Inspectors

- (1) The Director-General may authorize such persons as inspectors, as he may consider necessary for the proper enforcement of this Act.
- (2) Every inspector shall be furnished with a certificate signed by the Director-General and stating that he has been authorized as an inspector under this Act.
- (3) An inspector shall, before he exercises or performs any power or function under this Act, produce and exhibit to any person affected hereby, the certificate referred to in subsection (2).

27. Analysts, pharmacologists and pathologists

The Director-General may grant such authority to such analysts, pharmacologists and pathologists as he may consider necessary for the proper enforcement of this Act.

28. Powers of inspectors

- (1) An inspector may at all reasonable times-
 - (a) enter upon-
 - (i) any place or premises from which-
 - (aa) a person authorised under this Act to compound and dispense medicines or scheduled substances;
 - (bb) the holder of a licence as contemplated in section 22C (1) (b);
 - (cc) the holder of a certificate of registration of a medicine, conduct business.
 - (ii) any place, premises, vessel or aircraft if he or she suspects on reasonable grounds that an offence in terms of this Act has been or is being committed thereon or therein or that an attempt has been made or is being made to commit such an offence thereon or therein;
 - (iii) any private dwelling, with the consent of the occupier or under the authority of a warrant issued in terms of subsection (5) or without a warrant in terms of subsection (6);
 - (b) inspect any medicine or Scheduled substance, any book, record or documents that the inspector believes on reasonable grounds contains any information relevant to the administration or enforcement of this Act;
 - (c) seize any book, record, documents or medicine or scheduled substance or take so many samples of any such medicine or scheduled substance as he or she may consider necessary for the purpose of testing, examination or analysis in terms of this Act;
- (2) Any sample taken in terms of paragraph (d) of subsection (1) shall be taken in accordance with the prescribed methods and in the presence of the person who is in charge of such medicine or Scheduled substance, or if there is no such person or if he is absent for any reason, in the presence of any other witness, shall forthwith be packed and sealed and suitably labelled or marked in such manner as its nature may permit and shall then be transmitted to an analyst, pharmacologist or pathologist together with a certificate in the prescribed form signed by such inspector and a copy of the aforesaid certificate shall be handed or transmitted by registered post to the owner or seller of such medicine or Scheduled substance or his agent.
- (3) The analyst, pharmacologist or pathologist to whom a sample has been transmitted in terms of the provisions of subsection (2) shall with all convenient speed test, examine or analyse the sample delivered to him, and the result of the test, examination or analysis shall be stated in a certificate in the prescribed form.
- (4) The owner of the medicine or Scheduled substance from which the sample was taken may claim from the Director-General an amount equal to the market value thereof.
- (5) Where on application to a magistrate it appears to such magistrate from information on oath that there are reasonable grounds to believe that-
 - (a) the conditions for entry described in subsection (1)(a) exist in relation to a private dwelling;

- (b) entry to that private dwelling is necessary for any purpose relating to the administration or enforcement of this Act; and
 - (c) entry to the private dwelling has been refused or that entry thereto will be refused,
 - a magistrate may issue a warrant authorizing the inspector named therein to enter that private dwelling subject to such conditions as may be specified in the warrant
- (6) If an inspector believes on reasonable grounds that-
- (a) a warrant would be issued to him or her under subsection (5) if he or she applies for such warrant; and
 - (b) a delay in obtaining such warrant would defeat the object of the entry, search and seizure,
- he or she may without a warrant enter and search any premises for any medicines, scheduled substance, book, record or document relevant to the administration or enforcement of this Act and seize or take samples as contemplated in subsection (1)(c).

