

VICH/09/035 26 February 2009

# PRESS RELEASE

## **VICH IV Public Conference in Paris in June 2010**

The VICH IV Public Conference will be held in the headquarters of OIE, the World Organisation for Animal Health, in Paris on June 24 & 25, 2010. This was confirmed at the 22<sup>nd</sup> VICH Steering Committee meeting (25 & 26 February 2009) hosted by Canada, one of the observer countries. This public conference will focus on discussion sessions related to the new VICH global outreach initiative and will also comprise current activities of the Expert Working Groups. The two day public conference, that will follow a meeting of the OIE collaborating centres and reference laboratories, is expected to have a strong participation of representatives from non-VICH countries.

The Steering Committee exchanged views on ways of strengthening the partnership with OIE in order to improve the global availability of safe and efficacious veterinary medicinal products.

The Steering Committee proceeded with the revision at step 9 of the following final Guidelines:

VICH GL 18 (Quality - Impurities: residual solvents in new veterinary medicinal products, active substances and excipients) will be reviewed by written procedure by the Quality Expert Working Group;

VICH GL 36 (*Safety – microbiological ADI: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI*) will be reviewed by the newly established Microbiological ADI Expert Working Group.

The Steering Committee further adopted a revision of VICH GL 33 (Safety – Studies to evaluate the Safety of residues of veterinary drugs in human food: General Approach to Animal Testing) by inserting a reference to the 3 R's Principle (Refine, Reduce and Replace), highlighting the VICH adherence to the goal of minimising animal testing.

The Steering Committee acknowledged the completion of the draft Controlled Lists of Terms by the Pharmacovigilance Expert Working Group Task Force and expected the relevant Pharmacovigilance Guidelines to be finalised by the Expert Working Group in the near future.

Activities of the Metabolism and Residue Kinetics Expert Working Group were considered by the Steering Committee and the significant progress in the development of the four draft Guidelines (Determination and quantity of residues, Comparative metabolism studies in laboratory animals, Residue depletion and Analytical method validation) was acknowledged.

The Steering Committee also reviewed progress of the Expert Working Groups on Quality and Biologicals Quality Monitoring. The testing programme to complete VICH draft GL 34 (*Biologicals Mycoplasma - Test for the detection of Mycoplasma contamination*) was agreed to be completed in 2009. The latter Expert Working Group was also requested to address a new topic with the aim to develop a VICH Guideline establishing criteria for waiving Target Animal Batch Safety Testing for immunological veterinary medicinal products.

The VICH Safety Expert Working Group will be re-convened in order to address the Harmonisation of the Studies to Establish an Acute Reference Dose.

The 23<sup>rd</sup> meeting of the Steering Committee is scheduled for 5 and 6 November 2009 in Kobe, Japan.

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#### 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: World Organisation for Animal Health

#### INTERESTED PARTY

AVBC: Association of Veterinary Biologics Companies (USA)

For further information, please contact the VICH Secretariat: c/o IFAH, International Federation for Animal Health Rue Defacqz, 1 - 1000 Brussels (Belgium) sec@vichsec.org