UNITED NATIONS

E/NL.2007/19

2 April 2007

English only*

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative text / texts

NAMIBIA

Communicated by the Government of Namibia

NOTE BY THE SECRETARIAT

(a) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

(b) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003

*Note by the Secretariat: These documents are a direct reproduction of the text / texts communicated to the Secretariat.

V.07-82103 (E)

E/NL.2007/19

Act No. 13, 2003 **MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 2003**

ACT

To provide for the establishment of a Namibia Medicines Regulatory Council; for the registration of medicines intended for human and for animal use; for the control of medicines and scheduled substances; and to provide for incidental matters.

(Signed by the President on 13 August 2003)

ARRANGEMENT OF SECTIONS

BE IT ENACTED by the Parliament of the Republic of Namibia as follows:

Definitions

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

"advertisement", in relation to a medicine or a scheduled substance, means a written, a pictorial, a visual or other descriptive matter or verbal statement or reference -

(a) appearing in a newspaper, a magazine, a pamphlet or other publication;

(b) broadcast on television or radio;

(c) distributed to members of the public; or

(d) brought to the notice of members of the public in any manner,

which is intended to promote the sale of that medicine or scheduled substance, and "advertise" has a corresponding meaning;

"analyst" means an analyst to whom authority has been granted under section 37;

"animal" means animal as defined in the Animal Diseases and Parasites Act, 1956 (Act

No. 13 of 1956);

"appeal committee" means the appeal committee referred to in section 34(1);

"authorised prescriber" means a medical practitioner, a dentist, a veterinarian or a person authorised to prescribe a medicine under section 31(1) or (2);

"certificate of registration" means a certificate of registration issued in terms of section 19(7)(b), 20(4)(b) or 21(4)(c);

"chairperson" means the person elected as chairperson of the Council in terms of section 7(1);

"committee" means a committee established by the Board under this Act;

"complementary medicine" means a substance or a mixture of substances prepared and used or purported to be suitable for use in –

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

(b) restoring, correcting or modifying any somatic, psychic or organic function in humans or animals, in accordance with the principles of any of the following disciplines:

(i) Homeopathy;

(ii) Western herbal medicine;

(iii) African traditional medicine; or

(iv) Chinese herbal medicine;

"controlled chemical" means a chemical declared to be a controlled chemical under section 44(1)(dd);

"controlled equipment" means equipment declared to be controlled equipment under section 44(1)(dd);

"Council" means the Namibia Medicines Regulatory Council referred to in section 2;

"dentist" means a dentist as defined in the Medical and Dental Professions Act, 1993 (Act No. 21 of 1993);

"dispense", in relation to a medicine, means to –

(a) prepare;

(b) count out, measure or decant from a bulk supply;

(c) mix;

(d) dissolve; or

(e) disperse,

and dispose of, a medicine, for gain or otherwise, for the treatment of a particular person or animal, but does not include the actual administration of the medicine, and "dispensing" has a corresponding meaning;

"emergency medicine" means medicine needed for immediate relief of a symptom or needed for procedures in a practice, but does not include medicine for a patient to take away;

"essential drugs" means medicines listed in the prevailing Namibian Essential Drugs List published by the Ministry responsible for health;

"export" includes to deliver or supply within Namibia for dispatch to a destination outside of Namibia;

"health facility" means a health facility as defined in the Hospitals and Health Facilities Act, 1994 (Act No. 36 of 1994) or in the Veterinary and Para-veterinary Professions Proclamation, 1984 (Proclamation No. AG 14 of 1984);

"hospital" means a hospital as defined in the Hospitals and Health Facilities Act, 1994 (Act No. 36 of 1994);

"immediate container", in relation to a medicine or a scheduled substance, means a container which is in direct contact with the medicine or the scheduled substance, but is not a package liner;

"importer" means a person who brings a medicine, a scheduled substance, a controlled chemical, controlled equipment or a medical device into Namibia or causes a medicine, a scheduled substance, a controlled chemical, controlled equipment or a medical device (in this definition called goods) to be brought into Namibia, and includes a person who –

(a) owns the goods brought into Namibia;

(b) carries the risk for the goods brought into Namibia;

(c) represents to be the one who brought the goods into Namibia or who owns those goods;

(d) actually brings the goods into Namibia;

(e) is beneficially interested in any way in the goods brought into Namibia; or

(f) acts on behalf of a person referred to in paragraphs (a) to (e),

and "import" and "importation" have a corresponding meaning;

"inspector" means a person authorised as an inspector under section 35;

"interchangeable multi-source medicine" means medicine that contains the same quantities of the same active substances in the same dosage form and meets comparable standards as another medicine;

"international treaties" means treaties relating to narcotic drugs and psychotropic substances to which Namibia is a party;

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

"legal practitioner" means a legal practitioner as defined in the Legal Practitioners Act, 1995 (Act No. 15 of 1995);

"manufacture" means carry out operations including purchasing of material, processing, packaging, quality control, release and storage of medicinal products and related substances, and "manufacturing" has a corresponding meaning;

"manufacturer", means a person who manufactures or on whose direction manufacturing takes place;

"medical device" means any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent used or purported to be suitable for use for medical or veterinary purposes, and includes a part or an accessory of a medical device;

"medical practitioner" means a medical practitioner as defined in the Medical and Dental Professions Act, 1993 (Act No. 21 of 1993), or a medical intern as defined in that Act;

"medicinal purpose", in relation to a scheduled substance, means for the purpose of the treatment or prevention of a disease or some other definite curative or therapeutic purpose, but does not include the satisfaction of a habit, or the relief of a craving for the substance used or for any other such substance, except where the substance is administered or used under a programme approved for this purpose by the Minister;

"medicine" means –

(a) a substance or a mixture of substances used or purported to be suitable for use or manufactured or sold for use in -

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

(ii) restoring, correcting or modifying any somatic, psychic or organic function in humans or animals;

(b) a veterinary medicine; or

(c) a complementary medicine;

"Minister" means the Minister responsible for health;

"original immediate container" means the immediate container in which the medicine was originally distributed by the manufacturer;

"package" means a container in or by which an original immediate container of a medicine is enclosed, covered, contained or packed, but excludes bulk boxes in which that original immediate container or the package is transported;

"para-veterinary professional" means a person registered to practise a para-veterinary profession under the Veterinary and Para-veterinary Professions Proclamation, 1984 (Proclamation No. AG. 14 of 1984);

"patient" means –

(a) in the case of a medical practitioner, a dentist, a practitioner or a registered nurse, a person treated by the medical practitioner, the dentist, the practitioner or the registered nurse;

(b) in the case of a veterinarian or a para-veterinary professional, an animal treated by the veterinarian or the para-veterinary professional; and

(c) in the case of a pharmacist, a person, or an animal, treated by the pharmacist;

"Permanent Secretary" means the Permanent Secretary of the Ministry responsible for health;

"pharmaceutical technician" means a pharmaceutical technician as defined in the Pharmacy Profession Act, 1993 (Act No. 23 of 1993);

"pharmacist" means a pharmacist as defined in the Pharmacy Profession Act, 1993 (Act No. 23 of 1993);

"pharmacist's assistant" means a pharmacist's assistant as defined in the Pharmacy Profession Act, 1993 (Act No. 23 of 1993);

"pharmacist intern" means a pharmacist intern as defined in the Pharmacy Profession Act, 1993 (Act No. 23 of 1993);

"practitioner" means a practitioner as defined in the Allied Health Services Professions Act, 1993 (Act No. 20 of 1993);

"prescribe" means –

(a) prescribe by regulation under this Act; and

(b) in relation to a medicine, issue a written or oral instruction for a specific patient to receive a medicine specified in that instruction under such conditions as may be specified, and "prescription" has a corresponding meaning;

"public" includes a section of the public concerned with manufacturing, dispensing, selling or administering, or the issue of prescriptions for, medicines or scheduled substances;

"public need and interest" means the health care needs and interests of the greater Namibian community in respect of availability and equitable access to health care services;

"Public Service Act" means the Public Service Act, 1995 (Act No. 13 of 1995);

"register" –

(a) when used as a noun, means the medicines register or veterinary medicines register or complementary medicines register, or any other register kept in terms of section 17; and

(b) when used as a verb, means enter in a register referred to in paragraph (a);

"registered nurse" means a registered nurse as defined in the Nursing Professions Act, 1993 (Act No. 30 of 1993);

"Registrar" means the Registrar of Medicines appointed in terms of section 6;

"regulation" means a regulation made under this Act;

"scheduled substance" means any medicine or substance classified as a Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance in terms of section 29(1);

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

"staff member" means a staff member as defined in the Public Service Act;

"this Act" includes a regulation made under it;

"unscheduled medicine" means a medicine which is not classified in terms of section 29(1);

"veterinarian" means a person registered as such under the Veterinary and Para-veterinary Professions Proclamation, 1984 (Proclamation No. AG. 14 of 1984);

"veterinary medicines" means a substance or a mixture of substances, other than farm feed as defined in the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), used or purporting to be suitable for use or manufactured or sold for use in connection with -

(a) the diagnosis, treatment, prevention or cure of a disease, an infection or other unhealthy condition in animals;

(b) the maintenance or improvement of health, growth, production or working capacity in animals; or

(c) restoring, correcting or modifying a somatic or organic function, or for correcting or modifying behaviour, in animals;

"veterinary medicines committee" means the committee referred to in section 12(1);

"vice-chairperson" means the person elected as vice-chairperson of the Council in terms of section 7(1).

