



VICH/02/028
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PRESS RELEASE

10th VICH Steering Committee finalises VICH2 Conference programme and releases further Guidelines

The Steering Committee* of VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) met in Washington D.C., USA on 9, 10 and 11 April 2002 and reviewed the activities of the Expert Working Groups (EWGs).

The Steering Committee finalised the programme of the VICH2 international conference which will be hosted by Japan on 9 - 11 October 2002 in Tokyo. Since the VICH1 conference in 1999, a significant number of VICH Guidelines have been published in draft form or as final Guidelines. Participants to the conference are therefore warmly welcomed to take part in the discussions which will take place in special breakout sessions where the following VICH topics will be addressed: Ecotoxicity, Biologicals Quality Monitoring, Safety, Pharmacovigilance, Antimicrobial Resistance, Target Animal Safety, Quality and Efficacy of Anthelmintics.

Key-note speakers from the EU, Japan and the USA, as well as from Australia and New-Zealand will address special issues including: Quantifying Human Health Impacts of VMP Regulations, the challenges to international harmonisation and the role of regulatory authorities, the importance of VICH on a global perspective and the future implications of the VICH process.

The Steering Committee reviewed the VICH work programme and confirmed the work plan for the forthcoming years.

MEMBERS OF THE STEERING COMMITTEE

EU: European Commission - European Agency for the Evaluation of Medicinal Products

JMAFF: Japanese Ministry of Agriculture, Forestry and Fisheries

USA: US Food & Drug Administration – Center for Veterinary Medicine (CVM) and US Department of Agriculture – Center for Veterinary Biologics (USDA/CVB)

AHI: US Animal Health Institute

FEDESA: European Federation of Animal Health

JVPA-JAVB: Japanese Veterinary Pharmaceutical Association – Japanese Association of Veterinary Biologics

OBSERVERS

Australia/New Zealand: National Registration Authority (Australia)/Ministry of Agriculture and Forestry (New Zealand)

Avcare/AGCARM: National Association for Crop Production & Animal Health (Australia)/Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand

ASSOCIATE MEMBER

OIE: International Office of Epizootics

Two Guidelines were signed-off at step 6 VICH GL 25 – Testing of Residual Formaldehyde and VCH GL 26 - Testing of Residual Moisture, and were released for implementation in the 3 regions by May 2003.

The Steering Committee released 3 new safety draft Guidelines at Step 4: VICH GL 31- Safety of Residues of Veterinary Drugs in Human Food – Repeat-Dose (90 days) Toxicity Testing , GL 32 - Safety of Residues of Veterinary Drugs in Human Food – Developmental Toxicity Testing and GL 33 - Safety of Residues of Veterinary Drugs in Human Food – General Approach to Testing, for a 5 months public consultation period, in order to enable the safety EWG to finalise these draft Guidelines at its 7th meeting, which will take place immediately prior to the VICH2 conference in Tokyo.

VICH draft Guideline 34 – Testing for the Detection of Mycoplasma Contamination, was released for a 12 months public consultation period, pending the availability of reference strains which will be provided by the European Directorate for the Quality of Medicines (EDQM), and the Steering Committee agreed to review the length of the public consultation period at its next meeting.

The Steering Committee acknowledged the progress achieved by the EWGs on Quality, Ecotoxicity/Environmental Impact Assessment, Safety, Biologicals Quality Monitoring, Pharmacovigilance, Antimicrobial Resistance and Target Animal Safety.

The Steering Committee accepted the application of Canada to become an observer, and of CAMEVET to become an Interested Party to the VICH Steering Committee.

The 11th meeting of the Steering Committee is scheduled for 8,9 and 12 October 2002 in Tokyo, Japan, prior and immediately following the VICH2 conference.

For further information, please contact the VICH Secretariat:
c/o IFAH, International Federation for Animal Health
Rue Defacqz, 1 - 1000 Brussels (Belgium)
Phone: +32-2-5410111, fax: +32-2-5410119,
E-mail: vich@ifahsec.org , Website: <http://vich.eudra.org>