Medicines and Related Substances Control Act Act 13 of 2003

- Came into effect on 1st August, 2008

- Medicines and Related Substances Control Amendment Act, Act 8 of 2007
- Regulations
- Classification of Medicines and other Substances as Scheduled Substances

Medicines and Related Substances Control Act

Sections

1. Definitions
2. Continuation of Council, powers and functions
3. Constitution of Council
4. Disqualification for appointment as member of Council
5. Tenure of office of members
6. Vacation of office and filling of vacancies
7. Chairperson and vice – chairperson
8. Meetings of Council
9. Disclosure of interest
10. Remuneration
11. Executive committee
12. Veterinary medicines committee

24 Labels and advertisements

25 Prohibition on sale of medicines which do not comply with prescribed requirements

26 Publication or distribution of false advertisements concerning medicines

27 Council may authorize sale of unregistered medicines for certain purposes

28 Council to cause certain information to be furnished

29 Control of medicines and scheduled substances

30 Generic substitution

31 Licenses and permits

32 Publication of information relating to medicines, scheduled substances

- **Section 1 Definitions**

Animal: means all mammals except humans, all birds including poultry, all bees, all amphibians, all reptiles, all fish, all mollusc and all crustaceans

Immediate container: means a container which is in direct contact with the medicine or scheduled substance, but is not a package liner.

Medicine: means substance or mixture of substances for use in the diagnosis, treatment, mitigation, modification or prevention of a disease, abnormal physical or mental state or the symptoms in humans or animals;

Medicines and Related Substances Control Act

- ***Medicine***

  restoring, correcting or modifying any somatic, psychic or organic function in humans or animals

  b) a veterinary medicine

  c) a complementary medicine

- ***Minister:*** **means Minister responsible for health**

- ***Original immediate container:*** **means immediate container in which the medicine was originally distributed by the manufacturer**

Medicines and Related Substances Control Act

- ***Package:*** **contains the immediate container.**

- ***Patient:*** **a person (if treated by a medical practitioner, dentist , practitioner or registered nurse)**

  an animal (if treated by a veterinarian or para-veterinary professional)

  a person (if treated by a pharmacist)

- ***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**

Medicines and Related Substances Control Act

- ***Scheduled substance:*** **means any medicine or substance classified as a Schedule 0, 1, 2, 3, 4 or 5 substance.**

- ***Sell:*** **means retail, wholesale, import, offer, advertise keep, expose, transmit, consign, convey, deliver for sale,**
  - **authorize, direct or allow a sale,**
  - **prepare or possess for purposes of sale,**
  - **barter, or exchange or supply or dispose of to a person.**

- ***Veterinarian:*** **means a person registered in terms of Proclamation AG 14 of 1984**

Medicines and Related Substances Control Act

- ***Veterinary medicine:*** **means substance or mixture of substances, including stock remedies as defined in Act 36 of 1947, used for:**

1. **Diagnosis, treatment, prevention or cure of a disease, an infection or other unhealthy condition in animals**

2. **Maintenance or improvement of health, growth, production or working capacity in animals**

3. **Restoring, correcting or modifying a somatic or organic function or for correcting or modifying behaviour, in animals whether or not administered through a medical device**

- **Section 2 Continuation of Council and its powers and functions**
- **The old Medicines Control Council continues to exist as *Namibia Medicines Regulatory Council; NMRC***

- **Section 3 Constitution of Council**

3 Medical practitioners **- 1 medical specialist, 1 private medical practitioner, 1 employed by ministry responsible for health**

3 Pharmacists **- 1 in private practice, 1 employed by ministry responsible for health and any other pharmacists**

2 Veterinarians **appointed by the minister resp. for agriculture - 1 private, 1 state vet.**

Medicines and Related Substances Control Act

- ***One legal practitioner*** **appointed by minister responsible for justice**
- ***One registered nurse***
- ***One practitioner***
- ***One other person***

- **Names and dates of appointment published in the *Gazette***

- **Section 4 Disqualification for appointment as member of Council**

- **Section 5 Tenure of office of members**
- 3 years; eligible for re-appointment

- **Section 6 Vacation of office and filling of vacancies**

- **Section 7 Chairperson and vice-chairperson**
- Elected by members of Council
- May not hold their office for more than 2 consecutive three year terms.

- **Section 8 Meetings of Council**

- **Section 9 Disclosure of Interest**
- Every council or committee member must fully disclose commercial interest related to pharmaceutical or health care industry. Spouse included.
- May cause conflict of interest.
- Non –disclosure: heavy fines; council decisions invalid.

