REPUBLIC OF SOUTH AFRICA

MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT BILL

(As introduced)

(MINISTER OF HEALTH)

[B 72—97]

REPUBLIEK VAN SUID-AFRIKA

WYSIGINGSWETSONTWERP OP DIE BEHEER VAN MEDISYNE EN VERWANTE STOWWE

(Soos ingedien)

(MINISTER VAN GESONDHEID)

[W 72—97]

ISBN 0 621 27250 7

No. of copies printed 3 000

GENERAL EXPLANATORY NOTE:

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

Words underlined with a solid line indicate insertions in existing enactments.

BILL

To amend the Medicines and Related Substances Control Act, 1965, in relation to the definitions; to provide that the 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 a 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 shall be subject to the approval of the Minister; 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 require labels to be approved by the council; to prohibit bonusing and sampling of medicines; to further regulate the control of medicines and Scheduled substances; to provide for the licensing of certain persons to compound, dispense or manufacture medicines; to provide for generic substitution of medicines; to provide for the establishment of a pricing committee; to regulate the purchase and sale of medicines by wholesalers; to make new provision for appeals against decisions of the Director-General or the council; to further regulate the powers of inspectors; to increase the jurisdiction of magistrates' courts in respect of penalties in terms of this Act; to provide that the council may acquire and appropriate funds; to regulate anew the Minister's power to make regulations; and to provide for the rationalisation of certain laws relating to medicines and related substances that have remained in force in various territories of the national territory of the Republic by virtue of section 229 of the Constitution of the Republic of South Africa, 1993; and to provide for matters connected therewith.

BE IT ENACTED by the Parliament of the Republic of South Africa, as follows:—

Amendment of section 1 of Act 101 of 1965, as amended by section 1 of Act 65 of 1974, section 1 of Act 17 of 1979, section 1 of Act 20 of 1981 and section 1 of Act 94 of 1991

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

(a) by the substitution in subsection (1) for the definition of ''approved name'' of the following definition:

'' 'approved name', in relation to a medicine, means the **[internationally recognized]** international nonproprietary 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, **[1963 (Act No. 62 of 1963)]** 1993 (Act No. 194 of 1993);'';

(b) by the substitution in subsection (1) for the definition of ''dentist'' of the following definition:

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

(c) by the substitution in subsection (1) for the definition of ''Director-General'' of the following definition:

'' 'Director-General' means the Director-General: **[National]** Health **[and Population Development]**;'';

(d) by the insertion in subsection (1) after the definition of ''inspector'' of the following definition:

'' '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;'';

(e) by the deletion in subsection (1) of the definition of ''Medical Act'';

(f) by the substitution in subsection (1) for the definition of ''medical practitioner'' of the following definition:

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

(g) by the substitution in subsection (1) for the definition of ''Minister'' of the following definition:

'' 'Minister' means the Minister of **[National]** Health;'';

(h) by the insertion in subsection (1) after the definition of ''pharmacist'' of the following definitions:

'' '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;'';

(i) by the substitution in subsection (1) for the definition of ''practitioner'' of the following definition:

'' 'practitioner' means a person registered as such under the **[Associated]** Chiropractors, Homeopaths and Allied Health Service Professions Act, 1982 (Act No. 63 of 1982);'';

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

''(2) Subject to section 15C, **[A]** 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.''; and

(k) by the addition of the following subsection:

''(4) International tendering for medicines shall be allowed in the prescribed manner and on the prescribed conditions.''.

Amendment of section 2 of Act 101 of 1965, as amended by section 2 of Act 94 of 1991

2. Section 2 of the principal Act is hereby amended by the addition of the following subsection:

''(3) The council shall be a juristic person.''.

Substitution of section 3 of Act 101 of 1965, as amended by section 3 of Act 65 of 1974, section 1 of Act 36 of 1977, section 2 of Act 17 of 1979, section 46 of Act 97 of 1986 and section 3 of Act 94 of 1991

3. The following section is hereby substituted for section 3 of the principal Act:

"**Constitution of council**

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

Amendment of section 4 of Act 101 of 1965, as amended by section 4 of Act 65 of 1974

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

"(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.".