29. Offences

Any person who-

- (a) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties under this Act; or
- (b) contravenes or fails to comply with the provisions of section 14 (1), 18, 18A or 18B; or
- (c) contravenes the provisions of section 19 (1) or fails to comply with a notice issued under section 19 (2); or
- (d) contravenes the provisions of section 20 (1); or
- (e) contravenes or fails to comply with any condition imposed under section 15 (7); or
- (f) fails to comply with any direction given under section 23 or contravenes the provisions of section 23 (3); or
- (g) with fraudulent intent tampers with any sample taken in terms of this Act; or
- (h) makes any false or misleading statement in connection with any medicine or Scheduled substance-
 - (i) in an application for the registration thereof; or
 - (ii) in the course of the sale thereof; or
- (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
- (j) for purposes of business or trade makes use of any report or certificate made or issued by an inspector, analyst, pharmacologist or pathologist under this Act; or
- (k) contravenes any provision of section 22A, 22C (5) and (6), 22F, 22G or 22H or contravenes or fails to comply with any condition imposed thereunder;
- (l) contravenes or fails to comply with the provisions of section 34;

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

shall be guilty of an offence.

30. Penalties

- (1) Any person who is convicted of an offence referred to in section 29 shall be liable to a fine, or to imprisonment for a period not exceeding 10 years.
- (2) The court convicting any person of an offence under this Act may, upon the application of the prosecutor, declare any medicine or Scheduled substance in respect of which the offence has been committed to be forfeited to the State.
- (3) Any medicine or Scheduled substance forfeited under this Act shall be destroyed or otherwise dealt with as the Director-General may direct.
- (4) Notwithstanding anything to the contrary in any law contained, a magistrate's court shall be competent to impose any penalty provided for in this section.

31. Procedure and evidence

- (1) In any criminal proceedings under this Act-
 - (a) any quantity of a medicine or Scheduled substance in or upon any premises, place, vehicle, vessel or aircraft at the time a sample thereof is taken pursuant to the provisions of this Act shall, unless the contrary is proved, be deemed to possess the same properties as such sample;
 - (b)
 - (c) a certificate stating the result of a test, examination or analysis carried out in terms of the provisions of section twenty-eight and purporting to be signed by the analyst, pharmacologist or pathologist who carried out such test, examination or analysis, shall be accepted as prima facie proof of the facts stated therein;
 - (d) any statement or entry contained in any book, record or document kept by any owner of a medicine or Scheduled substance, or by the manager, agent or employee of such owner or found upon or in any premises occupied by, or any vehicle used in the business of, such owner, shall be admissible in evidence against him as an admission of the facts set forth in that statement or entry, unless it is proved that that statement or entry was not made by such owner, or by any manager, agent or employee of such owner in the course of his work as manager, or in the course of his agency or employment.
- (2)
- (3) The court in which any such certificate is adduced in evidence may in its discretion cause the person who signed such certificate to be summoned to give oral evidence in the proceedings in question or may cause written interrogatories to be submitted to him for reply, and such interrogatories and any reply thereto, purporting to be a reply from such person, shall be admissible in evidence in such proceedings.

32. Special defences in case of prosecutions

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33. Act or omission by manager, agent or employee

(1) Whenever any manager, agent or employee of any person (hereinafter called the employer) does or omits to do any act which it would be an offence under this Act for the employer to do or omit to do, then unless it is proved that-

- (a) in doing or omitting to do that act the manager, agent or employee was acting without the connivance or the permission of the employer; and
- (b) all reasonable steps were taken by the employer to prevent any act or omission of the kind in question; and
- (c) it was not under any condition or in any circumstances within the scope of the authority or in the course of the employment of the manager, agent or employee to do or omit to do acts, whether lawful or unlawful, of the character of the act or omission charged,

the employer shall be presumed himself to have done or omitted to do that act and shall be liable to be convicted and sentenced in respect thereof; and the fact that he issued instructions forbidding any act or omission of the kind in question shall not, of itself, be accepted as sufficient proof that he took all reasonable steps to prevent the act or omission.

(2) Whenever any manager, agent or employee of any such employer does or omits to do an act which it would be an offence under this Act for the employer to do or omit to do, he shall be liable to be convicted and sentenced in respect thereof as if he were the employer.

