



# GOVERNMENT GAZETTE

OF THE

# REPUBLIC OF NAMIBIA

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## CONTENTS

### GOVERNMENT NOTICE

*Page*

No. 233 Promulgation of Medicines and Related Substances Control Amendment Act, 2007  
(Act No. 8 of 2007), of the Parliament ..... 1

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## Government Notice

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### OFFICE OF THE PRIME MINISTER

No. 233

2007

### PROMULGATION OF ACT OF PARLIAMENT

The following Act which has been passed by the Parliament and signed by the President in terms of the Namibian Constitution is hereby published in terms of Article 56 of that Constitution.

No. 8 of 2007: Medicines and Related Substances Control Amendment Act, 2007.

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Act No. 8, 2007      **MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

**EXPLANATORY NOTE:**

- \_\_\_\_\_ Words underlined with a solid line indicate insertions in existing provisions.
- [            ] Words in bold type in square brackets indicate omissions from existing provisions.

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**ACT**

To amend the Medicines and Related Substances Control Act, 2003, so as to amend and delete certain definitions; to provide for a period within which the Council must be appointed; to provide for the appointment of chairpersons of committees established by the Council; to amend provisions relating to the classification of medicines and other substances as scheduled substances; to amend provisions relating to the manufacturing, packing and selling of specified Schedule 3 and specified Schedule 4 substances; to delete references to generic substitutions; to substitute references to Schedule 1, Schedule 2, Schedule 3 or Schedule 4 medicines by references to Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substances; to insert provisions relating to the registration of premises engaged in the manufacturing of medicines; to amend provisions relating to offences and penalties; to amend provisions relating to the destruction of forfeited medicines, scheduled substances or other things; to provide for the making of regulations in relation to medicines; to amend provisions relating to the exclusion of medicines from the operation of the Act; to amend the transitional provisions; to amend provisions relating to the repeal and amendment of certain laws; and to provide for matters incidental thereto.

*(Signed by the President on 21 December 2007)*

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

**Amendment of section 1 of Act No. 13 of 2003**

1. Section 1 of the Medicines and Related Substances Control Act, 2003 (hereinafter referred to as the principal Act) is amended -

(a) by the substitution for the definition of "animal" of the following definition:

"'animal' means all mammals with the exception of human beings, all birds including poultry, all bees, all amphibians, all reptiles, all fishes, all mollusc, all crustaceans and all bees [animal as defined in the Animal Diseases and Parasites Act, 1956 (Act No. 13 of 1956)];"

(b) by the substitution for the definition of "appeal committee" of the following definition:

"'appeal committee' means the appeal committee referred to in section 34(2)[(1)];"

(c) by the substitution for the definition of "authorised prescriber" of the following definition:

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

“‘authorised prescriber’ means a medical practitioner, a dentist, a veterinarian, [or] a person authorised to prescribe specified Schedule 1, Schedule 2 or Schedule 3 substances under section 31(1) or a pharmacist authorised to prescribe specified Schedule 2 or Schedule 3 substances under section 31(2) [a medicine under section 31(1) or (2)]”;

- (d) by the substitution for the definition of “committee” of the following definition:

“‘committee’ means a committee established by the Council [**Board**] under this Act;”;

- (e) by the substitution for the definition of “complementary medicine” of the following definition:

“‘complementary medicine’ means a substance or a mixture of substances prepared and used or purported to be suitable for use or manufactured or sold 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,

whether or not administered by or through a medical device;”;

- (f) by the deletion of the definition of “health facility”;

- (g) by the substitution for the definition of “manufacture” of the following definition:

“‘manufacture’ means to carry out operations, including the purchasing of material, processing, packaging, quality control, release and storage of medicinal products and related substances, and “manufacturing” has a corresponding meaning;”;

- (h) by the substitution for the definition of “medical practitioner” of the following definition:

“‘medical practitioner’ means a medical practitioner as defined in the Medical and Dental [**Professions**] Act, 2004 (Act No. 10 of 2004), [**1993 (Act No. 21 of 1993)**] or a medical intern as defined in that Act;”;

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

- (i) by the substitution for the definition of "medicine" of the following definition:

"'medicine' means -

- (a) a substance or a mixture of substances prepared and 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, mental [**psychic**] or organic function in humans or animals;

whether or not administered by or through a medical device;

(b) a veterinary medicine; or

(c) a complementary medicine;";

