Bettye Walters & Ólafur Valsson

US FDA & OIE SRR-SA

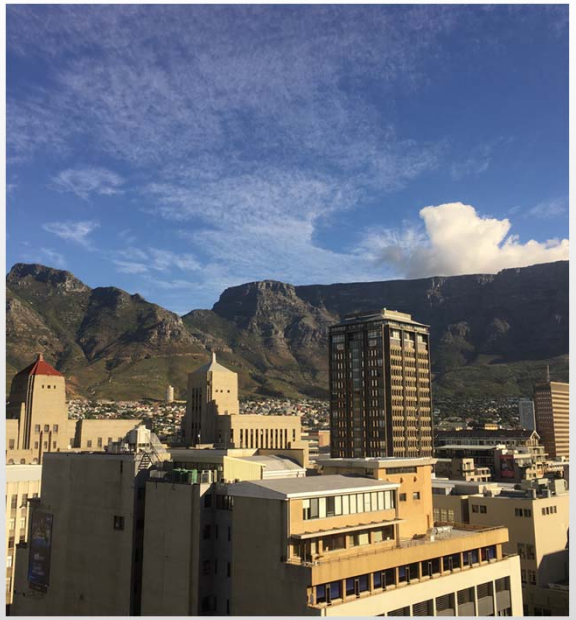
Update on VICH, focus on VOF including the update from the VICH 6th Public Conference

Regional Seminar for OIE National Focal Points for Veterinary Products
Cycle VI

Addis Ababa and Debre-Zeit, Ethiopia
9 – 11 July 2019

Date and venue

- Cape Town, RSA
- 26 – 28th February 2019



Objectives

Aim of the VICH 6th conference to:

- Provide a platform for and facilitate discussion on
  - harmonisation practices and collaboration on global convergence.
  - opportunities and challenges faced by regulatory authorities and industry worldwide and in Africa in particular.

- The conference was held in conjunction with the
  - 37th VICH steering committee meeting and the
  - 11th VICH Outreach Forum.

Target group

- The Conference targeted
  - Delegates from OIE Members and
  - Industry representatives

Participants

- Participants from 29 countries
- 10 African countries
- Between 130 and 140 participants

Speakers

from OIE, National Regulatory Authorities, Industry and Academia, NGOs, the World Bank and Bill and Melinda Gates Foundation

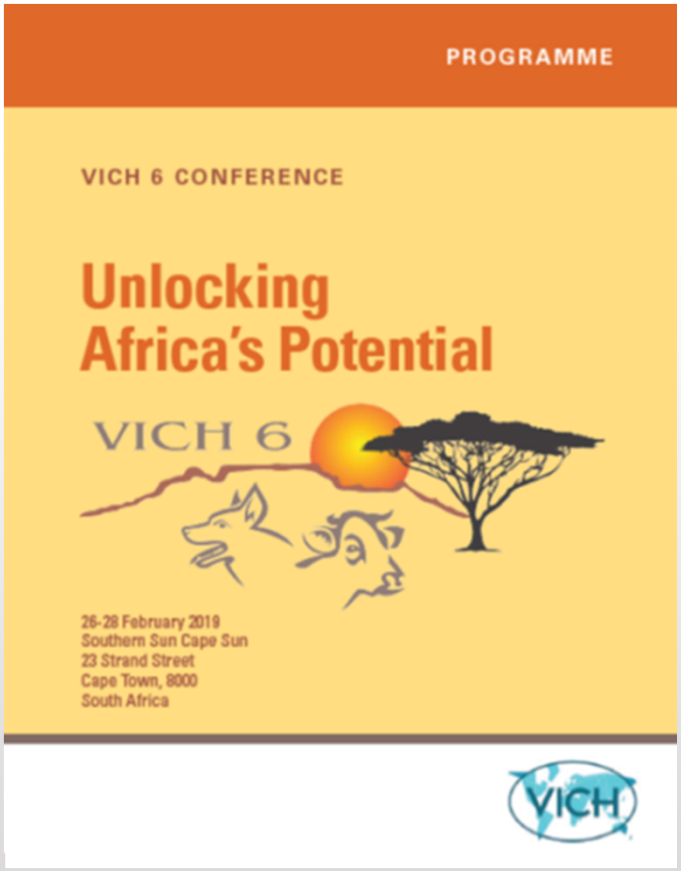
- Shared their experiences in implementing VICH guidelines,
- Discussed the benefits of adoption, and
- Elaborated on ways to advance efforts towards regulatory convergence.

Programme highlights

https://vich6.co.za/program/

Opening session

- The opening session highlighted how VICH was established, its history and what VICH is today
- Clarified the relationship between OIE and VICH.



