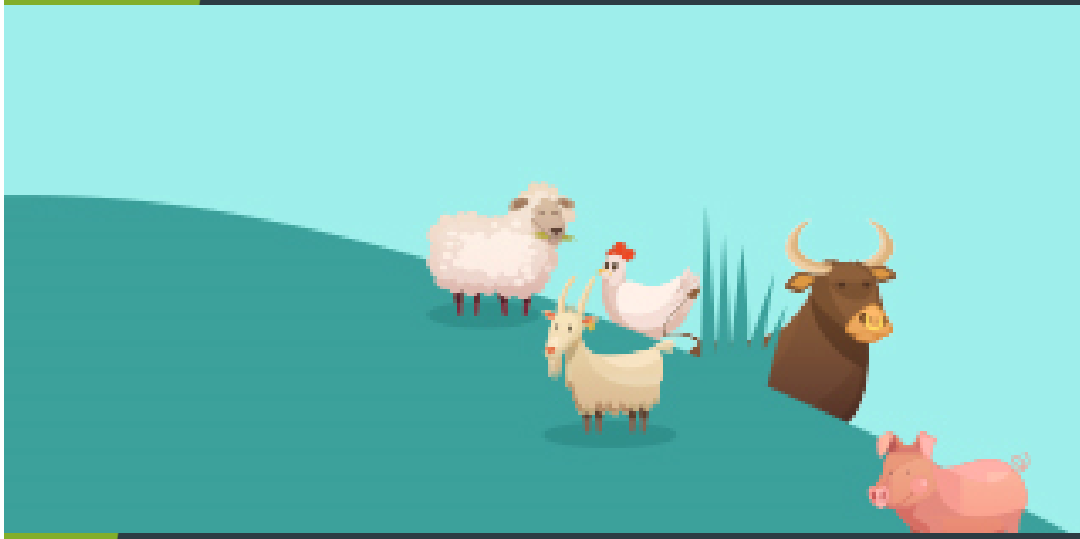


OIE SUB-REGIONAL WORKSHOP ON THE DATABASE ON ANTIMICROBIAL AGENTS INTENDED FOR USE IN ANIMALS IN EASTERN AND SOUTHERN AFRICA

ATELIER SOUS-RÉGIONAL DE L'OIE SUR LA BASE DE DONNÉES SUR LES AGENTS ANTIMICROBIENS DESTINÉS À ÊTRE UTILISÉS CHEZ LES ANIMAUX EN AFRIQUE ORIENTALE ET AUSTRALE

29 – 31 OCTOBER / OCTOBRE 2019 | MOMBASA, KENYA

# Siegfried Khaiseb

Namibia

# Medicines and Related Substances Control Act, Act 13 of 2003

- Came into effect on 1st August, 2008
- Custodian – Ministry of Health and Social Services (MoHSS)

***Definitions***

- ***Animal***: means all mammals except humans, all birds including poultry, all bees, all amphibians, all reptiles, all fish, all molluscs and all crustaceans
- ***Minister:*** means Minister responsible for MoHSS

## 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**

- ***Scheduled substance:*** **means any medicine or substance classified as a Schedule 0, 1, 2, 3, 4 or 5 substance.**
- ***Veterinarian:*** **means a person registered in terms of Veterinary and Veterinary Para-Professions Act 1 of 2013**

Medicines and Related Substances Control Act

- **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***

Medicines and Related Substances Control Act

# 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

# 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 |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

# 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 29 Control of medicines and scheduled substances

- Importers, wholesalers and manufacturers need permits and licences.
- 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 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