Substitution of section 6 of Act 101 of 1965, as amended by section 5 of Act 65 of 1974, section 3 of Act 17 of 1979, section 46 of Act 97 of 1986 and section 4 of Act 94 of 1991

5. The following section is hereby substituted for section 6 of the principal Act:

"**Disqualifications, vacation of office, filling of vacancies and declaration of interest**

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

(a) who is an unrehabilitated insolvent;

(b) who is disqualified under the 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 No. 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) If 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.''.

Amendment of section 9 of Act 101 of 1965, as amended by section 7 of Act 65 of 1974

6. Section 9 of the principal Act is hereby amended by the substitution for paragraph *(a)* of subsection (1) of the following paragraph:

''(a) subject to the approval of the Minister, from among its members an executive committee **[the majority of the members of which shall be persons appointed in terms of paragraphs *(a)* and *(c)* of subsection (2) of section *three*]**; and''.

Amendment of section 12 of Act 101 of 1965, as substituted by section 10 of Act 65 of 1974

7. Section 12 of the principal Act is hereby amended by the substitution for subsection (1) of the following subsection:

''(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.''.

Amendment of section 14 of Act 101 of 1965, as amended by section 1 of Act 29 of 1968, section 12 of Act 65 of 1974, section 6 of Act 17 of 1979 and section 7 of Act 94 of 1991

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

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

''(4) The provisions of subsection (1) shall not apply in respect of the sale of any medicine—

(a) compounded in the course of carrying on his or her professional activities by a **[medical practitioner]** pharmacist, **[practitioner or]** 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.''; and

(b) by the deletion of subsection (5).

Amendment of section 15 of Act 101 of 1965, as amended by section 2 of Act 29 of 1968, section 13 of Act 65 of 1974 and section 8 of Act 94 of 1991

9. Section 15 of the principal Act is hereby amended—

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

''(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.'';

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

''*(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) by the substitution for subsection (7) of the following subsection:

''(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 **[due]** regard to the succeeding provisions of this section be determined by the council.'';

(d) by the substitution for subsection (9) of the following subsection:

''(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 **[relevant]** medicine concerned subject to the said condition.'';

(e) by the substitution for subsection (11) of the following subsection:

''(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.''; and

(f) by the addition of the following subsection:

''(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.''.

Insertion of section 15C in Act 101 of 1965

10. The following section is hereby inserted in the principal Act after section 15B:

''**Measures to ensure supply of more affordable medicines**

15C. 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 No. 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)*.''.

Amendment of section 18 of Act 101 of 1965, as substituted by section 7 of Act 17 of 1979

11. Section 18 of the principal Act is hereby amended by the addition of the following subsections:

''(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.''.

Insertion of sections 18A, 18B and 18C in Act 101 of 1965

12. The following sections are hereby inserted in the principal Act after section 18:

''**Bonusing**

18A. No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme.

Sampling of medicines

18B. (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.

Code of ethics

18C. The Minister shall prescribe a code of ethics relating to the marketing policies of pharmaceutical companies.''.

Substitution of section 22A of Act 101 of 1965, as inserted by section 21 of Act 65 of 1974 and amended by section 9 of Act 17 of 1979

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

''**Control of medicines and Scheduled substances**

22A. (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 No. 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; 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 No. 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) 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.''.

Insertion of sections 22C, 22D, 22E, 22F, 22G and 22H in Act 101 of 1965

14. The following sections are hereby inserted in the principal Act after section 22B:

''**Licensing**

22C. (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 No. 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 manufacturer, wholesaler or distributer 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.

(6) Subsection (5) shall come into operation six months after the commencement of the Medicines and Related Substances Control Amendment Act, 1997.

Period of validity and renewal of licence

22D. 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.

Suspension and cancellation of licence

22E. (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.

Generic substitution

22F. (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.

Pricing committee

22G. (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.

Purchase and sale of medicines by wholesalers

22H. (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).''.

Substitution of section 24 of Act 101 of 1965, as substituted by section 11 of Act 94 of 1991

15. The following section is hereby substituted for section 24 of the principal Act:

''**Appeal against decision of Director-General or council**

24. (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.''.

Repeal of section 25 of Act 101 of 1965, as substituted by section 32 of Act 88 of 1996

16. Section 25 of the principal Act is hereby repealed.

Amendment of section 28 of Act 101 of 1965, as amended by section 26 of Act 65 of 1974 and section 12 of Act 17 of 1979

17. Section 28 of the principal Act is hereby amended by the substitution for paragraph *(a)* of subsection (1) of the following paragraph:

''(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 **[at or in which there is or is on reasonable grounds suspected to be any medicine or Scheduled substance]** 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;''.