(2) Notwithstanding anything contained in any other law, a medicine must be regarded as being the same as any other medicine registered in Namibia, if –

(a) its components, physical characteristics, quantity and quality are identical to those of that other medicine;

(b) it is manufactured by the same manufacturer; and

(c) the label and the information accompanying that medicine is approved by the Council.

(3) In determining whether or not the registration or availability of a medicine is in the public interest, regard must be had to its safety, quality and therapeutic efficacy in relation to its effect on the health of humans or animals, as the case may be.

(4) In the registration of medicines, the registration of essential drugs must receive priority.

Continuation of Council, and its powers and functions

2. (1) The council known as the Medicines Control Council established by the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), continues to exist under the name Namibia Medicines Regulatory Council.

(2) The Council may exercise the powers conferred, and must perform the functions assigned, to the Council by or under this Act.

(3) Without prejudice to the generality of subsection (2), the functions of the Council are to -

(a) advise the Minister and report to the Minister on any matter referred to the Council by the Minister for consideration and arising from the application of this Act; and

(b) register medicines and any other thing that is required or prescribed to be registered.

Constitution of Council

3. (1) The Council consists of the following members appointed by the Minister as follows:

(a) Three medical practitioners -

(i) one of whom is registered as a medical specialist;

(ii) one of whom is engaged in private medical practice; and

(iii) one of whom is employed by the Ministry responsible for health;

(b) three pharmacists -

(i) one of whom is engaged in private pharmaceutical practice;

(ii) one of whom is employed by the Ministry responsible for health; and

(iii) any other pharmacist;

(c) two veterinarians, nominated for appointment by the Minister responsible for agriculture-

(i) one of whom is engaged in private veterinary practice; and

(ii) one of whom is employed by the Ministry responsible for agriculture;

(d) one legal practitioner nominated for appointment by the Minister responsible for justice;

(e) one registered nurse;

(f) one practitioner who, in the opinion of the Minister, has sufficient knowledge of medicines and related substances; and

(g) one other person.

(2) For the purpose of appointment of members under subsection (1) -

(a) the Minister must, in respect of the members referred to in paragraphs (a), (b), (e) and (f) of subsection (1);

(b) the Minister responsible for agriculture, on the written request of the Minister, must in respect of the members referred to in paragraph (c) of subsection (1); and

(c) the Minister responsible for justice, on the written request of the Minister, must in respect of the member referred to paragraph (d) of subsection (1), publish a notice in the *Gazette* requesting any interested body to submit to the relevant Minister, within 30 days, the names of suitably qualified persons to be appointed as members of the Council.

(3) If the names referred to in subsection (2) are not submitted to the Minister who requested them within the period referred to in that subsection, that Minister must nominate suitably qualified persons for appointment as members of the Council and a person nominated under this subsection holds office as if his or her name was submitted in accordance with the said subsection (2).

(4) The Minister must give notice in the *Gazette* of the names and dates of appointment of the members of the Council and, in the case of a member appointed to fill a casual vacancy, the period for which he or she is appointed.

Disqualification for appointment as member of Council

4. A person does not qualify for appointment as a member of the Council, if the person -

(a) is an unrehabilitated insolvent;

(b) is disqualified in terms of any law from carrying on the profession in respect of which he or she is to be appointed as member;

(c) is not a Namibian citizen or a holder of a permanent residence permit; or

(d) has during the period of ten years immediately preceding the date of the intended appointment, been convicted of a criminal offence and sentenced to imprisonment without the option of a fine, irrespective of whether or not that sentence has been suspended, and has not received a free pardon.

Tenure of office of members

5. Subject to section 6, a member of the Council holds office for a period of three years from the date of his or her appointment and is eligible for re-appointment.

Vacation of office and filling of vacancies

6. (1) A member of the Council must vacate his or her office, if he or she -

(a) becomes subject to a disqualification referred to in section 4;

(b) has been absent from three consecutive meetings of the Council without the permission of the chairperson;

(c) resigns his or her office by written notice to the Minister; or

(d) is removed from office by the Minister under subsection (2).

(2) The Minister may, at the request of, or after consultation with, the Council by notice in writing, and if he or she is satisfied that there are sufficient reasons for doing so, remove a member of the Council from office after giving the member concerned a reasonable opportunity to be heard.

(3) If a member of the Council dies, or his or her office becomes vacant in terms of subsection (1), the Minister must, with due regard to section 3, appoint a person to fill the vacancy for the unexpired portion of the term of office of the member in whose stead he or she is appointed.

Chairperson and vice-chairperson
7. (1) The Council must elect a chairperson and a vice-chairperson from amongst the members of the Council.

(2) The chairperson and the vice-chairperson may not hold their offices for more than two consecutive terms of three years.

(3) The chairperson and the vice-chairperson may vacate their offices without terminating their membership of the Council.

Meetings of Council
8. (1) The first meeting of the Council must be held at such time and place as the Minister may determine, and thereafter, subject to subsection (3), meetings of the Council must be held at such times and places as the Council may determine, but the Council must hold at least one meeting every three months.

(2) If the Council has not determined the time and place for its next meeting, the chairperson must determine the time and place.

(3) The chairperson -

(a) may at any time convene a special meeting of the Council; and

(b) must convene a special meeting of the Council, if the Minister requests, or if at least three members of the Council request, him or her, in writing, to do so.

(4) The chairperson must convene a meeting requested in terms of subsection (3)(b) within 14 days after the date of receipt of the request and at such time and place as he or she may determine.

(5) The chairperson, or in his or her absence, the vice-chairperson, or in the absence of both the chairperson and the vice-chairperson, a member of the Council elected by the members present, must preside at a meeting of the Council.

(6) Notwithstanding subsection (8), a majority of the members of the Council constitutes a quorum at a meeting of the Council.

(7) A decision of a majority of the members of the Council present at a meeting of the Council is the decision of the Council and, in the event of an equality of votes, the person presiding has a casting vote in addition to his or her deliberative vote.

(8) Subject to subsection (6), a decision of the Council is not rendered invalid by reason only of a vacancy on the Council or of the fact that a person who is not entitled to sit as a member of the Council did so sit when the decision was taken, if that decision was taken by the requisite majority of the members who were present at the time and entitled to vote.

(9) The chairperson must cause a record to be kept of the proceedings of every meeting of the Council and must cause that record to be submitted to the Minister as soon as is practicable after a meeting of the Council.

Disclosure of interest

9. (1) A member of the Council or of a committee must, within a period of three months from the date of his or her appointment as a member of the Council or of a committee, declare in writing to the Minister or to the Council, as the case may be, his or her commercial interests related to the pharmaceutical or health care industry, which interests include, but are not limited to, any consultancy for, research grants from, or equity holding or directorship in, a pharmaceutical company, or any other payment or benefit in kind.

(2) If a member of the Council or of a committee, or his or her spouse, is in any way directly or indirectly interested in a matter, which is the subject of consideration by the Council or a committee and which may cause a conflict of interests in the performance of his or her duties as a member of the Council or as a member of any such committee, he or she must fully disclose the nature of that interest as soon as is practicable after the commencement of the meeting of the Council or of any such committee at which that matter is a subject of consideration and that member of the Council or of any such committee, may not take part in the consideration of, or vote on, a question relating to that matter.

(3) If a member of the Council or of a committee fails to disclose a conflict of interests as required by subsection (2) and is present at a meeting of the Council or of any such committee, or in any way participates in the consideration of, or votes on, a question relating to the matter referred to in that subsection, the proceedings in relation to that matter must, as soon as the non-disclosure is discovered, be rendered invalid and thereafter be reviewed by the Council or any such committee, as the case may be, in the absence of the member of the Council or the member of any such committee.

(4) A person who knowingly fails to comply with subsection (1) or (2) commits an offence and is liable on conviction to a fine not exceeding N$8 000 or to imprisonment for a period not exceeding two years or to both the fine and imprisonment.

Remuneration

10. (1) There must be paid to a member of the Council or of a committee, who is not in the full-time employment of the State, in respect of his or her services as a member of the Council or of any such committee, such remuneration as the Minister, in consultation with the Minister responsible for finance, may determine.

(2) Different amounts of remuneration may be determined under subsection (1) according to the different offices held on the Council or committee, or the work performed for the Council or committee, by the persons concerned.

Executive committee

11. (1) The Council must establish from amongst its members an executive committee, which consists of the chairperson and not more than four other members of the Council.

(2) Subject to the directions of the Council, the executive committee may exercise the powers, and must perform the functions, of the Council during the periods between the meetings of the Council.

(3) Unless specifically empowered by the Council to do so, the executive committee may not set aside or vary a decision of the Council.

(4) An action taken or a decision made by the executive committee is subject to review at the first ensuing meeting of the Council.

Veterinary medicines committee

12. (1) The Council must establish a veterinary medicines committee, which may exercise the powers conferred on, and must perform the functions assigned to, the veterinary medicines committee by this Act.