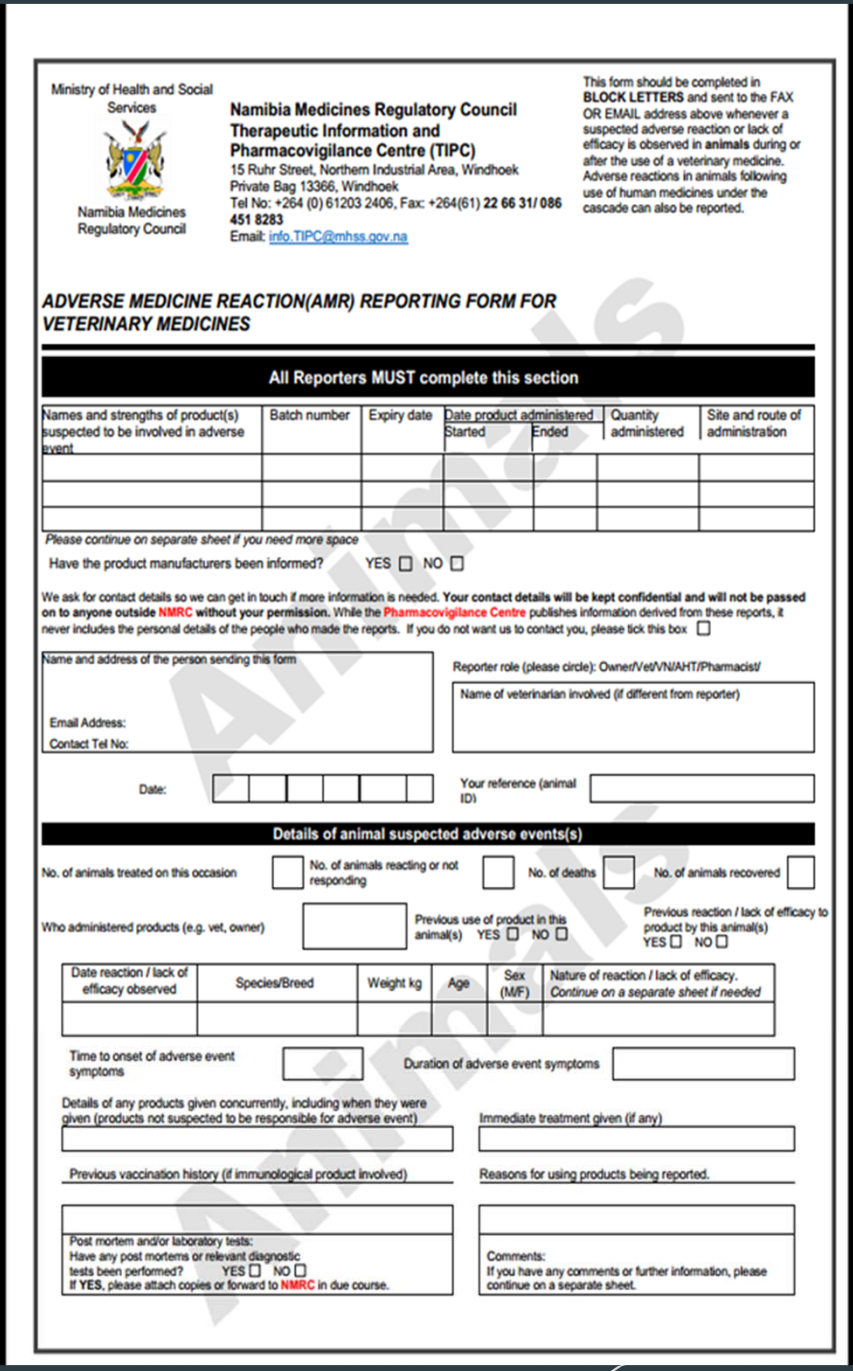
An Inspector may not search a ***person or home*** of an individual without a warrant issued by a judge.

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

## Pharmacovigilance System

- The Namibia Medicines Regulatory Council (NMRC) has a designated section (Therapeutics Information and Pharmacovigilance Center / TIPC) appointed to carry out Pharmacovigilance (PV) within the country
- The Regulations to the Act states the Marketing Authorisation Holder (MAH) must report adverse reactions 'within reasonable time
- The TIPC has a Veterinary Specific form created for reporting on adverse reactions related to all veterinary medicines

# Pharmacovigilance Document



Ministry of Health and Social Services

Namibia Medicines Regulatory Council

**Namibia Medicines Regulatory Council**
**Therapeutic Information and Pharmacovigilance Centre (TIPC)**
15 Ruhr Street, Northern Industrial Area, Windhoek
Private Bag 13366, Windhoek
Tel No: +264 (0) 61203 2406, Fax: +264(61) **22 66 31/ 086 451 8283**
Email: info.TIPC@mhss.gov.na

This form should be completed in **BLOCK LETTERS** and sent to the FAX OR EMAIL address above whenever a suspected adverse reaction or lack of efficacy is observed in **animals** during or after the use of a veterinary medicine. Adverse reactions in animals following use of human medicines under the cascade can also be reported.