(3) Any such manager, agent or employee may be so convicted and sentenced in addition to the employer.

33A Funds of council

(1) The funds of the council shall consist of-

- (a) State funds received through the Department of Health;
- (b) fees raised and interest on overdue fees;
- (c) money accruing to the council from any other source.

(2) (a) The council may accept money or other goods donated or bequeathed to the council, provided no condition is attached to such donation or bequest;

(b) Details of any such donation or bequest shall be specified in the relevant annual report of the council.

(3) The council shall utilise its funds for the defrayal of expenses incurred by the council in the performance of its functions under this Act.

(4) The council shall open an account with a bank as defined in section 1 (1) of the Banks Act, 1990 (Act 94 of 1990), and shall deposit in that account all money referred to in subsections (1) and (2).

(5) The council shall keep full and proper records of all money received or expended, of its assets and liabilities and of its financial transactions.

- (6) The records and annual financial statements referred to in subsection (5), shall be audited by the Auditor-General.
- (7) The council may invest money which is deposited in terms of subsection (4) and which is not required for immediate use in any manner as it may deem fit.
- (8) Any money which at the close of the council's financial year stands to the credit of the council in the account referred to in subsection (4) and money which has been invested in terms of subsection (7), shall be carried forward to the next financial year as a credit in the account of the council.

34. Preservation of secrecy

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

34A Delegation of powers

- (1) The Minister may in writing authorise the Director-General or any officer of the Department of Health to exercise any of the powers conferred upon the Minister by this Act other than the powers referred to in sections 3, 24 (1) and 35, or to exercise or perform any of the duties or functions conferred or imposed on the Minister in terms of this Act.
- (2) The Director-General may in writing authorize any officer of the Department of Health to exercise or perform in general or in a particular case or in cases of a particular nature, any power, duty or function, excluding any power, duty or function referred to in subsection (1), conferred or imposed on the Director-General by or in terms of this Act

35. Regulations

- (1) The Minister may, in consultation with the council, make regulations-
 - (i) prescribing the categories of persons by whom application may be made for the registration of any medicine or to whom a certificate of registration may be transferred;
 - (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 circumstances in which, the conditions on which and the persons or categories of persons to whom any medicine or Scheduled substance may be sold;
- (viii) prescribing the manner in which any package containing any medicine or Scheduled substance shall be labelled, packed or sealed;
- (ix) 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;
- (x) 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 such advertisement, or the distribution of any such advertisement to a specified person or a specified category of persons or to a specified organization or a specified category of organizations;
- (xi) 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;
- (xii) prescribing the particulars which shall be published in the *Gazette* in respect of any application for registration referred to in section 15(11);
- (xiii) prescribing the procedure at meetings of the council and of any committee appointed under section 9 (including the quorum in the case of committees) and the manner in which meetings of any such committee shall be called;
- (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 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;
- (xvi) requiring the furnishing of returns, reports and information in respect of Scheduled substances and plants from which any substance can be extracted, derived, produced or manufactures, and in respect of any medicine or other substance of which any such Scheduled substance is a component;
- (xvii) as to the transshipment or the exportation from or importation into the Republic of any Scheduled substance, specifying the ports or places at which such substances may be brought into the Republic;
- (xviii) authorizing and regulating or restricting the transmission through the Republic of Scheduled substances;
- (xix) prescribing the manner in which packages containing Scheduled substances shall be labelled when imported into or manufactured in the Republic and the persons by whom and the manner in which they shall be kept;
- (xx) 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;

