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PRESS RELEASE

Progress achieved on key international Guidelines at the 13th VICH Steering Committee meeting

The VICH Steering Committee held its 13th meeting on 7 and 8 October 2003 in Washington D.C. to assess the ongoing activities and discuss the future work of VICH.
A major milestone was achieved by the release of the Ecotoxicity/Environmental Impact Assessment Phase II draft Guideline, VICH GL 38 *(Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) – Phase II Draft Guidance*) for a 6-months public consultation until 15 April 2004.
The Steering Committee congratulated the members and the chairman of the Expert Working Group for their hard work and their commitment to fulfil this difficult task.

The Steering Committee acknowledged that the Antimicrobial Resistance Expert Working Group had completed its mandate by the signing-off of VICH draft GL 27 (*Guidance on Pre-Approval Information for Registration of New Veterinary Medicinal Products for Food Producing Animals with respect to Antimicrobial Resistance*).
This draft Guideline will be presented in the near future to the Steering Committee for sign-off and implementation a year later in the 3 regions. The Steering Committee congratulated the members and the chairman of the Expert Working Group for their dedicated work.

The Steering Committee reviewed the status of the work of the Target Animal Safety, the Biologicals Quality Monitoring and the Pharmacovigilance Expert Working Groups and provided guidance for their future activities.

The Steering Committee also reviewed the current VICH Workplan, defined the work to be achieved by 2005 and began the process of organising the VICH3 Public Conference to take place in the USA in Spring 2005.

The Steering Committee exchanged information on the views of the different regions concerning the second phase of international harmonisation after 2005. The Steering Committee created a Task Force composed of 1 representative from each of the 3 regions and 1 representative of the observer members, with the mandate to propose a structure and process for operations for VICH beyond 2005. The Task Force will be chaired by OIE.

The Steering Committee received an update on the implementation of the VICH Guidelines in the regions and was pleased to note that all the Guidelines were implemented within the previously targeted timeframes.

The 14th meeting of the Steering Committee meeting is scheduled for 12 and 13 May 2004 in Tokyo, Japan.

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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
IFAH-EUROPE: A division of IFAH, International Federation for Animal Health
JVPA: Japanese Veterinary Products Association

OBSERVERS
Australia/New Zealand: Australian Pesticides and Veterinary Medicines Authority (APVMA)/New Zealand Food Safety Authority (NZFSA)
Avcare/AGCARM: National Association for Crop Production & Animal Health (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: International Office of Epizootics

INTERESTED PARTIES
AVBC: Association of Veterinary Biologics Companies (USA)
CAMEVET: Representing Authorities and Industry Associations from Latin American countries

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