(2) The veterinary medicines committee consists of –

(a) one veterinarian designated by the Council from amongst its members, who must be the chairperson of the committee;

(b) two veterinarians designated by the Minister responsible for agriculture;

(c) one veterinarian designated by the Veterinary Association of Namibia; and

(d) one pharmacist who is a member of the Council.

(3) The veterinary medicines committee may appoint not more than two other persons to be additional members of the veterinary medicines committee, subject to approval by the Council.

(4) Section 6, with the necessary modifications, applies also to those members of the veterinary medicines committee, who are not members of the Council.

(5) The Council or the Permanent Secretary, as the case may be, may not exercise any powers, take a decision, or perform a function in terms of section 18(2), 19(4) or (11), 20(1) or (4), 21(4), 22(1) or (3), 25(2), 27(1) or (3), 29(1), (3), (15), (23), (24), (27) or (29), 29(1), 31(1), (2), (3), (4) or (5), 32, 33, 37, 42(a)(i), 44(1) or 45 with respect to a veterinary medicine, unless the veterinary medicines committee recommends so.

Other committees

13. The Council may -

(a) from time to time, establish such other committees as it may consider necessary to investigate and report to it on a matter, which is within the purview of the Council in terms of this Act; and

(b) appoint such persons, including persons other than members of the Council, as it may consider fit to be members of a committee established in terms of paragraph (a).

Restriction of liability

14. The Council or a committee or a member of the Council or of any such committee is not liable for any loss or damage arising out of, or in connection with, the performance of the Council's or the committee's or the member's duties under this Act, or in respect of any act or thing done in good faith by the Council or any such committee or member in the exercise of the powers or the performance of functions under this Act, unless the loss or damage is due to the Council's, the committee's or the member's willful misconduct, gross negligence or failure to comply with this Act or a direction or decision given under it.

Financial year and annual report
15. (1) The financial year of the Council begins on 1 April and ends on 31 March in the following year.

(2) The Council must submit a report to the Minister, not later than 30 September in each year, relating to the activities of the Council during the previous financial year.

(3) The Minister must lay the report referred to in subsection (2) on the Table in Parliament within 28 days after the date of the receipt of the report, if Parliament is then in ordinary session, or, if Parliament is not then in ordinary session, within 28 days after the commencement of its next ordinary session.

Appointment of Registrar of Medicines
16. (1) Subject to the Public Service Act and after consultation with the Council, the Minister must appoint a pharmacist to be the Registrar of Medicines.

(2) The Registrar must perform the functions assigned to the Registrar under this Act and such other duties as the Minister or the Permanent Secretary may from time to time assign to him or her.

(3) The Registrar -

(a) must attend meetings of the Council, but has no vote; and

(d) is the secretary of the Council.

Registers
17. (1) The Registrar must keep, separately, in the prescribed form-

(a) the medicines register relating to medicines, which are not veterinary medicines or complementary medicines;

(b) a veterinary medicines register relating to veterinary medicines;

(c) a complementary medicines register relating to complementary medicines; and

(d) such other registers as may be prescribed under this Act, in which the Registrar must enter the particulars of every medicine the registration of which has been approved by the Council in relation to the register concerned and such particulars in regard to any other thing as may be prescribed under this Act.

(2) The Registrar may in respect of any register referred to subsection (1) keep that register also in electronic form.

Prohibition on sale of medicines, which are subject to registration and are not registered
18. (1) Except as provided in this section or section 27, a person may not sell a medicine, which is subject to registration by virtue of a resolution published in terms of subsection (3), unless that medicine is registered.

(2) The Council, by resolution approved by the Minister, may from time to time determine that a medicine or a category of medicines is subject to registration in terms of this Act.

(3) A resolution referred to in subsection (2) –

(a) may relate only to medicines, which were available for sale in Namibia immediately prior to the date of publication of such resolution or only to medicines which were not so available then; and

(b) must be published by the Registrar in the *Gazette*.

(4) In the case of a medicine, which was available for sale in Namibia immediately before the date of publication in the *Gazette* of a resolution subjecting that medicine to registration, the sale of that medicine becomes prohibited –

(a) after six months from the date of publication of the resolution, if the registration of that medicine is not applied for before the expiry of that period; or

(b) one month after the date of publication in the *Gazette* of a notice in respect of that medicine in terms of section 19(13), if the registration of the medicine is applied for under section 19 within six months after the date of publication of the resolution and the application is rejected.

(5) Subsection (1) does not apply in respect of the sale of a medicine –

(a) compounded by a medical practitioner, a pharmacist, a practitioner, a registered nurse, a veterinarian, or a para-veterinary professional, in the course of carrying on his or her professional activities for a particular person or animal in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, the pharmacist, the practitioner, the registered nurse, the veterinarian or the para-veterinary professional; or

(b) compounded by a pharmacist in a quantity not greater than that prescribed under this Act for sale in the retail trade, subject to the conditions prescribed, or in a quantity for a particular person or animal as prescribed by a medical practitioner, a dentist, a practitioner, a veterinarian or a para-veterinary professional, as the case may be, if that medicine does not contain any component the sale of which is prohibited by this Act, or any component in respect of which an application has been rejected, and if that medicine has not been advertised.

Registration of medicines

19. (1) A person, who wishes to have a particular medicine registered, must submit an application to the Registrar in the prescribed form.

(2) The application referred to in subsection (1) must be accompanied by –

(a) the prescribed particulars;

(b) the prescribed sample of the medicine, where appropriate; and

(c) the prescribed application fee.

(3) The Registrar must, as soon as is practicable after the Registrar receives the application referred to in subsection (1), submit the application, the prescribed particulars and the prescribed sample, where appropriate –

(a) to the Council; and

(b) in the case of a veterinary medicine, also to the veterinary medicines committee, for consideration, and inform the applicant in writing that the application has been so submitted.

(4) If after consideration of an application, and after any investigation or inquiry, which the Council may consider necessary, the Council is satisfied that –

(a) the medicine in question is suitable for the purpose for which it is intended and complies with the prescribed requirements; and

(b) the registration of that medicine is in the public interest, the Council must approve the registration of that medicine.

(5) If the Council is not satisfied as contemplated in subsection (4), the Registrar must inform the applicant in writing –

(a) of the reasons for the Council's dissatisfaction; and

(b) that the applicant may within one month after the date of that notification, furnish the Registrar with any comments on the Council's reasons, which the applicant may wish to make.

(6) The Council must reject the application concerned –

(a) if comments as contemplated in paragraph (b) of subsection (5) are not received by the Registrar from the applicant within one month; or

(b) if after consideration of any comments received, the Council is still not satisfied as contemplated in subsection (4).

(7) If the Council approves of the registration of a medicine, the Registrar must -

(a) register that medicine; and

(b) in the prescribed form, issue to the applicant a certificate of registration in respect of that medicine.

(8) Every medicine must be registered under a name approved by the Council.

(9) The Registrar must allocate a registration number to every medicine registered under this Act.

(10) The registration number referred to in subsection (9) must be recorded in the relevant register and must be stated in the certificate of registration issued in respect of that medicine.

(11) The Council may determine the conditions of registration of a medicine under this Act.

(12) The Registrar must, as soon as is practicable after the date of expiry of the appropriate period referred to in section 18(4), publish in the *Gazette* the prescribed particulars in respect of all applications for registration received by him or her prior to that date.

(13) The Registrar must give notice in the *Gazette* of the rejection of an application under this section in respect of a medicine referred to in section 18(4) –

(a) if no appeal is lodged against the rejection within the period referred to in section 34, as soon as is practicable after that period; or

(b) if any appeal lodged is dismissed, as soon as is practicable after the decision dismissing the appeal has been given.

Amendment of entries in register

20. (1) The Registrar, on application by the holder of a certificate of registration issued in respect of a medicine, and with the approval of the Council, may amend the entry in a register with respect to that medicine.

(2) An application for the amendment of an entry in a register must be made to the Registrar in the prescribed form and must be accompanied by the prescribed application fee.

(3) As soon as is practicable after receipt of an application referred to in subsection (2), the Registrar must submit the application to the Council, and in the case of an application relating to a veterinary medicine, also to the veterinary medicines committee, for consideration.

(4) If the Council grants its approval in respect of an application submitted to it in terms of subsection (3), the Registrar must –

(a) make the required amendments in the relevant register; and

(b) if the name of the applicant changes, issue a new certificate of registration on the prescribed form to the applicant in respect of the medicine after receiving the existing certificate of registration in respect of that medicine for cancellation.

Transfer of certificate of registration
21. (1) The holder of a certificate of registration may transfer the certificate with the approval of the Council, to any other person, who qualifies by virtue of section 44(1)(c) to apply for the registration of a medicine.

(2) An application for approval of the transfer of a certificate of registration must be made to the Registrar on the prescribed form and must be accompanied by the certificate of registration in question and the prescribed application fee.

(3) The Registrar must, as soon as is practicable after receipt of the application referred to in subsection (2), submit that application to the Council for consideration.

(4) If the Council grants the application submitted to it in terms of subsection (3), the Registrar must –

(a) make the necessary entries in the register relating to the person to whom the certificate of registration is transferred;

(b) cancel the existing certificate of registration; and

(c) issue a new certificate of registration on the prescribed form to the person referred to in paragraph (a) in respect of the relevant medicine.

