



PUBLIC STATEMENT

Regulators & Industry Convene in Cape Town for First VICH Meeting and Public Conference in Africa

Cape Town, 1st March 2019.

Representatives from regulatory agencies and industry gathered in Cape Town, South Africa, on 27-28 February for the 6th VICH public conference. Participants discussed the theme *Unlocking Africa's Potential* and a common goal of increasing global access to safe, effective, high quality veterinary medicinal products. Presentations were delivered by regulators from Africa and abroad, the OIE, industry organizations, the World Bank and the Bill and Melinda Gates Foundation. The 6th VICH Conference was attended by 127 participants from 28 countries. This includes 64 regulators from around the world. There were 75 delegates from Africa with 49 individuals from the host country, Republic of South Africa.

The Conference was held in conjunction with the 37th VICH Steering Committee and 11th VICH Outreach Forum (VOF) meetings. The meetings were attended by 50 participants representing 21 national regulatory agencies or animal health industry organizations.

The 11th meeting of the VICH Outreach Forum, co-chaired by VICH and the OIE, drew participants from six continents. The forum featured technical training on VICH Guidelines (GLs), breakout discussions on withdrawal period studies, and interactive sessions to exchange ideas and share experiences between forum participants. The VOF co-chairs promoted the opportunities available to VOF members to contribute to VICH guideline development. Presentations by VOF members were a highlight of the event, including from the Kingdom of Saudi Arabia, the Russian Federation, and the Republic of India.

VICH announced the availability of new training materials on the VICH Quality Guidelines and the waiving of Target Animal Batch Safety Test. This training will be made available on the VICH website www.vichsec.org.

The VICH Steering Committee formally adopted VICH GL 57 Metabolism and Residue Kinetics: *Residues in Fish – Studies to evaluate the Metabolism and Residue Kinetics of veterinary drugs in food-producing species: marker residue depletion studies to establish product withdrawal periods in aquatic species*. This guideline is for implementation in the VICH regions by February 2020.

Progress continues in seven active Expert Working Groups: Electronic Standards Implementation (Pharmacovigilance), Safety, Quality, Biologicals Quality Monitoring, Metabolism and Residue Kinetics, Combination Products Guideline, and Anthelmintics.

The 38th VICH Steering Committee meeting and 12th VOF meeting are scheduled for 18 - 21 November 2019 in Tokyo, Japan.

About VICH:

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.

The presentations made at the Conference will be made publicly available on the VICH website (www.vichsec.org).

All VICH draft and final Guidelines are available on the VICH website.

MEMBERS OF THE STEERING COMMITTEE

EU: European Commission - European Medicines Agency (EMA)

Japan: Ministry of Agriculture, Forestry and Fisheries (JMAFF)

USA: US Food & Drug Administration (FDA) – Center for Veterinary Medicine (CVM) and US Department of Agriculture (USDA) – Center for Veterinary Biologics (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: Ministry for Primary Industries (MPI)

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 South African Health Products Regulatory Authority (SAHPRA)

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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