- **Section 10 Remuneration**

- **Section 11 Executive Committee**

- **Section 12 Veterinary Medicines Committee**

- Council must establish a veterinary medicines committee consisting of:
- One veterinarian from Council (chairperson)
- Two state veterinarians
- One veterinarian designated by the Veterinary Association of Namibia
- One pharmacists who is a member of Council

- The veterinary medicines committee may appoint one or two other persons to be additional members, subject to approval by Council.

Medicines and Related Substances Control Act

- ***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)**

- **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), 45**

- ***With respect to a veterinary medicine, unless the veterinary medicines committee recommends so.***

- **Section 13 Other Committees**
- **Section 14 Restriction of Liability**
- **Section 15 Financial Year and Annual Report**
- **Section 16 Appointment of Registrar of Medicines**
- **Secretary of Council, must attend Council meetings, has no vote.**

- **Section 17 Registers**

- **The Registrar must keep:**

1. **Medicines Register**
2. **Veterinary Medicines Register**
3. **Complementary Medicines Register**
4. **Other Registers as may be prescribed under this Act**

in which the particulars of every registered medicine is entered.

Medicines and Related Substances Control Act

ANNEXURE IV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
VETERINARY MEDICINES REGISTER
(section 17(1)(b) of the Act)
(regulation 7(b))

Name of medicine	Registration number	Approved name of each active ingredient	Dosage form	Applicant/ certificate holder	Date of registration	Conditions of registration

- **Section 18 Prohibition of Sale of unregistered Medicines**

- A person may not sell any medicine, unless it is registered
- Six months time to apply for registration for medicines previously sold in Namibia.
- Not applicable to own compounded medicine for specific patients, as long as none of the components are prohibited. (medicine may not be advertised)

Medicines and Related Substances Control Act

- **Section 19 Registration of Medicines**

- Applications → Registrar → Council

- Veterinary Medicines Applications → Council as well as Veterinary Medicines Committee.

- If Council is satisfied that the medicine is suitable for the purpose for which it is intended and complies with the prescribed requirements and is in the public interest,

- Then: ***Council must approve the registration of that medicine***

Medicines and Related Substances Control Act

- Certificate of Registration
- Registration number
- Recorded in the relevant register

Medicines and Related Substances Control Act

ANNEXURE VII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
CERTIFICATE OF REGISTRATION
(section 19(7) of the Act)
(regulation 9)

It is hereby certified that the Namibia Medicines Regulatory Council has approved in terms of section 19(4) of the Medicines and Related Substances Control Act, 2003 (Act No 13 of 2003), the registration of the medicine described below subject to the conditions set out below.

Registered name (proprietary name) of medicine: .....
Registration number: .....
Date of registration: .....
Approved name of every active ingredient and quantities thereof per dosage unit or per suitable mass or volume unit of medicine: .....
.....
.....
Dosage form: .....
Registered in the name of (name and business address of applicant): .....
.....
.....
.....
Name and address of manufacturer and the manufacturing facility: .....
.....
.....
.....

Name of the final product release controller: .....
.....
Name of the final product release responsibility: .....

Conditions of registration (Attached):

Issued at ..... on .....

Registrar of Medicines Stamp

Medicines and Related Substances Control Act

- **Section 20 Amendment of Entries in Register**
- **Section 21 Transfer of Certificate of Registration**
- **Section 22 Cancellation of Registration**
- **Section 23 Notification of Registration or Cancellation of registration in the *Gazette***
- **Section 24 Labels and Advertisements**

Medicines and Related Substances Control Act

- **Section 25 Prohibition of sale of medicines which do not comply with the prescribed requirements, and furnishing of information regarding medicines to the Council**
- **Section 26 Publication or distribution of false advertisements concerning medicines**
- **Section 27 Council may authorise sale of unregistered medicine for certain purposes**
- **Section 28 Council to cause certain information to be furnished**

- **Section 29 Control of medicines and scheduled substances**

- **The Minister, on recommendation of Council, must classify medicines and other substances by notice in the *Gazette* as Schedule 0, 1, 2, 3, 4 and 5 substances.**

- **Council must recommend only those medicines and substances, which it considers necessary to be classified.**

- **A person may not sell a medicine or a scheduled substance , except in accordance with prescribed conditions**

Medicines and Related Substances Control Act

- **Control of medicines and scheduled substances**
- **Importers, wholesalers and manufacturers need permits and licences.**
- **Schedule 1 substances may only be sold by pharmacists and their staff, medical practitioners, dentists and veterinarians. Every sale must be recorded in a prescription book or other permanent record.**
- **Schedule 2 , 3 and 4 substances may only be sold by pharmacists and their staff *on prescription,* medical practitioner, dentist and veterinarian. Differences in how oral and other prescriptions are handled by the pharmacist**
- **Records must be kept of every sale.**

