



PUBLIC STATEMENT

VICH and VICH Outreach Forum members meet in Tokyo

Tokyo, 21 November 2019.

The 38th VICH Steering Committee and 12th VICH Outreach Forum (VOF) meetings were held from 18 to 21 November in Tokyo, Japan. VICH promotes the establishment of safe and effective veterinary medicines across the world through wider international harmonisation of technical requirements for the registration of veterinary medicinal products.

The 12th meeting of the VICH Outreach Forum, co-chaired by VICH and the OIE, drew 55 participants representing 22 national regulatory agencies or animal health industry organisations from six continents. The forum featured technical training on VICH Guidelines (GLs), breakout discussions on Good Clinical Practice, as well as an interactive session on mutual recognition programs.

VICH announced new training material on the VICH Metabolism and Residue Kinetics Guidelines as well as a training video on the waiving of Target Animal Batch Safety Test (VICH GLs 50 & 55). These will be added to the material already available on the VICH website www.vichsec.org.

The VICH Steering Committee formally adopted VICH GL58 (Quality) – *Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV*. This Guideline is for implementation in the VICH regions by November 2020 and is of particular interest for the VOF member countries.

The Expert Working Group on Biologicals will begin work on two new draft Guidelines, following the adoption by the Steering Committee of two Concept Papers on *Test on the Presence of Extraneous Viruses in Veterinary Viral Vaccines* and a *Guideline for Safety Evaluation of Biotechnology-Derived/Biological Products*.

The Steering Committee also adopted the Concept Paper proposing minor revisions to Pharmacovigilance Guidelines 24 (*Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)*) and 29 (*Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)*).

The Steering Committee noted the reactivation of the Bioequivalence Expert Working Group. Progress continues in the other active Expert Working Groups: Safety, Quality, Metabolism and Residue Kinetics, Combination Products, and Anthelmintics.

The 39th VICH Steering Committee and 13th VOF meetings are scheduled for 16 - 19 November 2020 in Amsterdam, the Netherlands, Europe.

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.

All VICH draft and final Guidelines are available on the VICH website. The translations of several VICH Guidelines are available on the website of OIE at:

<https://www.oie.int/scientific-expertise/veterinary-products/vich-outreach-forum/>.

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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