Status of Requirements for Registration of Veterinary Medicines in Botswana

GALVmed/OIE stakeholder workshop on the harmonisation of the registration of veterinary medicinal products,

Johannesburg

9 -11 May 2017

Current Situation

Diseases of Animals Act (Chapter 37:01)

- No marketing authorisation granted for veterinary medicines
- Section 16 (vaccines, serum etc..) (pg 7)
  - Empowers the Director to issue permit for manufacturing or selling or importation veterinary medicines
  - Authorises importation of medicines registered by regulatory authorities in SADC countries and the EU

Current Situation

CAP 37-01 Diseases of Animals Act.pdf

Section 16. Vaccine, serum, etc.

(1) No person shall, except under and in accordance with the provisions of a permit issued by the Director, manufacture, sell or expose for sale any vaccine, serum, virus, biological product, therapeutic substance or other similar product or chemical used or to be used for the diagnosis or treatment of disease

(2) A permit issued under the provisions of subsection (1) shall be subject to such conditions as the Director may impose

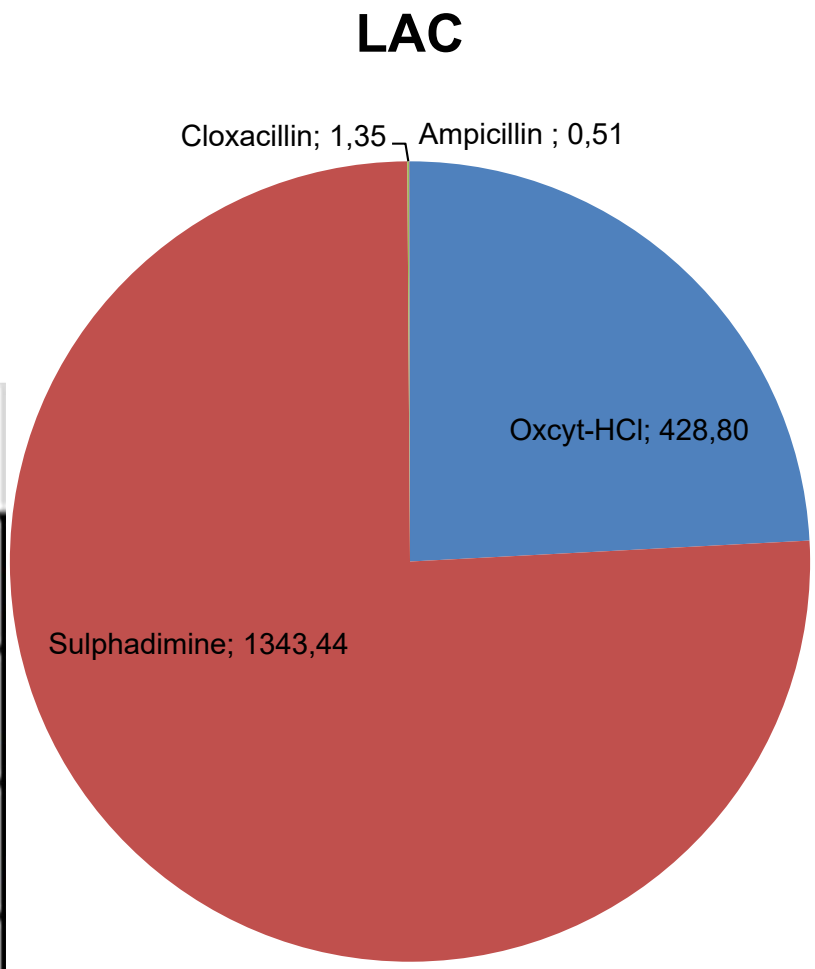
(3) (3) Any person who contravenes the provisions of this section shall be guilty of an offence.

Current Situation

- Supply chain monopoly by Livestock Advisory Centres (now BAMB) - 35 Centres country wide
- Subsidy on feed and veterinary medicines

Current Situation
Antibiotics imported by the LAC (2016)

Item	Qty. [Kg]
Oxcyt-HCl	428.80
Sulphadimine	1343.44
Cloxacillin	1.35
Ampicillin	0.51



Current situation…cont'd

- Diseases of animals subsidiary legislation
  - SI. 103.1987 prohibition of use of anabolics, etc (pg 52)

CAP 37-01 Diseases of Animals Subsidiary Legsilation (1).pdf

- Veterinary Surgeons Act (1977)

Medicines and Related Substances Act (MRSA)

- Parliament enacted the Medicines and Related Substances Act (MRSA) in 2013 to realise the policy objective of providing safe, effective and quality medicines.
- Repealed the Drugs and Related Substances Act (1992) which did not cover veterinary medicines

MRSA

Purpose

- To strengthen control and regulation of medicines
- To regulate the manufacture, import, export, distribution, sale and dispensing of medicines and the sale of related substances
- To establish a semi-autonomous Medicines Regulatory Authority (MRA) under the Ministry of Health and Wellness
- Director of Veterinary Services is an Ex-Officio member of Governing Board of the Authority

MRA

Will

- grant, renew, suspend or revoke Marketing Authorisation (MA) for human medicines and veterinary medicines
- be sponsible for licensing and inspecting premises (manufacturing, importers, exporters, distribution, wholesalers, pharmacies, dispensaries etc)
- ensure monitoring and reporting of adverse reactions to medicines (Pharmacovigilance)
- ensure that post marketing surveillance of medicines is done
- control advertising of Medicines

MRSA

Regulations under development

- To be in line with international standards;
  - OIE - Responsible and prudent use, AMR surveillance
  - Codex MRL standard
  - Protection of the environment
  - SADC guidelines for regulation of veterinary drugs

Thank you for listening!