

PRESS RELEASE

10 years of progress in VICH

At its latest meeting held on 17 and 18 October 2007 in Yokohama, Japan, the VICH Steering Committee celebrated 10 years of VICH marked by the 20th Steering Committee meeting. On this particular occasion, the Steering Committee presented an Outstanding Service Award to three of its members in recognition of their ongoing commitment to the VICH process since its beginning.

The Steering Committee applauded the significant progress achieved by the Pharmacovigilance Expert Working Group, which has successfully finalised VICH Guideline 24 (*Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)*), and VICH Guideline 42 (*Pharmacovigilance of Veterinary Medicinal Products – Data Elements for Submission of Adverse Event Reports*). The Steering Committee has signed off these VICH Guidelines at Step 6 and released them at Step 7 for implementation in the Regions.

The Steering Committee has further reviewed the VICH Draft Guideline 30 (*Pharmacovigilance of Veterinary Medicinal Products – Controlled list of Terms*) and confirmed the mandate of the VICH Task Force to finalise the harmonised list of terms for Pharmacovigilance reporting.

The Steering Committee received the report from the chairman of the Metabolism and Residue Kinetics Expert Working Group and congratulated the experts for the progress achieved.

The Steering Committee also reviewed the progress of the work of the Expert Working Groups on Quality, Biologicals Quality Monitoring and Target Animal Safety.

In order to monitor and maintain the VICH Guidelines implemented for more than 3 years, the Steering Committee adopted a methodology and an action plan for the review of the 27 concerned Guidelines until 2011.

A new way of presenting all VICH Guidelines will be posted on the redesigned VICH public website (www.vichsec.org), which will allow an easier access to individual Guidelines. The numbering of the VICH Guidelines has however not been modified.

The Steering Committee agreed to formalise further discussions on electronic presentation of Regulatory Documents to define solutions for future submissions.

The 21st meeting of the Steering Committee is scheduled for 8 and 9 July 2008, and will be hosted by OIE in its headquarters in Paris, France.

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 Food Safety Authority (NZFSA)

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 Food Inspection Agency (CFIA) - Veterinary Biologics Section (VBS)

CAHI: Canadian Animal Health Institute

ASSOCIATE MEMBER

OIE: Office International des Epizooties/World Animal Health Organisation

INTERESTED PARTY

AVBC: Association of Veterinary Biologics Companies (USA)

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