Cancellation of registration
22. (1) If the Council is of the opinion that –

(a) a person has failed to comply with a condition subject to which a particular medicine has been registered;

(b) a particular medicine does not comply with a prescribed requirement; or

(c) it is not in the public interest to make a particular medicine available to the public, the Council must cause notice in writing to be given of that fact by the Registrar to the holder of the certificate of registration issued in respect of that medicine.

(2) The notice referred to in subsection (1) must –

(a) specify the grounds on which the opinion of the Council is based; and

(b) indicate that the person to whom the notice is directed may within one month after the date of that notice submit to the Registrar any comments, which he or she may wish to make in connection with the matter.

(3) If -

(a) no comments as contemplated in subsection (2)(b) are received; or

(b) after consideration of any comments received, the Council is of the opinion that the registration of the medicine in question should be cancelled, the Council must direct the Registrar to cancel the registration of that medicine.

(4) If the holder of the certificate of registration issued in respect of a medicine fails to pay the prescribed fee in respect of the retention of the registration of that medicine before or on the prescribed date or such later date as the Registrar, with the approval of the Council, may determine on application by that person, the Registrar must cancel the registration of that medicine.

Notification of registration, or cancellation of registration, in the *Gazette*
23. The Registrar must give notice in the *Gazette* of the registration, or cancellation of registration, of a medicine in terms of this Act, and must in such notice specify –

(a) in the case of a registration of a medicine -

(i) the name under which that medicine is registered;

(ii) the active components of that medicine;

(iii) the name of the applicant;

(iv) the name of the manufacturer;

(v) the registration number allocated to that medicine in terms of section 19(9); and

(vi) the conditions, if any, subject to which that medicine is registered;

(b) in the case of a cancellation of registration of a medicine -

(i) the name under which that medicine was registered;

(ii) the name of the holder of the certificate of registration issued in respect of that medicine; and

(iii) the number which was allocated to that medicine in terms of section 19(9).

Labels and advertisements
24. (1) A person may not -

(a) sell a medicine or a scheduled substance, unless the immediate container and the package, if any, in which that medicine or scheduled substance is sold, bear a label stating the prescribed particulars; or

(b) advertise a medicine or a scheduled substance for sale, unless the advertisement complies with the prescribed requirements.

(2) The Council may authorise a deviation from the prescribed label format if, in its opinion, the circumstances of a particular case warrant a deviation.

Prohibition on sale of medicines, which do not comply with prescribed requirements, and furnishing of information regarding medicines to the Council

25. (1) A person may not sell a medicine, which has been registered in terms of this Act or in respect of which the Council has authorised the sale as contemplated in section 27, unless that medicine complies with the prescribed requirements.

(2) The Council may, by notice in writing, require a person, who manufactures, sells, administers or prescribes a medicine, or on whose direction a medicine is manufactured, sold or administered, to furnish the Council, within a period specified in that notice, with information, which that person has in his or her possession or which that person is in a position to obtain regarding that medicine.

(3) The Council may, if requested by a person to whom a notice under subsection (2) is addressed, extend the period specified in that notice.

Publication or distribution of false advertisements concerning medicines

26. (1) A person may not –

(a) publish, distribute or in any other manner bring to the notice of the public or cause to be published, distributed or to be brought to the notice of the public, a false or misleading advertisement concerning a medicine; or

(b) in an advertisement claim that the therapeutic efficacy and effect of a medicine is other than that stated by the Council in terms of section 28(a)(ii) or state or suggest that a medicine should be used for a purpose, under a circumstance, or in a manner, other than that stated by the Council in terms of that section.

(2) It is a sufficient defence in a prosecution for an offence under subsection (1)(a), if it is proved to the satisfaction of the court that the accused, not being a person selling the medicine to which the false or misleading advertisement, which is the subject of the prosecution, relates, did not know, and could not reasonably be expected to have known, that the advertisement was in any respect false or misleading, unless it is proved that the accused failed on demand by the Registrar, an inspector or a member of the Namibian Police, to furnish the name and address of the person on whose request or direction the advertisement was published, distributed or brought to the notice of the public.

Council may authorise sale of unregistered medicine for certain purposes

27. (1) The Council may authorise a person, in writing, to sell a specified quantity of a particular medicine, which is subject to registration in terms of section 18, but is not registered, during a specified period and to a specified person or institution.

(2) A medicine sold under the authority granted in terms of subsection (1) may be used for such purposes, in such manner and during such period, as the Council may determine in writing.

(3) If effect is not given to a determination made in terms of subsection (2), or if the Council is of the opinion that the risks of selling a specified quantity of a particular medicine in terms of subsection (1), outweigh the potential benefits, the Council may at any time, in writing, withdraw any authority granted in terms of the said subsection (1).

Council to cause certain information to be furnished
28. The Council must in such manner as it considers most suitable, and as soon as is practicable –

(a) in relation to a medicine, which has been registered after the commencement of this Act, cause medical practitioners, dentists, pharmacists, veterinarians, practitioners and the person who applied for the registration of that medicine to be informed -

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

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

(iii) of the purpose for which, the circumstances under which, and the manner in which, the medicine should be used; and (iv) regarding any other matter concerning the medicine, which, in the opinion of the Council, may be of value to those persons;

(b) after the registration of a medicine has been cancelled in terms of section 22, cause medical practitioners, dentists, pharmacists, veterinarians, practitioners and the holder of the certificate of registration issued in respect of that medicine to be informed of the cancellation of the registration.

Control of medicines and scheduled substances
29. (1) The Minister, on the recommendation of the Council and for the purpose of the control of medicines and other substances –

(a) must classify medicines and other substances, by notice in the *Gazette*, as Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substances; and

(b) may from time to time amend the Schedules referred to in paragraph (a) by notice in the *Gazette*:

Provided that the Council must recommend only those medicines and other substances, which it considers necessary to be classified.

(2) Subject to this section, a person may not sell a medicine or a scheduled substance, except in accordance with the prescribed conditions.

(3) Except as provided under the regulations made under section 44(1)(u) relating to own use, a person may not –

(a) in respect of medicines or scheduled substances -

(i) manufacture or pack and sell those medicines or scheduled substances, unless the person holds a licence contemplated in section 31(5)(a) or

(b) for the manufacture or packing and selling and the person complies with the specified conditions;

(ii) import or export those medicines or scheduled substances, unless the person holds a licence contemplated in section 31(5)(c) for the import or export and the person complies with the conditions determined by the Council;

(b) in respect of a scheduled substance, which is a Schedule 3 substance or Schedule 4 substance -

(i) manufacture or pack and sell the substance, unless the person holds a licence contemplated in section 31(5)(a) or (b), and in addition, holds a permit referred to

in subsection (15)(a) or (23)(a), as the case may be, for the manufacture or packing and selling of the Schedule 3 substance or Schedule 4 substance specified in the permit and the person complies with the prescribed conditions;

(ii) import or export the substance, unless the person holds a licence contemplated in section 31(5)(c), and in addition, holds a permit referred to in subsection (15)(b) or (23)(b), as the case may be, for the import or export of the Schedule 3 substance or Schedule 4 substance specified in the permit and the person complies with the prescribed conditions;

(iii) cultivate or collect a plant or a portion of a plant from which the Schedule 3 substance or Schedule 4 substance can be extracted or manufactured, unless the person holds a permit referred to in subsection (15)(c) or (23)(c), as the case may be, for the cultivation or collection of the plant or portion of a plant and the person complies with the prescribed conditions.

(4) A manufacturer or an importer of, or a wholesale dealer in, pharmaceutical products, may not sell medicines or scheduled substances to a person, who himself or herself may not sell those medicines or scheduled substances: Provided that such manufacturer, importer or wholesale dealer, who is –

(a) an authorised prescriber, but not a pharmacist; or

(b) a pharmacist, irrespective of whether that pharmacist is an authorized prescriber or not, may sell medicines or scheduled substances, subject to the other provisions of this section, for the purpose of consumption.

(5) Subject to subsection (6), a person may not sell an unscheduled medicine, if it is not in the original immediate container.

(6) Notwithstanding subsection (5), a pharmacist, a medical practitioner, a dentist, a veterinarian, a registered nurse, a para-veterinary professional or a practitioner may sell an unscheduled medicine in any other immediate container, if that immediate container complies with the prescribed requirements.

(7) A person, other than the following, may not sell a Schedule 1 substance:

(a) a pharmacist, or a pharmacist's assistant, pharmaceutical technician, or pharmacist intern, acting under the personal supervision of a pharmacist;

(b) a medical practitioner, a dentist, or a veterinarian, who holds a licence contemplated in section 31(3), subject to the conditions of that licence; or

(c) a person who holds a licence contemplated in section 31(1), subject to the conditions of that licence.

(8) A person, who sells a Schedule 1 substance, must record the prescribed particulars of every sale of that substance in a prescription book, or other permanent record, required to be kept in the prescribed manner.

