



Experience in Applying VICH Guidelines in South Africa.

REGIONAL SEMINAR FOR OIE FOCAL POINTS ON VETERINARY PRODUCTS.

MMALENCOE MOROE-RULASHE
DAFF-VET PUBLIC HEALTH.
SOUTH AFRICA.



agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

Outline

What is VICH?

VICH (Where SA fit In)

What is the role of VICH versus OIE?

Lessons learned from the involvement in VICH

Benefits to the usage of VICH guidelines

How SA is using VICH

VICH GLs: Harmonisation of technical requirements (regional level)



agriculture,
forestry & fisheries

Department:
Agriculture, Forestry and Fisheries
REPUBLIC OF SOUTH AFRICA

What is VICH?

- VICH, full name: The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
 - Is a multinational programme
 - VICH aims to provide harmonised guidance documents that describes the data to be provided in an application dossier for registration of a VMP.
 - VICH also establishes guidelines on the post-marketing safety monitoring of VMPs.

- ***Talks to the Registration Process Not Regulatory Process***



VICH (Where SA fit In)

➤ Membership

➤ Full Members

- European Union, Japan and United States
 - pledged to implement all VICH Guidelines, involved in all VICH works, have voting rights,

➤ Other Members (Regulatory Authority + the Vet Pharmaceutical Industry)

- Observers
- Canada, Australia, New Zealand and South Africa
 - Not pledged to implement all VICH Guidelines but encouraged to implement them, involved in VICH work, no voting rights,



VICH

➤ Other members

- Associate Member
- World Organization for Animal Health (OIE)
 - Not pledged to implement all VICH Guidelines but shares and encourage their usage, involved in some VICH work, no voting rights,
- Interested Party
- Veterinary Pharmaceutical Companies/Industry =
 - Not pledged to implement all VICH Guidelines but encouraged to use them, involved in VICH work, no voting rights.



What is registration of VMP?

- A process where regulatory authority ensures that the Veterinary Medicinal Product (VMP) is fit to be put on the market for sale and use.
- It involves the evaluation or assessment of studies done on the VMP during its development and production/manufacturing
- Studies to prove that the VMP:
 - Is safe for the animal that is intended for,
 - will work as proposed,
 - is manufactured safely and is of good quality, and
 - will not pose any risk to humans when the intended animal is eventually used as foodstuff.
 - ❖ (animal product, safe to be consumed)

Evaluation on the Quality, Safety (target animal safety and human health safety), and Efficacy of VMP



What is the role of VICH versus OIE

- VICH is a ***multinational organisation*** that develops harmonised data requirements,
 - i.e. guidelines for the scientific studies on quality, safety and efficacy that are required to obtain a registration of a veterinary medicinal product.

- OIE is a ***global organisation*** that develops animal health standards for international trade in animals and animal products that member countries (South Africa included) can use to protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers.
 - OIE is also responsible for improving the legal framework and resources of national Veterinary Services.
 - OIE is the associate member of VICH
 - VICH was established under the auspices of the OIE.



Lessons learned

➤ What has been learned from the involvement in VICH:

- Promotion of VICH
 - Initial Need for Education/ explanation of VICH and its work to gain support;
 - » Higher management (DG, DDG, CD)
 - » SA Vet Pharmaceutical Industry
 - Realisation of need to Clarify the aims or the objectives as outlined by VICH, b/c of general misunderstanding of VICH guidelines
 - » Seen as requirement not guidelines
 - » Seen as been too stringent
 - » not for small markets (not really cost effective).
 - » Costs of studies vs potential local market



Benefits to the usage of VICH guidelines and the harmonisation process.

- Initiated the need to review legislation and requirements for VMP
 - Review of Control Systems (Stock Remedies Policy)
 - SA guidelines in line with the international guidelines:(VICH)

- Allowed for better communication and relation with the Vet Pharmaceutical Industry.
 - reinforce and build trust between regulatory authorities and the VMP industry/ association.
 - VICH involvement calls for joined efforts (regulatory authorities and industry)

- Eliminated redundant testing requirements,
 - reduces testing usage of animals (Welfare Issues)



Benefits to the usage of VICH guidelines and the harmonisation process.

- Allowed for information sharing;
 - synergise efforts and
 - best utilisation of limited resources,

- Allowed for efficient use of resources by avoiding the need for creation of new technical requirements.

- Allowed for assurance of high standards for approval and registration/licensing of veterinary medicinal products;
 - Provided better regulatory certainty,
 - Provided uniformity
 - Clarity to the Pharmaceutical Industry.



How SA is using VICH

➤ Gradual (Bit by bit)

➤ VICH referenced in Documents:

▪ DAFF Documents/Law

○ Stock Remedy Policy

- Regulation regarding Stock Remedies under the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), DAFF web page: www.nda.agric.za

• Quoted from Document

» “The use of International Cooperation on Harmonization of Technical Requirements ([VICH](#)) and the World association for the Advancement of veterinary Parasitology (WAAVP) are encouraged”

○ Data Requirements for the Registration of Stock Remedies

» GCP Guidelines used in its entirety



How SA is using VICH

➤ DoH Doc/Guidelines

- National guidelines on Efficacy of Anti-mastitis products
 - » Section on target safety (usage of VICH Guidelines)
- VICH Guidelines referenced
 - » Efficacy and GCP of Veterinary Medicines. (GCP Guidelines)
- And others as outlined in the MCC Web page:
www.mccza.com or www.doh.gov.za



VICH GLs: Harmonisation of technical requirements

REGIONAL LEVEL/SCOPE:

- SADC member countries (South Africa included) developed the “Regional Guidelines for the Regulation of Veterinary Drugs in SADC Member States”

- Guidelines are meant to: (among others)
 - provide ground for harmonising veterinary drugs policies, legislation, registration and control
 - strengthen the regulatory framework for registration and quality control of veterinary drugs at national and at regional levels



VICH GLs: Harmonisation of technical requirements

- Guidelines were developed in conformity with international requirements in order to comply with food safety requirements as well as increase exports opportunities .
- Examples of International requirements used in the guidelines:
 - FAO Guidelines, WHO Guidelines, CODEX Guidelines, OECD Guidelines, OIE Codes of Practise and VICH Guidelines
- Guidelines have been approved by Council of Ministers in the SADC region (have to comply)
 - process: Implementation of document in the Region.



PRETORIA – The Jacaranda City