Keynote addresses

Highlighted

- Contribution of VICH to the Global One Health Approach with focus on AMR
- Benefits for outreach forum members
  - participation in guideline preparations
  - training on VICH guidelines

Implementation of VICH guidelines

- The US & Canada collaboration on registration of VMPs
- Benefits highlighted
  - More timely registration,
  - Synergism
  - Still room for country specific issues

13:00 ~ 14:00	**SESSION 3: IMPLEMENTING VICH GUIDELINES** *Moderator: Dr. Bettye Walters – Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA)* **By VICH Member** *Brandi Robinson – Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA)* **By VICH Observer** *Dr. Mary-Jane Ireland – Veterinary Drugs Directorate, Department of Health, Canada* **Possible Regulatory Obstacles and Perspectives in Adopting VICH Guidelines in VICH Outreach Forum Countries/Regions and How to Overcome Them** *Yuriy Kosenko – National Agency of Veterinary Products and Feed Additives, Ukraine*
14:00 ~ 15:15	**SESSION 4: VOICE OF INDUSTRIES** *Moderator: Rick Clayton – AnimalhealthEurope* **Stimulating Innovation** *Dr. Erik De Ridder – Elanco Animal Health* **Regulatory Convergence** *Dr. Alexander Boettner – Merck Animal Health* **Animal Health Product Availability and Accessibility** *Dr. Guillaume Agede – Ceva* **Q&A**
15:15 ~ 15:45	*Coffee Break*
15:45 ~ 17:00	**SESSION 5: EXISTING VICH GLS – HOT TOPICS** *Moderator: Dr. Ken Noda – Ministry of Agriculture, Forestry, and Fisheries, Japan (JMAFF)* **Academia's View of the Benefits of VICH** *Prof. Vinny Naidoo – Dean of the Faculty of Veterinary Science, University of Pretoria* **Registration of Antimicrobial Veterinary Medicinal Products – VICH GL 27** *Dr. Matthew Lucia – Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA)* **VICH and the 3Rs** *Dr. Nicholas Jarrett – Veterinary Medicines Division, European Medicines Agency (EMA)* **Waiver of Target Animal Batch Safety Test** *Dr Nick Nwankpa - Director, AU Pan-African Veterinary Vaccines Centre (AU-PANVAC) IOE Collaborating Centre* **Training Video Introduced by** *Dr. Koji Oishi (JVPA)*
19:00 ~ 22:00	*Gala Dinner*
DAY 2 (28 FEBRUARY 2019)	
8:30 ~ 12:00	*Registration Open*
9:00 ~ 10:15	**SESSION 6: NEW VICH GLS** *Moderator: Dr. Koji Oishi – Japan Veterinary Products Association (JVPA)* **Climatic Zone III/IV Stability Guideline** *Prof. Henry Leng – Chairperson, Pharmaceutical & Analytical Committee of the South African Health, Products Regulatory Authority* **Combination Products GL** *Brandi Robinson – Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA)*

VICH 6 CONFERENCE

Industry perspectives

- Support to and collaboration with regulatory authorities and convergence to improve
  - Timely registration of VMPs
  - Address counterfeit and substandard drugs
- Highlighted need for regional approach and
- Importance of Mutual Recognition
- Stimulate innovation

“Hot topics”

- Registration of antimicrobials (US AMR Risk Assessment guidelines)
- 3Rs (replacement, reduction and refinement) a VICH objective from 2007
- TABST (Target Animal Batch Safety Test) not used anymore in EU, Japan and US
- OIE position on TABST: can be eliminated in situations where other quality control measures are in place.

New VICH guidelines

- Climatic zone/stability guidelines (which concern particularly African Countries),
- Combination products,
- Aquatic species, and
- Bees and honey

Regional activities in Africa

- The importance of:
  - Public - private partnerships,
  - Speeding up product registration,
  - Lessons to learn from ZAZIBONA (collaboration and mutual recognition process between national medicines regulatory authorities of (6) SADC countries)

Global perspectives

- Emphasis on collaboration and harmonization using the VICH guidelines and how this can avail good quality affordable VMPs
- Information sharing and knowledge banking

Take home messages

Application of **VICH guidelines** is a **tool** to improve control and quality of VMPs and ultimately **safeguard** animal health and welfare, contributing to human health and wellbeing

Accessible and affordable quality VMPs
is the ultimate goal - the gold standard

The need for good governance and good regulatory practices can not be overemphasized

The **future is regulatory cooperation** and the **future is now**

WORLD ORGANISATION FOR ANIMAL HEALTH

Protecting animals, preserving our future

Thank you for your attention

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