Medicines and Related Substances Control Act

- **Control of medicines and scheduled substances**

- **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 may not exceed 30 days.**

- **The seller must retain the prescriptions for Schedule 4 substances at least 3 years.**

- **The seller must keep a register of Schedule 4 substances and must balance the register at least quarterly.**

Medicines and Related Substances Control Act

- **Control of medicines and scheduled substances**

- **A pharmacist may sell up to 25% more or less of a medicine than is specified on a prescription or order according to the immediate container of that substance as supplied to the pharmacist.**

- **A person in possession of a Schedule 3 or 4 substance or a prescription for them may not knowingly obtain another prescription from another prescriber, unless he informs him about it.**

- **A person who may sell medicines and scheduled substances may only supply them to another person who is also authorized to sell them.**
  (Wholesaler/importer/manufacturer to retailer)

Medicines and Related Substances Control Act

- **Control of medicines and scheduled substances**
- **Schedule 5 substances**
- **A permit (with certain conditions) issued by Council is required to manufacture, acquire, possess or supply a specific Schedule 5 substance.**
- **A permit is also required to cultivate, collect, acquire, possess or supply a plant or portion of plant from which a Schedule 5 substance can be extracted.**
- **The Permanent Secretary may import a Schedule 5 substance or plant or portion of a plant for the purpose of supplying it to a medical practitioner, veterinarian or scientist, for the treatment of a particular patient or for scientific purposes.**

Medicines and Related Substances Control Act

- **Control of medicines and scheduled substances**

- **A para-veterinary professional employed by a veterinarian may sell a *Schedule 1 and Schedule 2* substance for the treatment of an animal on a written prescription or on an oral instruction issued by that veterinarian**

Medicines and Related Substances Control Act

- **Section 30 Generic Substitution**

- **Section 31 Licences and Permits**
- **Licence required by a person lawfully performing a health service to acquire, possess and prescribe, use in respect of or sell to patients Schedule 1 , 2, or 3 substances.**

- **Licence required by pharmacist for Schedule 2 or 3 substances.**

- **Licence required by medical practitioner, dentist and veterinarian for the sale of Schedule 1, 2, 3 or 4 substances.**
- **Licence fee**

Medicines and Related Substances Control Act

- **Section 34 Appeal against decisions of Council**

- **Section 35 Inspectors**

- **Section 36 Powers of Inspectors**
- At all reasonable times
- In connection with any medicine, scheduled substance or other thing which is subject to this Act:

1. Enter any premises, place, vehicle, vessel or aircraft
2. Inspect any medicine or scheduled substance, book, record or document
3. Seize any medicine, scheduled substance, book, record or document as evidence.

Medicines and Related Substances Control Act

4. Take samples of medicines or scheduled substances
5. Submit samples for analysis

An Inspector may not search a ***person or home*** of an individual without a warrant issued by a judge.

The search of a person or home may not be excessively intrusive and must comply with the provisions of the Criminal Procedures Act.

Medicines and Related Substances Control Act

- **Section 37 Analyst**
- **Section 38 Offences**
- **Section 39 Penalties**
- **Maximum fine: N$ 40 000.00 or 10 years imprisonment**
- **Section 40 Presumptions and evidence**
- **Section 41 Special defences in case of prosecutions**

Medicines and Related Substances Control Act

- **Section 42 Preservation of secrecy and inappropriate use of information**
- **Section 43 Delegation of powers, and assignments of duties and functions**
- **Minister → Permanent Secretary → Ministry officials**
- **Section 44 Regulations**
- **Section 45 Exemptions**

- Section 46 Transitional provisions
- Section 47 Repeals, amendments and savings
- Section 48 Short title and commencement

- **Regulations**
- **Arrangements of Regulations**
- **Annexure I - Annexure XXXVIII**

Medicines and Related Substances Control Act: Regulations

- **Regulation 2 Division of medicines into categories for the purpose of registration**

- **Category A:**

  Human medicines, ready for administration without further manipulation

- **Category B:**

  Human medicines which cannot be administered without further manipulation

- **Category C:**

  Veterinary medicines ready for administration without further manipulation

Medicines and Related Substances Control Act: Regulations

- **Regulation 3 Persons who may apply for registration of medicine**
- **Regulation 11 Labeling of human medicines**
- **Regulation 12 Package inserts for human medicines**
- **Regulation 13 Patient information leaflet**