- (j) by the substitution for the definition of "patient" of the following definition:

"'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;";

- (k) by the substitution for the definition of "pharmaceutical technician" of the following definition:

"'pharmaceutical technician' means a pharmaceutical technician as defined in the Pharmacy [**Professions**] Act, 2004 (Act No. 9 of 2004) [**1993 (Act No. 23 of 1993)**];",

- (l) by the substitution for the definition of "pharmacist" of the following definition:

"'pharmacist' means a pharmacist as defined in the Pharmacy [**Professions**] Act, 2004 (Act No. 9 of 2004) [**1993 (Act No. 23 of 1993)**];";

- (m) by the substitution for the definition of "pharmacist's assistant" of the following definition:

"'pharmacist's assistant' means a pharmacist's assistant as defined in the Pharmacy [**Professions**] Act, 2004 (Act No. 9 of 2004) [**1993 (Act No. 23 of 1993)**];",

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

- (n) by the substitution for the definition of "pharmacist intern" of the following definition:

"'pharmacist intern' means a pharmacist intern as defined in the Pharmacy [Professions] Act, 2004 (Act No. 9 of 2004) [1993 (Act No. 23 of 1993)];";

- (o) by the substitution for the definition of "practitioner" of the following definition:

"'practitioner' means an allied or complementary health practitioner as defined in the Allied Health [Services] Professions Act, 2004 (Act No. 7 of 2004) [1993 (Act No. 20 of 1993)];";

- (p) by the substitution for the definition of "register" of the following definition:

"'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 to enter in a register referred to in paragraph (a);";

- (q) by the substitution for the definition of "registered nurse" of the following definition:

"'registered nurse' means a registered nurse as defined in the Nursing [Professions] Act, 2004 (Act No. 8 of 2004) [1993 (Act No. 30 of 1993)];";

- (1) by the substitution for the definition of "Registrar" of the following definition:

"'Registrar' means the Registrar of Medicines appointed in terms of section 16;";

- (m) by the substitution for the definition of "scheduled substance" of the following definition:

"'scheduled substance' means any medicine or substance classified as a Schedule 0, Schedule 1, Schedule 2, Schedule 3, Schedule 4 or Schedule 5 substance in terms of section 29(1);";

- (n) by the substitution for the definition of "veterinary medicine[s]" of the following definition:

"'veterinary medicine[s]' means a substance or mixture of substances, [**other than farm feeds as defined in the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947),**] including stock remedies as defined in the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), prepared and used or purporting to be suitable for use or manufactured or sold for use in connection with -

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

- (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,

whether or not administered by or through a medical device;".

**Amendment of section 3 of Act No. 13 of 2003**

2. Section 3 of the principal Act is amended by the substitution for the words preceding paragraph (a) of subsection (1) of the following words:

"The Council consists of the following members to be appointed by the Minister within six months after the date of commencement of this Act as follows:".

**Amendment of section 12 of Act No. 13 of 2003**

3. Section 12 of the principal Act is amended by the substitution for subsection (5) of the following subsection:

"(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, 37B(3), 37C, 37D(2), (3), (4) and (5), 37E, 42(a)(i), 44(1) or 45 with respect to a veterinary medicine, unless the veterinary medicines committee recommends so.".

**Substitution of section 13 of Act No. 13 of 2003**

4. The following section is substituted for section 13 of the principal Act:

**"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 -
  - (i) persons other than members of the Council, as it may consider fit to be members of a committee established in terms of paragraph (a);
  - (ii) the chairperson of such a committee."

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

**Amendment of section 29 of Act No. 13 of 2003**

5. Section 29 of the principal Act is amended -
- (a) by the substitution for subsection (1) of the following subsection:
- “(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 0, 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.”;

- (b) by the insertion of the following subsection after subsection (1):
- “(1A) Any Schedule 0 substance maybe sold in an open shop.”.
- (c) by the substitution for subsection (2) of the following subsection:
- “(2) Subject to this section, a person may not sell, have in his or her possession or manufacture a medicine or a scheduled substance, except in accordance with the prescribed conditions.”;
- (d) by the substitution for paragraph (a) of subsection (15) of the following paragraph:
- “(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;”; and
- (e) by the substitution for paragraph (a) of subsection (23) of the following paragraph:
- “(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;”.

