

PRESS RELEASE

OIE hosted the 21st VICH Steering Committee meeting

Brussels, 10 July 2008 - OIE (World Organisation for Animal Health) hosted the 21st meeting of the VICH Steering Committee on 8 and 9 July 2008 at its headquarters in Paris, France. OIE and VICH reviewed together ways of improving the outreach of VICH information and principles to other countries and regions wishing to benefit from VICH experience.

The Steering Committee systematically reviewed the 27 VICH Guidelines implemented for more than 3 years and agreed that the majority of the Guidelines did not require updating for the time being. The Steering Committee decided however that 3 of these Guidelines needed further attention and will be reviewed in more detail at the next Steering Committee meeting.

A milestone was achieved by the sign-off of the last two Target Animal Safety Guidelines at step 6, VICH Guideline 43 (*Pharmaceuticals: Target Animal Safety for Veterinary Pharmaceutical Products*), and VICH Guideline 44 (*Biologicals: Target Animal Safety for Veterinary live and inactivated Vaccines*) for implementation in the 3 regions by July 2009.

The Steering Committee congratulated the members and the chairman of the Expert Working Group for the successful drafting of 3 VICH Target Animal Safety Guidelines (including Guideline 41 – Reversion to Virulence) and their commitment to this difficult task.

The Steering Committee received the progress report from the chairman of the Metabolism and Residue Kinetics Expert Working Group and acknowledged that 4 draft Guidelines (Determination and quantity of residues, Comparative metabolism studies in laboratory animals, Residue depletion, Analytical method validation) would be submitted in the near future to the Steering Committee for endorsement for public consultation.

The Steering Committee applauded the significant progress achieved by the Pharmacovigilance Expert Working Group Task Force on the Controlled Lists of Terms. These lists are necessary for harmonised data exchange relating to Adverse Event Reports and will be finalised in early 2009.

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

In view of current scientific progress, the Steering Committee agreed to formalise further discussions on Target Animal Batch Safety Test for immunological veterinary medicinal products which has the potential to significantly contribute to the reduction of animal testing.

The Steering Committee agreed to monitor the developments in electronic submissions of regulatory documents in each region to facilitate a consistent approach.

The Steering Committee and OIE decided to organise the 4th VICH Public conference at the OIE headquarters in Paris in June 2010.

The 22nd meeting of the Steering Committee is scheduled for 25 and 26 February 2009, and will be hosted by Canada, an observer member.

WHAT IS VICH?

VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. Its full title is the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. VICH was officially launched in April 1996.

For more information on the objectives and structure of VICH, go to: <http://www.vichsec.org/en/what-is.htm#1>

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)

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