Amendment of section 29 of Act 101 of 1965, as amended by section 27 of Act 65 of 1974 and section 12 of Act 94 of 1991

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

(a) by the substitution for paragraphs *(a), (b), (c), (d), (e)* and *(f)* of the following paragraphs, respectively:

''(a) obstructs or hinders any inspector in the exercise of his or her powers or the **[carrying out]** performance of his or her duties under this Act; or

(b) contravenes or fails to comply with the provisions of section 14(1), **[or section]** 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 **[subsection (3) of that]** section 23(3); or''; and

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

''*(k)* contravenes any provision of section 22A, 22F, 22G or 22H or contravenes or fails to comply with any condition imposed thereunder;''.

Amendment of section 30 of Act 101 of 1965, as amended by section 28 of Act 65 of 1974 and section 13 of Act 94 of 1991

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

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

''(1) Any person who is convicted of an offence referred to in section 29 shall be liable to a fine **[not exceeding R40 000]**, or to imprisonment for a period not exceeding 10 years **[or to both such fine and such imprisonment]**.''; and

(b) by the addition of the following subsection:

''(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.''.

Amendment of section 31 of Act 101 of 1965, as amended by section 29 of Act 65 of 1974 and section 13 of Act 17 of 1979

20. Section 31 of the principal Act is hereby amended—

(a) by the deletion of paragraph *(b)* of subsection (1); and

(b) by the deletion of subsection (2).

Repeal of section 32 of Act 101 of 1965, as amended by section 30 of Act 65 of 1974

21. Section 32 of the principal Act is hereby repealed.

Insertion of section 33A in Act 101 of 1965

22. The following section is hereby inserted in the principal Act after section 33:

''**Funds of council**

33A. (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 No. 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.''.

Amendment of section 34A of Act 101 of 1965, as inserted by section 2 of Act 19 of 1976 and substituted by section 15 of Act 94 of 1991

23. Section 34A of the principal Act is hereby amended—

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

''(1) The Minister may in writing authorise the Director-General or any officer of the Department of **[National]** Health **[and Population Development]** to exercise any of the powers conferred upon **[him]** 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.''; and

(b) by the substitution in subsection (2) for the words ''National Health and Population Development'' of the word ''Health''.

Substitution of section 35 of Act 101 of 1965, as substituted by section 31 of Act 65 of 1974, and amended by section 3 of Act 19 of 1976, section 14 of Act 17 of 1979, section 7 of Act 20 of 1981, section 7 of Act 71 of 1991 and section 16 of Act 94 of 1991

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

''**Regulations**

35. (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;

(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 organisation or a specified category of organisations;

(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 such substance can be extracted, derived, produced or manufactured, and in respect of any medicine or other substance of which any such Scheduled substance is a component;

(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 substance may be brought into the Republic;

(xviii) authorising 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) authorising 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) authorising and regulating the purchase, acquisition, keeping or use of Scheduled substances by particular persons or categories of persons;

(xxii) authorising 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 a Scheduled substance, and the records which shall be kept in respect thereof;

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

(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) authorising, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, 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) with regard to any matter which in terms of this Act shall or may be prescribed; and

(xl) 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) and (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 recognised 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 amend or repeal any regulation made in terms of that subsection.''.

Repeal of section 37 of Act 101 of 1965, as substituted by section 18 of Act 94 of 1991

25. Section 37 of the principal Act is hereby repealed.

Substitution of section 37A of Act 101 of 1965, as inserted by section 34 of Act 65 of 1974

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

''**Amendment of Schedules**

37A. Notwithstanding the provisions of section 35(2), the **[The]** Minister may, on the recommendation of the council, from time to time by notice in the *Gazette* amend any Schedule **[to this Act]** prescribed under section 22A(2) by the inclusion therein or the deletion therefrom of any medicine or other substance, or in any other manner.''.

Repeal of Schedules to Act 101 of 1965, as added by section 36 of Act 65 of 1974

27. (1) Subject to subsection (2), Schedules 1 up to and including Schedule 9 of the principal Act are hereby repealed.