(9) A person, other than the following, may not sell a Schedule 2 substance:

(a) a pharmacist, or a pharmacist's assistant, pharmaceutical technician, or pharmacist intern, acting under the personal supervision of a pharmacist -

(i) on a written prescription issued by an authorised prescriber, or on an oral instruction from an authorised prescriber, who is known to the pharmacist, and taken and reduced to writing by the pharmacist concerned: Provided that the sale

may be repeated for up to six months, if the authorised prescriber has indicated the number of times the prescription may be repeated; or

(ii) if the pharmacist holds a licence contemplated in section 31(2), subject to the conditions of that licence;

(b) a medical practitioner, a dentist or a veterinarian, who holds a licence contemplated in section 31(3), subject to the conditions of that licence; or

(c) a person who holds a licence contemplated in section 31(1), subject to the conditions of that licence.

(10) A person who sells a Schedule 2 substance must record the prescribed particulars of every sale of that substance in a prescription book, or other permanent record, required to be kept in the prescribed manner.

(11) Except as permitted by this section, a person may not use, possess or administer a Schedule 3 or Schedule 4 substance, except for medicinal purposes or such other scientific purposes as the Minister may approve.

(12) The Minister may grant authority to a person referred to in the authority, and subject to such conditions as the Minister may specify in that authority, for the administration of a Schedule 3 or Schedule 4 substance for the satisfaction of a habit, or the relief of a craving for the substance administered or for any other such substance.

(13) A person, other than the following, may not sell a Schedule 3 substance:

(a) a pharmacist, or a pharmacist's assistant, pharmaceutical technician, or pharmacist intern, acting under the personal supervision of a pharmacist -

(i) on a written prescription issued by an authorised prescriber, or on an oral instruction from an authorised prescriber, who is known to the pharmacist, and taken and reduced to writing by the pharmacist concerned: Provided that -

(aa) within seven days after giving an oral instruction, the authorized prescriber concerned furnishes the pharmacist with a written prescription confirming that instruction;

(bb) the sale may be repeated for up to six months, if the authorized prescriber concerned has indicated the number of times the prescription may be repeated; or

(ii) if the pharmacist holds a licence contemplated in section 31(2), subject to the conditions of that licence;

(b) a medical practitioner, a dentist or a veterinarian, who holds a licence contemplated in section 31(3), subject to the conditions of that licence;

(c) a person who holds a licence contemplated in section 31(1), subject to the conditions of that licence.

(14) A person who sells a Schedule 3 substance must record the prescribed particulars of every sale of that substance in a prescription book, or other permanent record, required to be kept in the prescribed manner.

(15) On application by a person, who may manufacture, pack and sell, import or export scheduled substances under a licence contemplated in section 31(5) -

(a) the Council may issue a permit in the prescribed form and manner to a person to manufacture or pack and sell a specified Schedule 3 substance;

(b) the Permanent Secretary may issue a permit in the prescribed form and manner to the person to import or export a specified Schedule 3 substance;

(c) the Council may issue a permit in the prescribed form and manner to the person to cultivate or collect a plant, or a portion of a plant, from which a specified Schedule 3 substance can be extracted or manufactured.

(16) The Permanent Secretary or the Council, as the case may be, may issue a permit referred to in subsection (15), if the Permanent Secretary or the Council is satisfied that the substance or plant in question is reasonably required for the treatment of a patient or in the public interest.

(17) The Permanent Secretary or the Council, as the case may be, may cancel a permit issued in terms of subsection (15) at any time, if any condition on which the permit was issued is not met.

(18) The permit referred to in subsection (15)(c) is valid for such period, not exceeding 12 months from the date of issue, as the Council may determine.

(19) A person, other than the following, may not sell a Schedule 4 substance:

(a) a pharmacist, or a pharmacist intern acting under the personal supervision of a pharmacist, on a written prescription, which is not older than 14 days, issued by an authorised prescriber, or, in an emergency, on an oral instruction from an authorised prescriber, who is known to the pharmacist, and taken and reduced to writing by the pharmacist concerned: Provided that -

(i) within 72 hours after giving the oral instruction, the authorized prescriber concerned furnishes the pharmacist with a written prescription confirming that instruction, and the period of treatment on the oral instruction does not exceed 48 hours; and

(ii) the exact quantity on the prescription is sold;

(b) a medical practitioner, a dentist or a veterinarian, who holds a licence contemplated in section 31(3), subject to the conditions of that licence.

(20) A person who sells a Schedule 4 substance must record the prescribed particulars of every sale of that substance –

(a) in the register of Schedule 4 substances, which that person must keep at his or her business premises for not less than three years from the date of the last entry in it; and

(b) in a prescription book, or other permanent record, required to be kept in the prescribed manner.

(21) A person may not repeat the sale of a Schedule 4 substance on the same prescription, and the period of treatment covered by a prescription referred to in subsection (19) may not exceed 30 days.

(22) A seller must retain the prescription referred to in subsection (19)(a) for not less than three years.

(23) On application by a person, who may manufacture, pack and sell, import or export scheduled substances under a licence contemplated in section 31(5) -

(a) the Council may issue a permit in the prescribed form and manner to a person to manufacture or pack and sell a specified Schedule 4 substance;

(b) the Permanent Secretary may issue a permit in the prescribed form and manner to the person to import or export a specified Schedule 4 substance;

(c) the Council may issue a permit in the prescribed form and manner to the person to cultivate or collect a plant, or a portion of a plant, from which a specified Schedule 4 substance can be extracted or manufactured.

(24) The Permanent Secretary or the Council, as the case may be, may cancel a permit issued in terms of subsection (23) at any time, if any condition on which the permit was issued is not met.

(25) A permit referred to in subsection (23)(c) is valid for such period, not exceeding 12 months from the date of issue, as the Council may determine.

(26) A person, who may sell Schedule 4 substances under subsection (19), must keep a register of Schedule 4 substances in the prescribed manner and must balance the register against physical stock at least quarterly.

(27) Subject to subsection (29), a person may not –

(a) manufacture, acquire, possess, use or supply a Schedule 5 substance, unless he or she has been issued with a permit by the Council, subject to conditions determined by the Council; or

(b) cultivate, collect, acquire, possess, use or supply a plant, or a portion of a plant, from which a Schedule 5 substance can be extracted or manufactured, unless he or she has been issued with a permit by the Council, subject to conditions determined by the Council, authorizing him or her to cultivate, collect, acquire, possess, use or supply such a plant or portion of a plant.

(28) The permit referred to in subsection (27) is valid for such period, not exceeding 12 months from the date of issue, as the Council may determine.

(29) Notwithstanding subsection (27), the Permanent Secretary may import or acquire a Schedule 5 substance or a plant, or portion of a plant, from which a Schedule 5 substance may be extracted or manufactured, for the purpose of supplying it, on such conditions as he or she may determine, to a medical practitioner, a veterinarian or a scientist for the treatment of a particular patient or such scientific purpose as the Minister, on the recommendation of the Council, may approve.

(30) Subject to subsection (31), a pharmacist may sell a greater or a lesser quantity of a Schedule 2 substance than the quantity specified in a prescription or order, according to the immediate container of that substance as supplied to the pharmacist.

(31) Notwithstanding subsection (30), the quantity of a Schedule 2 substance sold in terms of that subsection may not deviate by more than twenty-five percent of the quantity specified in the prescription or order in question.

(32) A person in possession of a Schedule 3 or a Schedule 4 substance, or in possession of a prescription for a Schedule 3 or a Schedule 4 substance, may not, during the period that he or she is in possession of that substance or during the period covered by that prescription, knowingly obtain from another authorised prescriber another such prescription, unless that person first discloses to that authorised prescriber the possession of the substance or the existence of the prior prescription.

(33) Notwithstanding the other provisions of this section -

(a) a medical practitioner, a dentist, or a veterinarian, may sell an emergency medicine in the course of lawfully carrying on his or her professional activities to, or for, a patient under his or her care or treatment;

(b) a person employed by a manufacturer of, or wholesale dealer in, pharmaceutical products, and authorised to do so by that manufacturer or wholesale dealer, may exhibit a Schedule

1 or a Schedule 2 substance to a medical practitioner, a dentist, a pharmacist or a veterinarian on prescribed conditions;

(c) a para-veterinary professional employed by a veterinarian, which veterinarian holds a licence issued under section 31(3), may sell a Schedule 1 or a Schedule 2 substance for the treatment of an animal, on a written prescription or on an oral instruction issued by that veterinarian;

(d) a person who may sell a medicine for the purpose of consumption under this section may sell that medicine at cost to any other person, who may lawfully sell the same medicine for the purpose of consumption; and

(e) the Minister may exempt a person or class of persons from the application of this section by notice in the *Gazette* and on such conditions as the Minister considers necessary, if in the opinion of the Minister, the exemption is necessary for medicinal purposes and is not in conflict with the provisions of international treaties.

Generic substitution
30. (1) A pharmacist -

(a) must inform all members of the public, who visit his or her pharmacy with a prescription, of the benefits of substituting the requested medicine with an interchangeable multi-source medicine; and

(b) subject to subsections (2) and (3), may dispense an interchangeable multisource medicine instead of the medicine on the prescription.

(2) If a pharmacist dispenses an interchangeable multi-source medicine, he or she must note the brand name, or the name of the manufacturer, of that interchangeable multi-source medicine in the prescription book, or other permanent record, required to be kept in the prescribed manner.