- **Regulation 14 Labeling of veterinary medicines**

- The immediate container must have a label:
- “veterinary medicine”
- Proprietary (trade) name
- Registration number
- Dosage form
- Name of active ingredient and quantity thereof in dosage unit
- Name and percentage of bacteriostatic or bacteriocidal preservative
- Content of the package in appropriate unit or volume
- Indications for use (if practicable)

Medicines and Related Substances Control Act: Regulations

- **Labeling of veterinary medicines**

- Recommended dosage (if practicable)
- Instruction “shake the bottle before use” (if applicable)
- If injectable, route of administration
- In case of scheduled substance: NS followed by the number
- Batch number
- Expiry date
- Name of holder of certificate of registration
- Storage (temperature) requirements
- “For external use only” (where applicable)
- “Keep out of reach of children”

Medicines and Related Substances Control Act: regulations

- **Labeling of veterinary medicine**

- **In case of medicine for food producing animals warning regarding the possibility of ingredients of the medicine being present in eggs, milk of tissue and the withdrawal period**

- **Any other specified warning**

- **Any other information which the applicant wants to put on, if it is authorized by Council**

- **Also applicable to outer label of package (but then the label on the immediate container needs less information)**

Medicines and Related Substances Control Act: regulations

- This does not apply to any medicine sold for the treatment of a specific animal by a veterinarian or pharmacist on prescription.
- In this case the package must have a label with the following:

1. Name of the medicine or active ingredient
2. Name of the person to whom the medicine has been sold and a description of the animal to be treated.
3. Directions for use
4. Reference number
5. Warning regarding withdrawal period
6. Date of dispensing
7. Batch number
8. Expiry date

- **Regulation 15 Package inserts for veterinary medicines**

- Scheduling status
- Proprietary name
- Dosage form
- Name of active ingredient and quantity per dosage unit
- Category of pharmacological classification
- Pharmacological action
- Pharmacokinetic and pharmacodynamic properties
- Withdrawal period
- Side effects and special precautions

Medicines and Related Substances Control Act: Regulations

- **Package insert**

- Known signs of overdose and particulars of treatment
- Quantity and strength of active ingredient per dosage unit
- Storage directions (temp); stability after opening of the original package.
- Registration number
- Name and business address of manufacturer as well as of holder of certificate of registration
- Any other information which Council may determine from time to time

- **Regulation 18 Advertising of medicines**

- Medicines which do not contain scheduled substances or Schedule 0 or Schedule 1 substance may be advertised to the public.

- Medicines containing Schedule 2, 3 or 4 substances may only be advertised to medical practitioners, dentists, veterinarians, pharmacists or nurses

- Or in publications which are normally only made available to members of the above professions

Medicines and Related Substances Control Act: regulations

- **Advertising**
- **If a medicine is verbally advertised for the first time to a member of the above professions, written information must be provided at the same time.**
- **An advertisement of a medicine for the public must be approved by Council**
- **Regulation 17 Informing Council of adverse reactions**
- **Registration certificate holder must inform Council**

Medicines and Related Substances Control Act: regulations

ANNEXURE IX

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
REPORT OF ADVERSE DRUG REACTION
(regulation 17(5))

TO:
The Registrar of Medicines
Namibia Medicines Regulatory Council
Ministry of Health and Social Services
Private Bag 13198
WINDHOEK

Full names and surname or record number of patient: ……*
Age: …… Gender: …… Weight: ……

ADVERSE REACTION DESCRIPTION Date: ……
……
……
……
……
……

DRUG THERAPY Indicate suspected drug(s): Trade Name and Batch No.	Daily dosage and route	Date therapy started	Date therapy stopped	Reasons for use

Treatment of reaction

OUTCOME	Recovered	Not yet recovered	Unknown	Fatal

(This matter will be followed up and you will be informed of the outcome)
Comments: (e.g. relevant history, allergies, previous exposure)
……
……
……
……

- **Regulation 23 Requirements for prescriptions**

1. Date of issue of the prescription
2. Name, strength and quantity of the medicine in figures ***as well as words***
3. Name and address of person to whom the medicine is being sold
4. Animal species
5. Instructions for administration in dosage and frequency
6. Withdrawal period
7. Name, qualification and address of the prescriber (may be printed on the prescription)
8. If the script can be repeated, the number of times it may be repeated

Medicines and Related Substances Control Act: Regulations

- **Prescriptions**

- **Prescriber must keep a record of the diagnosis relevant to the prescription and must indicate the diagnosis on the prescription.**

- **Prescriber may only write an initial prescription after seeing and physically examining the patient in person.**

Medicines and Related Substances Control Act: Regulations

- **Prescriptions**

- **A pharmacists dispensing a faxed, e-mailed, telephonic or other electronic transmission of a prescription, must:**

