

PRESS RELEASE

First VICH Outreach Forum meeting paves the way for wider international cooperation

The first meeting of the VICH Outreach Forum took place in conjunction with the 27th VICH Steering Committee meeting that was held in Brussels from 26 to 28 June. The Steering Committee and the OIE (World Organisation for Animal Health) welcomed the representatives from countries and regions across the globe interested in using VICH Guidelines.

The Forum participants shared their experiences with the use of VICH Guidelines and took the opportunity to discuss the challenges and opportunities for their wider uptake.

The participants considered ways to raise awareness of VICH Guidelines in other parts of the world and to progress international harmonisation of technical requirements for the registration of veterinary medicinal products.

The Steering Committee, OIE and participants to the Forum collaborated to develop a series of actions intended to facilitate the broader understanding of VICH activities and how they can be integrated into regulatory systems of Forum members.

The Steering Committee congratulated the Microbiological ADI Expert Working Group for the finalisation of the revision of VICH Guideline 36 (*Safety – microbiological ADI: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI*) which has been published for implementation in the regions in June 2013. This Guideline is available on the VICH website (www.vichsec.org).

The Steering Committee reviewed and acknowledged the progress in the drafting of VICH concept papers and new VICH guidelines by the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation, Biologicals Quality Monitoring, Quality, Safety, Metabolism and Residue Kinetics and Bioequivalence.

The Steering Committee noted that the VICH Draft Guideline 34 (*Biologicals: Mycoplasma - Test for the detection of Mycoplasma contamination*) and the VICH Draft Guideline 35 (*Pharmacovigilance: ESTD - Electronic Standards for Transfer of Data*) are expected to be finalised in the near future.

The 28th VICH Steering Committee meeting and the 2nd VICH Outreach Forum meeting are scheduled between 18 and 21 February 2013 in Washington DC, USA.

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

IFAH-EUROPE: representing the European Animal Health Industry

JVPA: Japanese Veterinary Products Association

OBSERVERS

Australia/New Zealand: Australian Pesticides and Veterinary Medicines Authority (APVMA)/New Zealand Ministry of Agriculture and Forestry

The Alliance/AGCARM: Animal Health Alliance (Australia) Ltd./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

ASSOCIATE MEMBER

OIE: World Organisation for Animal Health

INTERESTED PARTY

AVBC: Association of Veterinary Biologics Companies (USA)

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