(3) A pharmacist may not dispense an interchangeable multi-source medicine –

(a) if the person who issued the prescription referred to in subsection (1) has written on that prescription in his or her own hand the words “no substitution” next to the item prescribed;

(b) if the patient expressly objects to a substitution;

(c) if the retail price of the interchangeable multi-source medicine is higher than that of the medicine specified on the prescription; or

(d) if the product has been declared not substitutable by the Council in terms of subsection (5).

(4) A pharmacist, who sells an interchangeable multi-source medicine in accordance with this Act, does not incur a greater liability in respect of that sale than the liability which he or she would have incurred had he or she sold the medicine specified in the prescription referred to in subsection (1).

(5) The Council must from time to time publish in the *Gazette* a list of medicines, which the Council declares not substitutable.

Licences and permits

31. (1) The Council may issue a licence on application in the prescribed form by a person, who lawfully performs a health service, other than a person referred to in subsection (2) or (3), authorizing that person to –

(a) acquire;

(b) possess; and

(c) prescribe, use in respect of, or sell to, his or her patients, specified Schedule 1, Schedule 2 or Schedule 3 medicines, subject to such conditions as the Council may determine, if the Council is satisfied that granting such a licence is in the public need and interest and that the person possesses the required competence to possess, prescribe, use, or supply those scheduled medicines.

(2) The Council may issue a licence on application in the prescribed form by a pharmacist, authorizing that pharmacist to –

(a) prescribe; and

(b) sell to persons in respect of whom he or she has issued a prescription under paragraph (a), specified Schedule 2 or Schedule 3 medicines, subject to such conditions as the Council may determine, if the Council is satisfied that granting such a licence is in the public need and interest and that the pharmacist possesses the required competence to prescribe those scheduled medicines.

(3) The Council may issue a licence on application in the prescribed form by a medical practitioner, a dentist or a veterinarian, authorizing that medical practitioner, dentist or veterinarian to sell Schedule 1, Schedule 2, Schedule 3 or Schedule 4 medicines to his or her patients, subject to such conditions as the Council may determine, if the Council is satisfied that granting such a licence is in the public need and interest and that the medical practitioner, the dentist or the veterinarian has the required competence to dispense those scheduled medicines.

(4) Notwithstanding the other provisions of this section, the Minister, on the recommendation of the Council, may issue a permit to a person, who is not a pharmacist, authorizing that person to manufacture or pack and sell a medicine or a scheduled substance subject to conditions specified in the permit.

(5) The Council –

(a) must issue a licence to a person, who is the holder of a permit issued by the Minister under subsection (4), to manufacture or pack and sell a medicine or a scheduled substance;

(b) may issue a licence, on application by a pharmacist, authorizing him or her to manufacture or pack and sell a medicine or scheduled substance subject to such conditions as the Council may determine;

(c) may issue a licence, on application by a person who may sell a medicine or a scheduled substance under this Act, authorizing that person to import or export that medicine or scheduled substance subject to such conditions as the Council may determine.

(6) The Registrar must register, in the prescribed form, every person issued with a licence or permit under this section.

(7) If a medical practitioner, a dentist, a pharmacist, a veterinarian or other person granted a licence under this section ceases to carry out the functions authorised in that licence, he or she must notify the Registrar accordingly in writing and return the licence in question to the Registrar, and the Registrar must remove the name of that person from the relevant register.

(8) A licence referred to in this section must be issued on payment of the fee prescribed for the particular licence.

(9) A licence or permit issued under this section may be revoked, if a condition on which it was issued is not met.

Publication of information relating to medicines, scheduled substances or any other things subject to this Act

32. (1) Notwithstanding section 42, the Council may disclose any information in respect of the prescribing, dispensing, administration and use of a medicine or a scheduled substance, or any other thing, which is subject to this Act, if the Council considers it expedient and in the public interest to disclose that information.

(2) The Council may publish the information referred to in subsection (1) or release it to the public in a manner that the Council considers fit.

Disposal of undesirable medicines

33. (1) If the Council is of the opinion that it is not in the public interest that a medicine or a scheduled substance be made available to the public, the Council may –

(a) by notice in writing handed or transmitted by registered post to any person direct that person; or

(b) by notice in the *Gazette* direct any person, to -

(i) return any quantity of that medicine or scheduled substance in his or her possession to the manufacturer, supplier or importer of that medicine or scheduled substance; or

(ii) deliver or send that medicine to any other person designated by the Council.

(2) The Council may, by notice in writing, direct any -

(a) manufacturer, supplier or importer of a medicine or a scheduled substance referred to in subsection (1), who has any quantity of that medicine or scheduled substance, including any quantity returned to him or her in pursuance of a direction made under subsection (1); or

(b) any other person to whom any quantity of a medicine or a scheduled substance referred to in subsection (1) has been delivered or sent, to dispose of that quantity in such manner, subject to regulations made under section 44(1)(w), as the Council may determine.

(3) A person may not sell a medicine or a scheduled substance, which is the subject of a notice under subsection (1), unless the notice has been withdrawn by the Council or set aside on appeal.

Appeal against decisions of Council

34. (1) A person who is aggrieved by a decision of the Council may appeal in the manner, and within the period, prescribed, against that decision to the Minister.

(2) The Minister must appoint an appeal committee to hear an appeal lodged under subsection (1), which appeal committee must consist of –

(a) a judge, or a legal practitioner who has practised as such for a period of at least five years, and who must be the chairperson of the committee;

(b) a pharmacologist or other person with special knowledge of the actions and applications of medicines; and

(c) if the appeal relates to -

(i) a medicine or a scheduled substance, other than a veterinary medicine or a complementary medicine, a medical practitioner, who is registered as a specialist in the country in which he or she is practising, and a pharmacist;

(ii) a veterinary medicine, a veterinarian and a pharmacist;

(iii) a complementary medicine, a practitioner of the relevant discipline; and

(iv) a medical device or any other thing, which is subject to this Act, a specialist or a technician, who has expert or special knowledge or experience of that device or other thing.

(3) The Minister may not appoint a person as a member of an appeal committee, if that person has a direct or indirect interest in the affairs of the appellant or the Council.

(4) The appeal committee must hear the appeal under subsection (1) on the date, at the place and at the time determined by the appeal committee, and the appeal committee must notify the appellant and the Council in writing prior to that date of such date, place and time.

(5) The appeal committee may, for the purposes of the determination of an appeal -

(a) summon a person, who -

(i) may be able to give material information concerning the subject of the appeal; or

(ii) the appeal committee believes has in his or her possession or under his or her control any document or thing, which may have a bearing on the subject of the appeal, to appear before the appeal committee at a date, place and time specified in the summons, to be interrogated or to produce that document or thing, and retain for examination any document or thing produced by that person;

(b) administer an oath to, or accept an affirmation from, a person called as a witness at the appeal; and

(c) call a person present at the hearing of the appeal as a witness and interrogate him or her and require him or her to produce any document or thing in his or her possession or under his or her control.

(6) The chairperson of the appeal committee must determine the procedure to be followed at the hearing of an appeal.

(7) The appeal committee may, after hearing an appeal –

(a) confirm, set aside or vary the relevant decision of the Council; and

(b) direct the Council to execute the decision of the appeal committee in connection with the appeal.

(8) The decision of the appeal committee must be in writing and a copy of the decision must be furnished to the Minister, to the appellant and to the Council.

Inspectors
35. (1) The Permanent Secretary may authorise such persons to act as inspectors as he or she may consider necessary for the enforcement of this Act.

(2) Every inspector must be furnished with a certificate signed by the Permanent Secretary, stating that he or she is authorised to act as an inspector under this Act.

(3) Before an inspector exercises a power conferred on, or performs a function assigned to, an inspector under this Act, he or she must exhibit the certificate referred to in subsection (2) to a person affected by the exercise of that power or by the performance of that function.

Powers of inspectors
36. (1) Subject to subsection (6), an inspector may at all reasonable times and in connection with any medicine, scheduled substance or any other thing, which is subject to this Act -

(a) enter any premises, place, vehicle, vessel or aircraft at or in which there is on reasonable grounds suspected to be any medicine, scheduled substance or any other thing, which is subject to this Act;

(b) inspect any medicine or scheduled substance, a book, record or document, or any other thing referred to in paragraph (a), found in or on any premises, place, vehicle, vessel or aircraft referred to in the said paragraph (a);

(c) seize any medicine or scheduled substance, a book, record or document, or any other thing referred to in paragraph (a), found in or on any premises, place, vehicle, vessel or aircraft referred to in the said paragraph (a), and appearing to afford evidence of a contravention of a provision of this Act; and

(d) take as many samples of a medicine or a scheduled substance referred to in paragraph (b) or (c), or any other thing, which is subject to this Act and of which a person can take a sample, as he or she may consider necessary for the purpose of examination or analysis in terms of this Act.

(2) A sample taken in terms of subsection (1)(d) must -

(a) be taken in accordance with the prescribed methods and in the presence of the person who is in charge of the medicine or the scheduled substance referred to in subsection (1)(b) or (c), or if there is no such person or if he or she is absent for any reason, in the presence of any other witness;

(b) immediately be packed and sealed and suitably labeled or marked in such manner as its nature may permit; and

(c) be transmitted to an analyst together with a certificate in the prescribed form signed by the inspector who took the sample.