(2) Any reference in any law or document to any medicine or other substance referred to in any Schedule to the principal Act prior to the date of commencement of subsection (1) shall be construed from that date as a reference to the corresponding medicine or other substance prescribed by the Minister under section 22A of the principal Act, as substituted by section 13 of this Act.

Substitution of section 40 of Act 101 of 1965

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

''**Short title**

40. This Act shall be called the Medicines and Related Substances **[Control]** Act, 1965.''.

Substitution of long title of Act 101 of 1965, as substituted by section 22 of Act 94 of 1991

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

"**ACT**

To provide for the registration of medicines intended for human and for animal use; for the 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.".

Repeal of sections 9, 16*(c)* up to and including *(h)*, 19, 21, 23, 24 and 25 of Act 94 of 1991

30. Sections 9, 16*(c)* up to and including *(h)*, 19, 21, 23, 24 and 25 of the Medicines and Related Substances Control Amendment Act, 1991 (Act No. 94 of 1991), are hereby repealed.

Repeal of laws

31. The laws mentioned in the Schedule are hereby repealed to the extent set out in the third column thereof, to the extent to which those laws formed a part of the legislation of the areas of the former—

(a) Republics of Transkei, Bophuthatswana, Venda and Ciskei; and

(b) self-governing territories of Lebowa, Gazankulu, Qwaqwa, KwaZulu, KwaNdebele and KaNgwane in terms of the Self-governing Territories Constitution Act, 1971 (Act No. 21 of 1971).

Extension of application of Act 101 of 1965

32. The Medicines and Related Substances Act, 1965, and all amendments thereof, shall apply throughout Republic.

Short title and commencement

33. This Act shall be called the Medicines and Related Substances Control Amendment Act, 1997, and shall come into operation on a date fixed by the President by proclamation in the *Gazette*.

SCHEDULE
(Section 31)

No. and year of law	Short title	Extent of repeal
Act No. 101 of 1965	Medicines and Related Substances Control Act, 1965	The whole
Act No. 29 of 1968	Drugs Control Amendment Act, 1968	The whole
Act No. 88 of 1970	Drugs Control Amendment Act, 1970	The whole
Act No. 95 of 1971	Drugs Laws Amendment Act, 1971	Section 7
Act No. 65 of 1974	Drugs Control Amendment Act, 1974	Sections 1 up to and including 37
Act No. 19 of 1976	Medicines and Related Substances Control Amendment Act, 1976	The whole
Act No. 36 of 1977	Health Laws Amendment Act, 1977	Section 1
Act No. 17 of 1979	Medicines and Related Substances Control Amendment Act, 1979	The whole
Act No. 20 of 1981	Medicines and Related Substances Control Amendment Act, 1981	The whole
Act No. 71 of 1991	Businesses Act, 1991	Items 1 and 2 as they appear in column 3 of Schedule 3 opposite Act No. 101 of 1965
Act No. 94 of 1991	Medicines and Related Substances Control Amendment Act, 1991	Sections 1 up to and including 22
Transkei		
Act No. 27 of 1978	Medicines and Related Substances Control Act, 1978	The whole

MEMORANDUM ON THE OBJECTS OF THE MEDICINES AND RELATED SUBSTANCES CONTROL AMENDMENT BILL, 1997

The Bill's primary object is to bring the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) (''the principal Act''), into line with the National Drug Policy of the Department of Health. The objectives of the Bill are set out in more detail hereunder:

(a) The Bill provides in clause 5 for the termination of office of a member of the council if the Minister is satisfied that he or she has violated the internal rules of conduct as determined by the council. A member of the council or of a committee of the council is also obliged to declare all his or her commercial interests related to the pharmaceutical or health care industry. To obviate any possible bias, the Bill provides that such a member shall recuse himself or herself from any discussion or decision making to which the said interest relates or may relate.

(b) In clause 9 procedures are proposed that will expedite the registration of essential medicines in order to have them available on the market as quickly as possible. It is also proposed that the registration of all medicines will remain valid for a period of five years after which they will be subject to re-evaluation, thereby ensuring greater safety and better quality.