***ADVERSE MEDICINE REACTION(AMR) REPORTING FORM FOR VETERINARY MEDICINES***

**All Reporters MUST complete this section**

| Names and strengths of product(s) suspected to be involved in adverse event | Batch number | Expiry date | Date product administered | | Quantity administered | Site and route of administration |
|---|---|---|---|---|---|---|
| | | | Started | Ended | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

*Please continue on separate sheet if you need more space*

Have the product manufacturers been informed? YES ☐ NO ☐

We ask for contact details so we can get in touch if more information is needed. **Your contact details will be kept confidential and will not be passed on to anyone outside NMRC without your permission.** While the Pharmacovigilance Centre publishes information derived from these reports, it never includes the personal details of the people who made the reports. If you do not want us to contact you, please tick this box ☐

Name and address of the person sending this form

Email Address:

Contact Tel No:

Reporter role (please circle): Owner/Vet/VN/AHT/Pharmacist/

Name of veterinarian involved (if different from reporter)

Date:

Your reference (animal ID)

**Details of animal suspected adverse events(s)**

No. of animals treated on this occasion

No. of animals reacting or not responding

No. of deaths

No. of animals recovered

Who administered products (e.g. vet, owner)

Previous use of product in this animal(s) YES ☐ NO ☐

Previous reaction / lack of efficacy to product by this animal(s) YES ☐ NO ☐

| Date reaction / lack of efficacy observed | Species/Breed | Weight kg | Age | Sex (M/F) | Nature of reaction / lack of efficacy. *Continue on a separate sheet if needed* |
|---|---|---|---|---|---|
| | | | | | |

Time to onset of adverse event symptoms

Duration of adverse event symptoms

Details of any products given concurrently, including when they were given (products not suspected to be responsible for adverse event)

Immediate treatment given (if any)

Previous vaccination history (if immunological product involved)

Reasons for using products being reported.

Post mortem and/or laboratory tests:
Have any post mortems or relevant diagnostic tests been performed? YES ☐ NO ☐
If **YES**, please attach copies or forward to NMRC in due course.

Comments:
If you have any comments or further information, please continue on a separate sheet.

# Veterinary Medicines Registered as Growth Promotors

| Applicant Certificate holder | Name of medicine | Approved name of each active ingredient | Dosage form | Registration number | Date of registration | Schedule (Condition of registration) |
|---|---|---|---|---|---|---|
| Logos Pharmaceutical (Pty)Ltd | Promote | Tylosin Phosphate (equivalent to active Tylosin 10%) | Oral: premix powder | V95/25.1/89 | 30/08/1995 applied | NS0 |
| Logos Pharmaceutical (Pty)Ltd | Nicrazin 25% | Nicarbazin 25.4%m/m | Oral: premix powder | V95/25.1/90 | 30/08/1995 applied | NS0 |
| Fort Dodge Animal Health (Pty) Ltd | Salcostat plus | Dinitolmide 25%m/m; Ethopabate 1.6%m/m | Oral: premix powder | V97/25.1/600 | 12-Nov-1997 | NS0 |
| Zoetis South Africa (Pty) Ltd, | Bio-Cox 120G | Salinomycin Sodium 120g/kg | Oral: premix | V02/25.1/843 | 14.03.2002 | NS0 |
| Zoetis South Africa (Pty) Ltd, | Avatec | Lasalocid Sodium 150.0mg/g | Oral: premix | V02/25.1/848 | 07.03.2002 | NS0 |
| Eco Animal Health Southern Africa (Pty) Ltd | Salecox 120 | Salinomycin Sodium 120g/kg | Powder | V94/25.1/1149 | 2/10/1994 | NS0 |
| Elanco Animal Health | Elancoban 200 | Monensin sodium 200 g/kg | Oral: Premix Powder | V14/25.1/1227 | 3/4/2014 | NS0 |
| Elanco Animal Health | Maxiban 160 | Narasin 8% m/v and Nicarbazin 8% M/V | Oral: Premix Powder | V14/25.1/1228 | 3/4/2014 | NS0 |
| Elanco Animal Health | Monteban 100 | Narasin 100 g/kg | Oral: Premix Powder | V14/25.1/1229 | 3/4/2014 | NS0 |
| Elanco Animal Health | Rumensin 200 | Monensin sodium 200 g/kg | Oral: Premix Powder | V14/25.1/1230 | 3/4/2014 | NS0 |
| Elanco Animal Health | Surmax 100 | Avilamycin 100 g/kg | Oral: Premix Powder | V14/25.1/1231 | 3/4/2014 | NS0 |
| Virbac SA | | | Feed | | | |

## Medicines and Related Substances Control Act: Regulations

- Thank you