(3) A copy of the certificate referred to in subsection (2)(c) must be handed or transmitted by registered post to the owner or seller of the medicine or the scheduled substance, or other thing, referred to in subsection (1)(d), from which the sample was taken in terms of subsection (1)(d) or to the agent of that owner or seller.

(4) The analyst to whom a sample has been transmitted in terms of subsection (2)(c) must with all convenient speed examine or analyse the sample delivered to him or her, and state the result of the examination or analysis in a certificate in the prescribed form.

(5) The owner of the medicine or the scheduled substance, or other thing, from which the sample was taken under subsection (1)(d), may claim from the Permanent Secretary an amount equal to the cost of the sample, unless it is proven that the medicine or the scheduled substance does not comply with the provisions of this Act.

(6) Notwithstanding subsection (1), an inspector performing his or her functions under this section may not search the person or the home of an individual, unless the search has been authorised by a warrant issued by a judge, or a magistrate of the district in which the person or the home is situated, on oath by the inspector concerned that –

(a) there are reasonable grounds to suspect that -

(i) that person or persons in that home are contravening this Act or the conditions in a certificate of registration; or

(ii) a medicine or a scheduled substance, a book, record, document or any other thing, which may afford evidence of a contravention of this Act, is in that home; and

(b) the search is necessary for a purpose referred to in Article 13(1) of the Namibian Constitution, but nothing in this subsection prohibits a search without a warrant under Article 13(2)(b) of the Namibian Constitution.

(7) The search of the person or the home of an individual by an inspector -

(a) may not be excessively intrusive, having regard to the contravention suspected; and

(b) must comply with section 21(3)(a) and (4) and section 29 of the Criminal Procedure Act, 1977 (Act No. 51 of 1977).

(8) A police officer may accompany and assist an inspector, who is performing of his or her functions under this Act.

Analysts
37. The Permanent Secretary, after consultation with the Council, may grant authority to such analysts as he or she may consider necessary to examine or analyse samples of medicines, scheduled substances or of other things, taken by an inspector under section 36(1)(d).

Offences
38. A person commits an offence if he or she -

(a) obstructs or hinders an inspector in the exercise of his or her powers or the carrying out of his or her duties under this Act;

(b) contravenes section 18(1), 24(1), 26(1) or 30(1)(a) or (3);

(c) contravenes section 25(1) or fails to comply with a notice issued under subsection (2) of that section;

(d) contravenes or fails to comply with a condition imposed under section 19(11) or a determination made under section 27;

(e) fails to comply with a direction given under section 33 or contravenes subsection (3) of that section;

(f) with fraudulent intent tampers with a sample of a medicine, scheduled substance or of any other thing, taken under this Act;

(g) makes a false or misleading statement -

(i) in an application for the registration of a medicine or other application required under this Act; or

(ii) in the course of the sale of a medicine or a scheduled substance;

(h) sells a medicine or a scheduled substance in a container on which a false or misleading statement in connection with the contents is written;

(i) for purposes of business or trade, makes use of a report or certificate made or issued by an inspector or analyst under this Act;

(j) contravenes section 29 or fails to comply with any condition prescribed in respect of that section;

(k) fails to comply with any condition prescribed in respect of section 18(5);

(l) fails to comply with conditions of a permit granted in terms of section 31(4);

(m) contravenes section 31(7);

(n) contravenes section 42; or

(o) without reasonable grounds refuses to comply with a summons issued under section 34(5)(a).

Penalties

39. (1) A person who is convicted of an offence specified in section 38 is liable to a fine not exceeding N$40 000 or to imprisonment for a period not exceeding 10 years or to both the fine and imprisonment.

(2) The court convicting a person of an offence under this Act may declare a medicine or a scheduled substance, or other thing, to which the offence relates, to be forfeited to the State.

(3) A medicine or a scheduled substance, or any other thing, forfeited in terms of subsection (2) must be destroyed or dealt with in the prescribed manner or as the Permanent Secretary may direct.

Presumptions and evidence

40. (1) In criminal proceedings relating to this Act -

(a) any quantity of a medicine or a scheduled substance in or on any premises, place, vehicle, vessel or aircraft at the time a sample of that medicine or that scheduled substance is taken under this Act must, unless the contrary is proved, be deemed to possess the same properties as that sample;

(b) a certificate stating the result of an examination or analysis carried out in terms of section 36(4) and purporting to be signed by the analyst who carried out the examination or the analysis, must be accepted as prima facie proof of the facts stated in the certificate;

(c) a statement or entry contained in a book, record or document kept by the owner of a medicine or a scheduled substance, or by a manager, an agent or an employee of that owner, or found on or in any premises occupied by, or a place or vehicle used in the business of, that owner, is admissible in evidence.

(2) A prosecution may not be instituted as a result of any examination or analysis carried out in terms of subsection (4) of section 36, unless a copy of the certificate issued by an analyst in terms of that subsection, has been handed or transmitted by registered post to the person who is to be accused, at least 14 days prior to the institution of the prosecution of that person.

(3) The court in which a certificate referred to in subsection (2) is adduced in evidence may -

(a) cause the analyst, who signed that certificate, to be summoned to give oral evidence in the proceedings in question; or

(b) cause written interrogatories to be submitted to the analyst for reply, and those interrogatories and any reply to them, purporting to be a reply from that analyst, are admissible in evidence in those proceedings.

Special defences in case of prosecutions
41. It is sufficient defence for a person charged with the sale of a medicine in contravention of section 25, if the person proves that he or she –

(a) acquired that medicine from a lawful source in Namibia and obtained a written proof of purchase from that lawful source; and

(b) had no reason to believe that the medicine did not comply with that section.

Preservation of secrecy and inappropriate use of information
42. Subject to section 32, a person may not -

(a) disclose to any other person any information acquired by him or her in the exercise of his or her powers or the performance of his or her functions under this Act and relating to the business or affairs of any other person, except -

(i) with a written authority from the Permanent Secretary, on the recommendation of the Council;

(ii) for the purposes of -

(aa) the exercise of his or her powers or the performance of his or her functions under this Act; or

(bb) legal proceedings under this Act or any other law; or

(iii) when required to do so by a court or under any law; or

(b) use any information referred to in paragraph (a) for self-gain or for the benefit of his or her employer.

Delegation of powers, and assignment of duties and functions
43. (1) The Minister may delegate, in writing, to the Permanent Secretary, or to a staff member in the Ministry responsible for health, any of the powers conferred on the Minister by this Act, except a power referred to in section 3, 34(1) and 44, and may assign any of the duties or functions imposed on the Minister in terms of this Act.

(2) The Permanent Secretary may delegate, in writing, to a staff member in the Ministry responsible for health, a power conferred, or assign a function imposed, on the Permanent Secretary by or in terms of this Act, except a power delegated, or a function assigned, to the Permanent Secretary in terms of subsection (1).

(3) A delegation, or assignment, under subsection (1) or (2) does not divest the Minister or the Permanent Secretary of the powers delegated, or the duties or functions assigned.

Regulations

44. (1) The Minister, after consultation with the Council, may make regulations -

(a) generally for the efficient carrying out of the objects of this Act;

(b) with regard to a matter which in terms of this Act is required or permitted to be prescribed;

(c) prescribing the persons or classes of persons, who may apply for the registration of a medicine;

(d) prescribing the forms to be used in an application for registration of a medicine and the particulars which must be furnished with any such application;

(e) prescribing the form of a certificate of registration of a medicine to be issued under this Act;

(f) prescribing the form and manner of an application for a permit or a licence in terms of this Act, the manner of issuing a permit or a licence and the form of every permit or licence;

(g) prescribing the form in which the register of medicines, which are not veterinary medicines or complementary medicines, the veterinary medicines register, the complementary medicines register and any register required in this Act must be kept and the particulars which must be entered in it;

(h) prescribing the forms of registers, prescription books, records, and other documents, which must be kept or used in respect of scheduled substances, the manner in which they must be kept, the particulars which must be entered in them and the place where, and the period for which, they must be retained;

(i) prescribing the particulars which must 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 must be issued and the period for which any such prescription or order must be retained;

(j) prescribing the samples of a medicine and the quantity of that medicine, which must accompany an application for the registration of a medicine;

(k) subject to section 29, prescribing the circumstances in which, the conditions on which, and the persons or categories of persons by whom or to whom, a medicine or a scheduled substance may be sold;

(l) prescribing the manner in which a package containing a medicine or a scheduled substance must be labeled, packed or sealed;

(m) prescribing the particulars to be furnished with a medicine or a scheduled substance sold regarding its use, and the manner in which those particulars must be furnished;

(n) prescribing the particulars which must appear in an advertisement relating to a medicine or a scheduled substance or prohibiting the inclusion of any specified particulars in an advertisement relating to a medicine or a scheduled substance, or the distribution of any

such advertisement to a specified person or specified category of persons or to a specified organization or a specified category of organizations;

(o) prescribing the requirements with which a medicine or any component of that medicine must comply in regard to composition, therapeutic suitability and effect, purity or any other property;

(p) prescribing the particulars which must be published in the *Gazette* in respect of a notice required to be given in the *Gazette* in terms of this Act;

