



PRESS RELEASE

Unlocking Africa's Potential - VICH goes to Africa in 2019

Bruges, 28 June 2018.

The 36th VICH Steering Committee and 10th VICH Outreach Forum (VOF) meetings were held from 25 to 28 June 2018 in Bruges, Belgium. VICH is a trilateral cooperation programme among the European Union, Japan and the United States of America driving the harmonisation of technical requirements for the registration of Veterinary Medicinal Products. Fifty participants representing twenty-one national regulatory agencies or animal health industry organizations attended the meeting.

The Steering Committee finalised the programme for the 6th VICH Public Conference (www.vich6.co.za) that will be held on 27 & 28 February 2019 in Cape Town, South Africa, a VICH Observer member country. The Public Conference “Unlocking Africa’s Potential” will provide a particular opportunity to attract regulators and industry representatives from the African continent as well as delegates from all regions of the world. It will provide insights into the VICH global outreach activities, as well as the current work achieved by the different VICH Expert Working Groups. The aim of the Conference is also to learn more about the expectations from Outreach Forum members regarding the harmonisation of technical requirements for data necessary for registration, and to debate how VICH and medicines availability can improve the global human and animal health.

The 10th meeting of the VICH Outreach Forum, co-chaired by VICH and the OIE, drew participants from six continents. The forum featured presentations on VOF member experiences, technical training on VICH Guidelines (GLs) and interactive sessions to exchange ideas and shared experiences between forum participants. The representative from Uganda reported on the East African Community (EAC) experience with the regional Mutual Recognition System in the EAC. The Steering Committee provided insight on the use of the VICH Anthelmintics GLs and the VOF members shared their experiences on assessing the efficacy of Anthelmintics and the local use of the VICH Anthelmintics GLs. Further discussions focused on medicated premixes, the considerations to set up a simple pharmacovigilance system, an overview of the Metabolism and Residue Kinetics (MRK) GLs, and the implementation of the VICH Bioequivalence GL.

The VICH Steering Committee, the OIE, and the Forum participants discussed the scope and missions of VICH and the VOF, and reviewed the expectations of Forum members for future activities.

The Steering Committee released draft VICH GL 58 (*Stability: Climatic Zones III and IV - Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV*) for a six months public consultation period until 31st December 2018.

The Steering Committee adopted final VICH GL 56 (*MRK: Residues in Honey - Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Species: Study Design Recommendations for Residue Studies in Honey for establishing MRLs and Withdrawal Periods*) for implementation in the VICH regions by June 2019.

The Steering Committee reviewed and acknowledged the progress of the work of the Expert Working Groups on Electronic Standards Implementation (Pharmacovigilance), Safety, Quality, Biologicals Quality Monitoring, Metabolism and Residue Kinetics, Combination Products Guideline and Anthelmintics.

All VICH draft and final Guidelines are available on the VICH website (www.vichsec.org).

The 37th VICH Steering Committee meeting and the 11th VOF meeting are scheduled to take place, in conjunction with the VICH 6 Public Conference, between 24 February and 1 March 2019 in Cape Town, South Africa.

MEMBERS OF THE STEERING COMMITTEE

EU: European Commission - European Medicines Agency

JMAFF: Japanese Ministry of Agriculture, Forestry and Fisheries

USA: US Food & Drug Administration (FDA) – Center for Veterinary Medicine (CVM) and US Department of Agriculture – Center for Veterinary Biologics (USDA/CVB)

AHI: US Animal Health Institute

AnimalhealthEurope: representing the European Animal Health Industry

JVPA: Japan Veterinary Products Association

OBSERVERS

Australia: Australian Pesticides and Veterinary Medicines Authority (APVMA)

New Zealand: New Zealand Ministry for Primary Industries

AMA: Animal Medicines Australia

AGCARM: Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand

Canada: Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian Centre for Veterinary Biologics (CCVB)

CAHI: Canadian Animal Health Institute

South Africa: Department of Agriculture, Forestry and Fisheries (DAFF) and Department of Health

SAAHA: South African Animal Health Association

ASSOCIATE MEMBER

OIE: World Organisation for Animal Health

INTERESTED PARTY

AVBC: Association of Veterinary Biologics Companies, USA

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