**Amendment of section 30 of Act No. 13 of 2003**

6. Section 30 of the principal Act is amended by the substitution for the heading of the following heading:

**“Substitution of medicine on prescription with interchangeable multi-source medicine”.**

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

**Substitution of section 31 of Act No. 13 of 2003**

7. The following section is substituted for section 31 of the principal Act:

**“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), authorising 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 substances, [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 substances [medicines].

(2) The Council may issue a licence on application in the prescribed form by a pharmacist, authorising 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 substances, [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 substances [medicines].

(3) The Council may issue a licence on application in the prescribed form by a medical practitioner, a dentist or a veterinarian, authorising that medical practitioner, dentist or veterinarian to sell Schedule 1, Schedule 2, Schedule 3 or Schedule 4 substances [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 substances [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, authorising that person to manufacture, [or] pack and sell a medicine or a scheduled substance subject to conditions specified in the permit.



**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

- (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, authorising 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, authorising 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."

**Amendment of section 33 of Act No. 13 of 2003**

8. Section 33 of the principal Act is amended by the substitution for subsection (1) of the following subsection:

"(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] -

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

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

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

**Insertions of sections 37A, 37B, 37C, 37D, 37E and 37F in Act No. 13 of 2003**

9. The following sections are inserted in the principal Act after section 37:

**“Premises to be registered**

**37A.** (1) No person may manufacture any medicine on any premises unless -

- (a) the premises are registered in terms of this Act in respect of the manufacturing concerned; and
- (b) the premises are under the continuous personal supervision of a pharmacist or a person contemplated in section 31(4).

(2) Subsection (1) prevails over any other provision to the contrary contained in any other law, and nothing in any other law is deemed to authorise any person to act in contravention of subsection (1).

**Application for registration of premises**

**37B.** (1) A person who wishes to have a premises registered as contemplated in section 37A(1), must submit an application to the Registrar in the prescribed form.

(2) An application referred to in subsection (1) must be accompanied by -

- (a) the prescribed particulars, if any; and
- (b) the prescribed application fee.

(3) The Registrar must submit, as soon as is practicable after he or she has received the application referred to in subsection (1), the application and the prescribed particulars, if any, to the Council for consideration, and must inform the applicant in writing that the application has been so submitted.

**Consideration of application and registration of premises**

**37C.** (1) On receipt of an application referred to in section 37B(1), the Council -

- (a) may, if satisfied that the application meets the requirements of this Act and subject to subsection (2), approve the application; or
- (b) may -
- (i) conduct such investigation or inquiry as it considers necessary, including any presentation by the applicant; and
- (ii) require further particulars from the applicant.

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

(2) In considering an application referred to in section 37B(1), the Council must have regard to -

- (a) whether or not the registration is reasonably required in the public interest;
- (b) the suitability of the premises for the purposes for which the registration is required;
- (c) the safe custody of the medicines to be stored on the premises;
- (d) whether or not the applicant is the holder of a licence or permit contemplated in section 31(4) or 31(5).

(3) If the Council approves an application referred to in section 37B(1) -

- (a) the Council may determine such conditions as it considers necessary or desirable having regard to the purpose for which the premises are to be registered and the need for the safe custody of medicines to be stored on the premises; and
- (b) the Registrar must then -
  - (i) enter in the relevant register the prescribed particulars and any conditions determined by the Council, and
  - (ii) issue to the applicant a licence in the prescribed form.

(4) Subject to the provisions of subsection (5), if the Council refuses to approve an application referred to in section 37B(1), the Registrar must inform the applicant in writing of such refusal and the reasons for the refusal.

(5) If the Council intends -

- (a) to refuse to approve an application referred to in section 37B(1); or
- (b) to approve such application subject to conditions determined by the Council,

the Registrar must inform the applicant in writing of such intention and the reasons thereof and that the applicant may make, if he or she so wishes, within such period, being not more than 14 days, as the Council may specify, written representations in relation to the intention concerned.

**Validity and renewal of licences**

**37D.** (1) A licence issued in terms of section 37B(3)(b)(ii) is valid, unless cancelled or suspended, for a period of 24 months and may be renewed before its expiry.