- **Verify the authenticity of the prescription**

- **Make a permanent copy of the prescription and retain it for record**

- **Obtain the original prescription within 7 working days.**

- **Regulation 25 Permanent records for Schedule 1, 2 and 3 substances.**
- **On each premises where S 1, 2 or 3 substances are kept and sold:**

- **Book or other permanent record; to be kept for at least 3 years after the date of last entry. Must contain:**

1. **Date of sale**
2. **Name of scheduled substance**
3. **Dosage form, strength and quantity**
4. **Name and residential address of person to whom the substance was sold**
5. **Name of seller**

Medicines and Related Substances Control Act: Regulations

- **Regulation 26 Records to be kept by manufacturer, wholesaler, importer or exporter in respect of Schedule 4 and specified Schedule 3 substances**
- **Regulation 28 Import permits for Schedule 4 and specified Schedule 3 Substances**
- **Regulation 29 Export permits for the Schedule 4 and specified Schedule 3 substances**
- **Regulation 30 Manufacturing permit for Schedule 4 and specified Schedule 3 substances**

Medicines and Related Substances Control Act: Regulations

ANNEXURE XIV

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
IMPORT/EXPORT PERMIT* FOR A SCHEDULE 4 OR A SPECIFIED SCHEDULE 3 SUBSTANCE
(section 29(15)(b) and 23(b) of the Act)
(regulations 28(1) and 29(2))

I, (full names and surname ..... the Permanent Secretary: Ministry of Health and Social Services, hereby authorise .....
..... (name of applicant and, if the application is made on behalf of a body corporate, the name of the body corporate) being a registered .....
....practising/conducting *business at .....
.....(physical address) to import/export* the following Schedule 4/specified Schedule 3* substance/preparation,* subject to the conditions, if any, set out herein:

(a) the name of the substance/preparation:* .....
(b) the quantity of the substance/preparation* (calculated as a base) .....
.....
(c) the dosage form of the substance/preparation:* .....

Conditions, if any: .....
.....
.....
The consignment will be imported/exported* through ....
.....(border post, airport or harbour).

Issued at ..... on .....

Period of validity of permit: .....

.....
Signature of Permanent Secretary: Ministry of Health and Social Services

*Delete whichever is not applicable.

- **Regulation 31 Permit for cultivation of plants for the production of Schedule 4 and specified Schedule 3 substances**

- **Regulation 27 Registers and prescription books or other permanent records in respect of Schedule 4 substances**

1. Name and business address of the supplier
2. Date of receipt
3. Quantity received
4. Name and address of the person to whom sold
5. Date of sale
6. Quantity sold
7. Physical quantity remaining in stock
8. Signature of the person making the entry in the register

Medicines and Related Substances Control Act: Regulations

ANNEXURE XII

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
SCHEDULE 4 SUBSTANCES REGISTER AND PRESCRIPTION BOOK
(section 29(20) of the Act)
(regulation 27(1))

SUBSTANCE …..…… FORM ……. DOSE, MASS OR VOLUME UNIT ……..……...

Date received or issued	Supplier's name and address	Supplier's Invoice No or Import permit No	Purchaser's name and address	Ref. No	Prescriber's Name and address	Units received	Units issued	Balance	Signature

Medicines and Related Substances Control Act: Regulations

- **Schedule 4 Register**
- **Register must be retained at the business address for at least 3 years after the date of last entry**
- **If such a record is kept in electronic form, it must be held in the form of a computer print-out**
- **Print-out must be made monthly and dated, signed and filed.**
- **Records must be stored separately and in an orderly manner so that they can be accessed easily**
- **The entry must be made on the date and time of the transaction**

- **Regulation 33 Destruction and disposal of medicines and scheduled substances**

- **Schedule 4 and 5 and specified Schedule 3 substances may only be destroyed in the presence of an inspector or a member of NAMPOL. Certificate must be issued (Annexure XX)**

Medicines and Related Substances Control Act: Regulations

ANNEXURE XX

NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES
CERTIFICATE OF DESTRUCTION AND DISPOSAL OF SCHEDULED SUBSTANCES AND MEDICINES
(regulation 33(1))

1. Details of premises where the scheduled substances or medicines were found:

Name: .....

Postal address: .....

Physical address: .....

Name of person in charge: .....

2. Items destroyed:

Name of scheduled substance or medicine	Quantity	Reason for destruction

3. Method of destruction and disposal: .....
.....
.....
.....

4. Name of inspector / Authorised person: .....

.....
Signature of Inspector/Authorised person

.....
Date

.....
Signature of person in charge of premises

.....
Date

- I hope I have not confused you too much!!!
- Thank you