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PRESS RELEASE

The 19th VICH Steering Committee consolidates progress and embarks on new topics for harmonisation

The VICH Steering Committee held its 19th meeting on 24 and 25 January 2007 in Washington DC, USA, which was chaired by Dr S. Sundlof, Director of FDA/CVM.

The Steering Committee continued to make good progress in the second Phase of VICH, where it agreed to take measures to improve the efficiency of the VICH process. These measures were incorporated in the Organisational Charter of VICH and the new version of the Charter will be published shortly on the VICH website.

To establish the procedures for a systematic review of the 36 VICH Guidelines that have been implemented over the past 10 years, the Steering Committee adopted a guidance document on the monitoring and maintenance of VICH Guidelines which have been implemented for more than 3 years.

The Steering Committee signed-off at step 6, three Quality Guidelines that were implemented in 2000 and have been revised by the Quality Expert Working Group at step 9 of the VICH procedure to update the scientific requirements: GL 3 - Revised *(Stability Testing of New Veterinary Drug Substances and Medicinal Products)*, GL 10 - Revised *(Impurities in New Veterinary Drug Substances)* and GL 11 - Revised (*Impurities in New Veterinary Medicinal Products*). These Guidelines will be distributed to the regions for implementation by January 2008.

The Steering Committee agreed to work towards establishing a Safety Expert Working Group that will have the mandate to develop a Guideline identifying data requirements for the elaboration of an Acute Reference Dose for Veterinary Medicinal Products with respect to consumer safety.

The Steering Committee discussed the possible electronic submission of sections of Registration Dossiers and decided that a concept paper on this topic will be prepared for discussion at the next meeting.

The Steering Committee confirmed its support for the principle to reduce, refine or replace animal testing (3Rs) and to promote the use of alternative test methods, and will shortly issue a statement of principle. The Steering Committee was addressed on this topic by the US

Interagency Coordinating Committee on the Validation of Alternative Test methods (ICCVAM).

The Steering Committee adopted a Concept Paper on Bracketing and Matrixing Designs for Stability Testing of new Drug Substances and Products and mandated the Quality Expert Working Group to develop a Guideline on this topic.

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

The Steering Committee recommended changes to the layout of the VICH website at the following address: www.vichsec.org .

The 20th meeting of the Steering Committee is scheduled for 17 and 18 October 2007, in Japan.

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: National Association for Animal Health Products (Australia)/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)

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