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PRESS RELEASE

5th VICH Public Conference in Tokyo in October 2015

The 29th VICH Steering Committee meeting was held in Auckland from 11 to 14 November 2013, hosted by Australia and New Zealand, who actively participate as VICH observer countries. The Steering Committee welcomed the first participation of South Africa as an observer member of the VICH Steering Committee.

The Steering Committee decided that the 5th VICH Public Conference will be held in Tokyo, Japan on 28 & 29 October 2015. This public conference will focus on current activities of the Expert Working Groups as well as on the VICH global outreach initiative.

The third meeting of the VICH Outreach Forum took place in conjunction with the 29th VICH Steering Committee meeting. The Steering Committee, OIE and the Forum participants discussed means to improve the understanding of the implementation of VICH Guidelines in Outreach Forum member countries and regions as well as to enhance the participation of Outreach Forum members in VICH technical activities.

The Steering Committee supported the input from China for the development of a new VICH discussion paper as well as the participation of an expert from Argentina in the Metabolism and Residue Kinetics Expert Working Group's development of a Guideline on residue studies in honey.

The Steering Committee released for public consultation the draft VICH GL 52 (*Bioequivalence: Blood Level Bioequivalence Study*) for a 6 months consultation period.

The Steering Committee completed for implementation by December 2015 the following guidelines in the VICH regions, representing an important milestone in the development of internationally harmonised pharmacovigilance:

- VICH GL 24 *(Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs*)
- VICH GL 30 (*Pharmacovigilance of Veterinary Medicinal Products: controlled list of terms*)
- VICH GL 35 (*Pharmacovigilance: Electronic Standards for Transfer of Data*)
- VICH GL 42 (*Pharmacovigilance: Data Elements for Submission of Adverse Events Reports*).

These guidelines are available on the VICH website (www.vichsec.org).

The Steering Committee took note of the advanced status of the VICH draft GL 53 (Electronic File Format - Electronic Exchange of Documents: File Format Requirements) which will be released for a 6 months public consultation in the near future.

The Steering Committee reviewed and acknowledged the progress of the work of the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation; Quality; Safety; Biologicals Quality Monitoring; Metabolism and Residue Kinetics, Electronic File Format and Bioequivalence.

The 30th VICH Steering Committee meeting and the 4th VICH Outreach Forum meeting are scheduled between 23 and 26 June 2014 in Brussels, Europe.

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: Japan 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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