(2) An application for the renewal of a licence must be made to the Registrar, and must be -

- (a) in the prescribed form;

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

- (b) made in such manner and within such period, as may be prescribed; and
  - (c) accompanied by the prescribed application fee.
- (3) On receipt of an application for the renewal of a licence the Council may, if it is -
- (a) satisfied that the application meets the requirements of subsection (2), approve the renewal of the licence; or
  - (b) of the opinion that -
    - (i) the conditions subject to which the licence was issued have not been observed; or
    - (ii) it would not be in the public interest for the licence to be renewed,the Council must give notice thereof in writing to the applicant concerned.
- (4) A notice referred to in subsection (3)(b) must -
- (a) specify the grounds on which the opinion of the Council is based; and
  - (b) indicate that the applicant may within one month after the receipt thereof, submit to the Council any comments he or she may wish to submit in connection with the matter.
- (5) If -
- (a) no comments have been submitted to the Council as contemplated in subsection (4); or
  - (b) after the consideration of any comments submitted, the Council is of the opinion for any reason specified as contemplated in subsection (4)(a) that the licence concerned should not be renewed, the Council must refuse the renewal of the licence and must inform the Registrar accordingly.
- (6) On receiving the information referred to in subsection (5) the Registrar must make the appropriate entries in the register referred to in section 37F.
- (7) If the renewal of a licence has been refused as contemplated in subsection (5) the Council may approve, at the request of the applicant concerned, and subject to the payment of the prescribed application fee, a temporary renewal of the licence, for such period and subject to such conditions as the Council may specify, to enable the applicant to lodge an appeal against the decision of the Council, and such temporary renewal is valid until the appeal has been determined or abandoned.
- (8) The holder of a licence who voluntarily abandons, before the expiration of the licence, the registered premises to which a licence relates, must return the licence to the Registrar.

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

**Cancellation, suspension, alteration and variation of licences**

- 37E.** (1) If the Council is of the opinion that -
- (a) the conditions subject to which a licence has been issued, have not been observed;
  - (b) the person to whom a licence has been issued is wrongfully dealing in or supplying or possessing medicines, or has been convicted of an offence involving dishonesty; or
  - (c) it is in the public interest that -
    - (i) a licence be cancelled;
    - (ii) a licence be suspended;
    - (iii) the purpose for which a licence was issued, be altered; or
    - (iv) the conditions subject to which a licence was issued, be varied,

the Council must give notice in writing to the holder of the licence concerned.

- (2) A notice given in terms of subsection (1) must -
- (a) specify the grounds on which the opinion of the Council is based; and
  - (b) indicate that the person to whom it is directed may within one month after the receipt of the notice, submit to the Council any comments he or she may wish to submit in connection with the matter.
- (3) If -
- (a) no comments have been submitted to the Council as contemplated in subsection (2); or
  - (b) after the consideration of any comments submitted, the Council is of the opinion for any reason specified as contemplated in subsection (2)(a) that the licence concerned be cancelled, suspended, the purpose for which the licence was issued, be altered or the conditions subject to which the licence was issued, be varied, the Council may -
    - (i) cancel the licence, and impose a period of disqualification, not exceeding three years, during which the person concerned may not be issued with a licence;
    - (ii) suspend the licence;
    - (iii) alter the purposes for which the licence was issued; or
    - (iv) vary the conditions subject to which the licence was issued.

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

(4) Subject to subsection (5), a decision of the Council contemplated in subsection (3) has immediate effect notwithstanding the lodging of any appeal against the decision of the Council.

(5) If a licence has been cancelled or suspended the Council may, subject to such conditions as it may determine, authorise the holder of the licence concerned to continue to operate under the original licence until the appeal is determined or has been abandoned.

**Effect of non-renewal or cancellation of licence**

**37F.** If a licence has not been renewed as contemplated in section 37D(5) or has been cancelled as contemplated in section 37E(3), the registration of the premises lapses."

**Amendment of section 38 of Act No. 13 of 2003**

10. Section 38 of the principal Act is amended by the insertion after paragraph (m) of the following paragraph:

"(mA) contravenes section 37A(1)".

**Amendment of section 39 of Act No. 13 of 2003**

11. Section 39 of the principal Act is amended -

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

"(2) The court convicting a person of an offence under this Act may -

(a) declare a medicine or a scheduled substance, or other thing, to which the offence relates, to be forfeited to the State;

(b) in the case of a second or subsequent conviction in respect of a person who is the holder of a licence or permit issued in terms of this Act, order that such person be disqualified indefinitely from holding a licence or permit concerned."; and

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

"(3) A medicine or a scheduled substance, or any other thing, forfeited in terms of subsection (2) must be destroyed or dealt with -

(a) in the prescribed manner; or

(b) if no regulations have been made which prescribe the manner of destruction thereof, in such manner as the Permanent Secretary may direct."