- (xxi) authorizing and regulating the purchase, acquisition, keeping or use of Scheduled substances by particular persons or categories of persons;
- (xxii) authorizing and regulating the possession by persons entering or departing from the Republic of specified quantities of Scheduled substances for personal medicinal use;
- (xxiii) as to the disposal or destruction of a medicine or Scheduled substance, and the records which shall be kept in respect thereof;
- (xxiv) as to the importation, exportation, 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;
- (xxv) 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;
- (xxvi) 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;
- (xxvii) authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device or class of medical devices or medicines in respect of its safety, quality and efficacy;
- (xxviii) with regard to any matter to ensure the safety, quality and efficacy of medicines and medical devices;
- (xxix) 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;
- (xxx) as to the disposal or destruction of a Scheduled substance which has become unfit for use, and the report to be furnished in respect thereof;
- (xxxi) prescribing the fee to be paid to the registrar in respect of an application for the registration, and in respect of the registration of a medicine, Scheduled substance or medical device, the fee to be paid annually to the registrar in respect of the retention of the registration of a medicine, Scheduled substance or medical device and the date on which such annual fee shall be paid;
- (xxxii) prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, the issuing of permits and certificates under this Act, the issuing or renewal of any licence under this Act, the performance of inspections to assess the quality of medicines, Scheduled substances or medical devices for the purpose of registration and the evaluation of changes to the particulars contained in registers;
- (xxxiii) relating to appeals against decisions of the Director-General or the council;
- (xxxiv) relating to the conditions under which medicines or Scheduled substances may be sold;
- (xxxv) relating to the repackaging of medicines in patient-ready packs;
- (xxxvi) relating to the safety, quality and efficacy of any interchangeable multi-source medicine;
- (xxxvii) relating to the scientific, pharmaceutical, clinical and other skills required by a member of the council or by a member of the executive committee of the council to evaluate the quality, efficacy and safety of medicines;

- (xxxviii) relating to the safety, quality and efficacy of imported medicines;
- (xxxix) relating to the control and conduct of clinical trials;
- (xl) with regard to any matter which in terms of this Act shall or may be prescribed; and
- (xli) 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 or her intention to make that regulation and inviting interested persons to furnish him or her 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 or her 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) A regulation under subsection (1)(xxxi) of (xxxii) shall be made only in consultation with the Minister of Finance.
- (5) Regulations made under subsection (1)(xi) 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) (a) Regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith of a fine, or imprisonment for a period not exceeding 10 years.
- (b) Notwithstanding anything to the contrary in any law contained a magistrate's court shall be competent to impose any penalty provided for in paragraph (a).
- (8) Notwithstanding the provisions of subsection (1), the Minister may, if he or she deems it to be in the public interest, after consultation with the executive committee appointed under section 9, make regulations relating to any matter referred to in subsection (1) or to amend or repeal any regulation made in terms of that subsection.

36. Exclusion of any drug from operation of Act

The Minister may, on the unanimous recommendation of the members present at any meeting of the council, by notice in the *Gazette* exclude, subject to such conditions as he may determine, any medicine from the operation of any or all of the provisions of this Act, and may in like manner amend or withdraw any such notice.

36A Minister may prohibit the manufacture, sale or use of certain veterinary medicines

Notwithstanding anything to the contrary in this Act or in any other law contained, the Minister may by notice in the Gazette for any reason other than the safety, quality or therapeutic efficacy of a veterinary medicine-

- (a) prohibit the manufacture, sale or use of any veterinary medicine containing a substance mentioned in the notice; or
- (b) prohibit such manufacture, sale or use, except in accordance with such conditions as may be specified in the notice,

and may in like manner repeal or amend such notice.

37. Medicines manufactured for export

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37A Amendment of Schedules

Notwithstanding the provisions of section 35 (2), the Minister may, on the recommendation of the council, from time to time by notice in the Gazette amend any Schedule prescribed under section 22A (2) by the inclusion therein or the deletion there from of any medicine or other substance, or in any other manner.

38. Operation of Act in relation to other laws

The provisions of this Act shall be in addition to and not in substitution for any other law which is not in conflict with or inconsistent with this Act.

39. State bound

This Act binds the State.

40. Short title

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