Medicines and Related Substances Control Act 101 of 1965 after amendment by the Medicines and Related Substances Control Amendment Act (Act 90 of 1997)

Long title

ACT

To provide for the registration of medicines intended for human and for animal use; for the registration of medical devices; for the establishment of a Medicines Control Council; for the control of medicines, Scheduled substances and medical devices; for the control of manufacturers, wholesalers and distributors of medicines and medical devices; and for the control of persons who may compound and dispense medicines; and for matters incidental thereto.

Section 1 (1)

'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);

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

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

'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;

'Medical Act' - deleted

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

'Minister' means the Minister of Health;

'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;

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

Section 1 (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.

Section 1 (4)

International tendering for medicines shall be allowed in the prescribed manner and on the prescribed conditions.

Section 2 (3)

The council shall be a juristic person.

Section 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.

Section 4 (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.

Section 4 (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.

Section 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 ceases to hold any qualification necessary for his or her appointment;

(c) if he or she becomes mentally ill, as defined in the Mental Health Act, 1973 (Act 18 of 1973);

(d) if he or she is convicted of an offence and is sentenced to imprisonment without the option of a fine;

(e) if he or she has been absent from more than two consecutive meetings of the council without the council's leave; or

(f) 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) f the office of any member becomes vacant before the expiration of the period for which he or she was appointed, the Minister may, subject to the provisions of section 3, 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.

Section 9 (1) (a)

subject to the approval of the Minister, from among its members an executive committee; and

Section 12 (1)

The Minister may, subject to the laws governing the public service and after consultation with the council, appoint and revoke such appointment of an officer to be styled the Registrar of Medicines, who shall perform the functions and carry out the duties assigned to or imposed upon the registrar by or under this Act and such other functions and duties as may from time to time be assigned to or imposed upon him or her by the Minister or the Director-General.

Section 14 (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 licence 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.

Section 14 (5) - deleted

Section 15 (2)

The registrar shall-

(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.

Section 15 (3) (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.

Section 15 (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.

Section 15 (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.

Section 15 (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.

Section 15 (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.

Section 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).

Section 18 (3)

The label referred to in subsection (1) shall be approved by the council.

Section 18 (4)

The council may authorise a deviation from the prescribed format and contents of any label.

Section 18 (5)

The Minister may prescribe additional requirements for the labelling of medicines.

Section 18A - Bonusing

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

Section 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.

Section 18C - Code of ethics

The Minister shall, after consultation with the pharmaceutical industry and other stakeholders, prescribe a code of ethics relating to the marketing policies of pharmaceutical companies.

Section 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 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 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 7 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 substance, or manufacture any 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 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 Schedule 6 or Schedule 7 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 the prescribed conditions.

(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 Schedule 6 or Schedule 7 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 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 permits by the 1961 Single Convention on Narcotic Drugs referred to in paragraph (a).

(c) Notwithstanding paragraph (b), no such importation 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 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, Schedule 6 or Schedule 7 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.

Section 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, 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 prescribed under the Pharmacy Act, 1974 (Act 53 of 1974), by the Interim Pharmacy Council of South Africa.

(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, 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, act as a wholesaler of or distribute, as the case may be, any medicine or medical device unless he or she is the holder of a licence contemplated in the said subsection.

(7) Subsections (5) and (6) shall come into operation six months after the commencement of this section.

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.

Section 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.

Section 22F - Generic substitution

(1) Subject to subsections (2), (3) and (4), a pharmacist shall-

(a) inform all members of the public who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine; 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.

Section 22G - Pricing committee

(1) The Minister shall appoint 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).

(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) shall sell a medicine at a price greater 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.

Section 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).

Section 24 - Appeal against decision of Director-General or council

(1) Any person aggrieved by a decision of the Director-General or the council, as the case may be, 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 a person appointed on account of his or her knowledge of the law, with at least 10 years experience thereof;

(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 Director-General or the council; and

(b) direct the Director-General or the council, as the case may be, 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 Director-General or the council, as the case may be.

(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) An appeal shall lie from any decision of the appeal committee to the High Court.

Section 28 (1) (a)

enter upon-

(i) any place or premises from which a person authorised under this Act to compound and dispense medicines or Scheduled substances or from which the holder of a licence as contemplated in section 22C (1) (b) conducts business; or

(ii) any premises, place, vehicle, vessel or aircraft if he or she has reason to suspect that an offence in terms of this Act has been or is being committed at or in such premises, place, vehicle, vessel or aircraft or that an attempt has been made or is being made there to commit such an offence;

Section 29 (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

Section 29 (b)

contravenes or fails to comply with the provisions of section 14 (1), 18, 18A or 18B; or

Section 29 (c)

contravenes the provisions of section 19 (1) or fails to comply with a notice issued under section 19 (2); or

Section 29 (d)

contravenes the provisions of section 20 (1); or

Section 29 (e)

contravenes or fails to comply with any condition imposed under section 15 (7); or

Section 29 (f)

fails to comply with any direction given under section 23 or contravenes the provisions of section 23 (3); or

Section 29 (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;

Section 30 (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.

Section 30 (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.

Section 30 (1) (b) and (2) - deleted

Section 32 - repealed

Section 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.

Section 34A (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.

Section 34A (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.

Section 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 at 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;

Section 37 - repealed

Section 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.

Section 39 - State bound

This Act binds the State.

Section 40 - Short title

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

Schedules 1 to 9 inclusive – repealed

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