(q) prescribing the procedure at meetings of the Council and of any committee, other than the appeal committee appointed in terms of section 34, including the quorum in the case of a committee, and the manner in which meetings of a committee must be called;

(r) requiring the furnishing of returns, reports and information in respect of scheduled substances, and plants from which any such substance can be extracted or manufactured, and in respect of a medicine or other substance of which a scheduled substance is a component;

(s) as to the transshipment or the importation into, or exportation from, Namibia of a scheduled substance, and specifying the ports or places at which that substance may be imported into, or exported from, Namibia;

(t) authorizing and regulating the transmission through Namibia of scheduled substances;

(u) authorizing and regulating the possession by persons or groups of persons entering, or departing from, Namibia of specified quantities of scheduled substances for their own medicinal use;

(v) relating to the importation, conveyance, keeping, storage, processing and packing of medicines, and scheduled substances, and the manner in which medicines and scheduled substances must be kept and controlled in different categories of hospitals and health facilities;

(w) in consultation with the Minister responsible for the environment, relating to the disposal or destruction of a medicine or a scheduled substance, and the records which must be kept and the reports to be furnished in respect of that medicine or that scheduled substance;

(x) relating to the summary seizure and disposal of a scheduled substance found in possession, or under the control, of a person not entitled under this Act to keep or use it;

(y) 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 those samples;

(z) prescribing the methods to be employed, and the form of the certificates to be issued, in connection with the examination or analysis of samples of medicines or scheduled substances, or of any other thing, taken under this Act;

(aa) prescribing, in consultation with the Minister responsible for finance -

(i) the fee payable to the Registrar in respect of the application or registration, and in respect of the registration, of a medicine or a medical device;

(ii) the fee payable to the Registrar in respect of the retention of the registration of a medicine or a medical device;

(iii) the fee payable for an authorization granted in terms of section 27(1) for the sale of an unregistered medicine;

(iv) any other fee payable in terms of this Act; and

(v) the date on which a fee referred to in this paragraph is payable;

(bb) prescribing the registration, and the form and manner of the registration, of medical devices;

(cc) regulating or prohibiting the registration, manufacture, modification, importation, storage, transportation, sale, use or destruction of a medical device or category of medical devices;

(dd) declaring chemicals or equipment to be controlled chemicals or controlled equipment for the purpose of controlling the use of those chemicals or the equipment in the manufacture of Schedule 3, Schedule 4 and Schedule 5 substances;

(ee) regulating or prohibiting the manufacture, importation, transshipment or exportation of controlled chemicals or controlled equipment;

(ff) prescribing methods of identifying an importer of controlled chemicals or controlled equipment, the purpose for which those chemicals are, or the equipment is, used and the quantities of the chemicals or equipment, which the importer handles annually;

(gg) prescribing the minimum standards for good manufacturing practices to be followed in the manufacture of medicines;

(hh) prescribing the quantities of unregistered medicine, which may be compounded and sold in the pharmaceutical trade and the conditions under which that medicine may be sold;

(ii) prescribing the form and manner of, and the fee for, an application for the registration of premises and things used, and persons engaged, in the pharmaceutical business; and

(jj) relating to anything that may be registered under this Act.

(2) Not less than three months before a regulation is made under subsection (1), the Minister must cause the text of that 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 the Minister with any comments on it or with any representations they may wish to make in regard to that regulation.

(3) Subsection (2) does not apply in respect of -

(a) a regulation to which, after the provisions of that subsection have been complied with, the Minister has made changes in consequence of comments or representations received by him or her in pursuance of the notice issued under the said subsection (2); or

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

(4) Regulations may be made under this section in respect of -

(a) particular medicines or scheduled substances; or

(b) particular categories of medicines or scheduled substances; or

(c) medicines or scheduled substances other than particular categories of medicines or scheduled substances, and different provisions may be made in respect of different medicines or scheduled substances or different categories of medicines or scheduled substances.

(5) A regulation made under this section may prescribe penalties for a contravention of that regulation or failure to comply with it, not exceeding a fine of N$4 000 or imprisonment for a period not exceeding one year or both the fine and imprisonment.

Exemptions
45. (1) The Minister, after consultation with the Council, may exclude by notice in the *Gazette* a medicine from the operation of any or all the provisions of this Act, subject to such conditions as he or she may determine.

(2) The exclusion referred to in subsection (1) may be amended or withdrawn by notice in the *Gazette*.

(3) Substances controlled by international treaties may only be exempted to such extent as is provided for in those treaties.

Transitional provisions
46. (1) A person, who was in office as -

(a) a member of the Medicines Control Council established by the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), or a member of a committee of that Council;

(b) the chairperson or vice-chairperson of the Council referred to in paragraph (a); or

(c) the Registrar of Medicines appointed under the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), immediately before the date of commencement of this Act, continues in such office for the period for which the person was appointed to that office.

(2) The Schedules to the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), continue to apply, until the Minister publishes a notice in the *Gazette* in terms of section 29(1).

(3) A person, who immediately before the commencement of this Act –

(a) was practicing as a medical practitioner, a dentist, a veterinarian or a pharmacist; or

(b) was the holder of a permit issued under section 22A(12) of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and was acquiring, keeping, using, supplying, selling or prescribing, as the case may be, scheduled medicines, the acquisition, keeping, use, supply, sale or prescription of which must be licenced under this Act, may continue to acquire, keep, use, supply, sell, or prescribe, those medicines without a licence during the period of 3 months beginning with the date of commencement of this Act.

(4) A person referred to in subsection (3), who wishes to continue to acquire, keep, use, supply, sell, or prescribe, as the case may be, scheduled medicines referred to in that subsection after the period of 3 months beginning with the date of commencement of this Act, must apply, before the expiry of the said period of 3 months, for a licence contemplated in section 31, and may continue to acquire, keep, use, supply, sell, or prescribe, those medicines -

(a) until his or her application for a licence is -

(i) granted;

(ii) refused; or

(b) if the person has appealed against a refusal of his or her application, until the decision of the appeal committee is communicated to him or her in terms of section 34(8).

Repeals, amendments and savings

47. (1) Subject to subsection (2), the laws specified in the second column of the Schedule are repealed or amended to the extent set out in the third column of that Schedule.

(2) Notwithstanding subsection (1) any notice, authorization, order, approval or certificate issued, made or granted or any other thing done in terms of a provision of a law repealed by that subsection is, except in so far as may be otherwise required by this Act, deemed to have been issued, made, granted or done under the corresponding provision of this Act.

Short title and commencement

48. This Act is called the Medicines and Related Substances Control Act, 2003, and comes into operation on a date to be determined by the Minister by notice in the *Gazette*.

SCHEDULE

LAWS REPEALED OR AMENDED

(Section 47(1))

No. and year of law	Short title	Extent of repeal or amendment
Act No. 36 of 1947	Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947	(a) Amended by the substitution in the said Act, except in sections 1, 3(1), 7(2)(a), and 15(1)(a), (b) (c) and (d) for – (i) the words "stock remedy", wherever they occur, of the words "farm feed"; (ii) the words "fertilizers, farm feeds, agricultural remedies and stock remedies", wherever they occur, of the words "fertilizers, farm feeds and agricultural remedies"; (iii) the words "fertilizers, farm feeds, agricultural remedies or stock remedies", wherever they occur, of the words "fertilizers, farm feeds or agricultural remedies"; and (iv) the words "fertilizer, farm feed, agricultural remedy or stock remedy", wherever they occur, of the words "fertilizer, farm feed or agricultural remedy"; (b) Amended by the deletion – (i) in section (1), of the definition of "stock remedy"; (ii) in section 7(2)(a), of the words "or stock remedy"; (iii) of section 7(2)(b); (iv) in section 15(1) - (aa) in paragraph (a), of the words "stock remedy", where they occur a second time; (bb) in paragraph (b), of the words "stock remedy"; (cc) in paragraph (c), of the words "stock remedy", where they occur a third time; (dd) in paragraph (f), of the words "stock remedy, where they occur the first time; (v) in section 15(3)(b), of the words "stock remedy" and

No. and year of law	Short title	Extent of repeal or amendment
		(vi) in section 23 (1) - (aa) in paragraph (a), of the words "stock remedies"; and (bb) in paragraph (h), of the words "or stock remedies", where they occur the first time; (c) Amended by the substitution for section 26 of the following section: **"Short title** **26.** This Act is called the Fertilizers, Farm Feeds and Agricultural Remedies Act, 1947.".
Act No. 101 of 1965	Medicines and Related Substances Control Act, 1965	The repeal of the whole
Act No. 29 of 1968	Drugs Control Amendment Act, 1968	The repeal of the whole
Act No. 88 of 1970	Drugs Control Amendment Act, 1970	The repeal of the whole
Act No. 95 of 1971	Drugs Laws Amendment Act, 1971	The repeal of the whole
Act No. 65 of 1974	Drugs Control Amendment Act, 1974	The repeal of the whole
Act No. 19 of 1976	Medicines and Related Substances Control Amendment Act, 1976	The repeal of the whole
Act No. 36 of 1977	Health Laws Amendment Act, 1977	The repeal of the whole
Act No. 19 of 2000	Medicines and Related Substances Control Amendment Act, 2000	The repeal of the whole