(c) At present the principal Act does not provide for the importation of a medicine of which the components are identical to those of another medicine already registered in the Republic unless the imported medicine is registered as well. In clause 10 the removal of this impediment is envisaged by allowing for the importation of such a medicine subject to conditions prescribed by the Minister. This would result in lowering the prices of medicines and ensure the supply of more affordable medicines to all the people of South Africa.

(d) It is proposed in clause 12 that the bonusing and sampling of medicines, which are aimed at influencing the prescription of certain medicines, be prohibited. It is also proposed that a code of ethics relating to marketing policies be prescribed for all pharmaceutical companies in order to have uniform guidelines and to eliminate discrepancies.

(e) The current provisions of the principal Act regarding the scheduling and handling of Scheduled substances are rigid and they hamper the council in its efforts to regulate the sale of medicines and Scheduled substances more efficiently. The Bill envisages the repeal of all the Schedules to the principal Act and to empower the Minister to prescribe them by regulation. It is provided in clause 13 that certain conditions upon which Schedule 2, 3, 4, 5 or 6 substances may be sold be inserted in section 22A. Any person selling these substances will be obliged to comply with the said conditions, thus ensuring greater safety and better quality. The Bill, furthermore, seeks to enable registered nurses and persons, other than medical practitioners or dentists, registered under the Health Professions Act, 1974, to also supply medicines. This would strengthen the health team needed to provide a more accessible and affordable health service for all the people of South Africa.

(f) (i) To ensure more effective control, the Bill provides in clause 14 that a medical practitioner, dentist, practitioner, nurse and other person registered under the Health Professions Act, 1974, may compound or dispense medicines only on the authority and subject to the conditions of a licence issued by the Director-General. A manufacturer, wholesaler or distributor of a medicine or medical device will likewise be obliged to apply to the council for a licence to manufacture, act as wholesaler of or distribute any medicine or medical device.

(ii) The prescribing of interchangeable multi-source medicines is a world-wide trend aimed at curbing the cost of health services. Manufacturers of interchangeable multi-source medicines are able to produce high-quality medicines at a cost well below that of their innovator counterparts, resulting in lower prices. The council evaluates the safety, efficacy and quality of interchangeable multi-source medicines at the same level as for innovator medicines. It is now proposed in clause 14 that generic substitution be made a legal option within the requirements of the principal Act.

(iii) The establishment of a pricing committee is proposed to monitor the pricing of medicines and to make recommendations to the Minister on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic as well as on an appropriate dispensing fee to be charged by authorised dispensers. This would also result in lowering the prices of medicines.

(g) It is proposed in clause 15 that an appeal committee be appointed by the Minister on an *ad hoc* basis consisting of no fewer than three persons to hear an appeal against a decision of the Director-General or the council, as the case may be. It is also proposed that the chairperson shall be a person appointed on account of his or her knowledge of the law with at least 10 years experience. Furthermore, to ensure impartiality it is proposed that no member shall have a direct or indirect interest in the affairs of the appellant or respondent.

(h) In clause 17 the powers of inspectors are regulated further to authorise them to enter upon any premises from which a person authorised to compound or dispense medicines, or from which a manufacturer, wholesaler or distributer licenced under the principle Act, conducts business. It is also envisaged that any other premises, place, vehicle, vessel or aircraft may be entered upon by an inspector for inspection purposes only if he or she has reason to suspect that an offence in terms of the principle Act has been or is being committed there or that an attempt has been or is being made there to commit such an offence.

(i) The Bill provides in clause 22 that the council shall be funded by State funds and by funds obtained in terms of section 35(1)(xxxi) and (xxxii) of the principal Act, and by money accepted by or other goods donated or bequeathed to the council. With a view to the responsible management of the funds of the council, it is envisaged that the accounting records of the council be audited by the Auditor-General.

(j) In clause 31 the Bill provides for the rationalisation of certain laws relating to medicines that have remained in force in the various areas of the national territory of the Republic named in the Schedule to the Bill. At the same time it is proposed that the corresponding laws of the former Republics and self-governing territories, which have remained in force by virtue of section 229 of the Constitution of the Republic of South Africa, 1993 (Act No. 200 of 1993), be repealed. In clause 32 the Bill further seeks to make the principle Act applicable throughout the Republic.

In the opinion of the State Law Advisers and the Department the Bill should be dealt with in terms of section 76 of the Constitution of the Republic of South Africa, 1996.