**Amendment of section 44 of Act No. 13 of 2003**

12. Section 44 of the principal Act is amended by the substitution for paragraphs (s) to (y) of subsection (1) of the following paragraphs:

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

- (s) as to the transshipment or the importation into, or exportation from, Namibia of a scheduled substance or a medicine, and specifying the ports or places at which that substance or medicine may be imported into, or exported from, Namibia;
- (t) authorising and regulating the transmission through Namibia of scheduled substances or medicines;
- (u) authorising and regulating the possession by persons or groups of persons entering, or departing from, Namibia of specified quantities of scheduled substances or medicines 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 or medicine 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 must [**may**] be taken under this Act and the form of the certificates to be issued by inspectors in respect of those samples;".

**Substitution of section 45 of Act No. 13 of 2003**

13. The following section is substituted for section 45 of the principal Act:

**"Exclusions**

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 excluded [**exempted**] to such extent as is provided for in those treaties."

**Amendment of section 46 of Act No. 13 of 2003**

14. (1) Section 46 of the principal Act is amended -

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

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**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

- “(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 until the day immediately preceding the day on which the Minister appoints the members of the Council as contemplated in section 3(1) [for the period for which the person was appointed to that office].”;

- (b) by the insertion of the following subsections after subsection (1):

“(1A) Subject to this Act -

- (a) the Medicines Control Council established by the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), must perform the functions of the Council until a day immediately preceding the day on which the Minister appoints the members of the Council as contemplated in section 3(1);
- (b) any committee of the Council referred to in paragraph (a) must perform the functions of the corresponding committee, if any, until a day immediately preceding the day on which -
  - (i) in the case of a committee contemplated in sections 11 and 12 of the Act, the Minister appoints the members of the Council as contemplated in section 3(1);
  - (ii) in the case of a committee established by the Council, the corresponding committee is established by the Council.

(1B) Subsections (1) and (1A) are not so construed as to prohibit the Council from establishing the veterinary medicines committee immediately after the commencement of this Act.”; and

- (c) by the insertion of the following subsection after subsection (2):

(2A) For purposes of the application of subsection (2) -

- (a) any reference to Schedule 1 or 2 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), is construed as a reference to Schedule 1 of this Act;
- (b) any reference to Schedule 3 or 4 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), is construed as a reference to Schedule 2 of this Act;



**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

- (c) any reference to Schedule 5 or 6 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), is construed as a reference to Schedule 3 of this Act;
- (d) any reference to Schedule 7 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), is construed as a reference to Schedule 4 of this Act; and
- (e) any reference to Schedule 8 or 9 of the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965), is construed as a reference to Schedule 5 of this Act.”.

**Substitution of section 47 of Act No. 13 of 2003**

15. The following section is substituted for section 47 of the principal Act:

**“Repeals, amendments and savings**

**47. (1) Subject to subsection (2) -**

- (a) the -
  - (i) Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965);
  - (ii) Drugs Control Amendment Act, 1968 (Act No. 29 of 1968);
  - (iii) Drugs Control Amendment Act, 1970 (Act No. 88 of 1970);
  - (iv) Drugs Laws Amendment Act, 1971 (Act No. 95 of 1971);
  - (v) Drugs Control Amendment Act, 1974 (Act No. 65 of 1974);
  - (vi) Medicines and Related Substances Control Amendment Act, 1976 (Act No. 19 of 1967);
  - (vii) Health Laws Amendment Act, 1977 (Act No. 36 of 1977);
  - (viii) Medicines and Related Substances Control Amendment Act, 2000 (Act No. 19 of 2000),are repealed;
- (b) all amendments to the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), contained in the Schedule are repealed.

**Act No. 8, 2007      MEDICINES AND RELATED SUBSTANCES  
CONTROL AMENDMENT ACT, 2007**

(2) Notwithstanding subsection (1) any notice, regulation, authorisation, order, approval or certificate issued, made or granted or any other thing done in terms of a provision of a law repealed or amended 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**

**17.** This Act is called the Medicines and Related Substances Control Amendment Act, 2007, and comes into operation on a day to be determined by the Minister by notice in the *Gazette*.

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