International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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PRESS RELEASE

The future of VICH outlined at the 14th VICH Steering Committee meeting

At its 14th meeting on 12 and 13 May 2004 in Tokyo the VICH Steering Committee agreed on priorities for the future. VICH will continue to consider the development of new Guidelines, however as the end of the first phase approaches (2005), the Steering Committee recognised that in the second phase, monitoring and updating the 32 implemented Guidelines will become more important. For any potential future topics increased emphasis will be put on a cost/benefit analysis.

OIE will lead a special Task Force to finalise a strategy paper on future activities, which will be considered at the next Steering Committee meeting.

Another milestone was achieved by the sign-off of the last two Safety Guidelines at step 6, VICH Guideline 36 (General approach to establish a microbiological ADI), and VICH Guideline 37 (Repeat-dose (chronic) toxicity) for implementation in the 3 regions by May 2005.

The Steering Committee congratulated the members and the chairman of the Expert Working Group for the successful drafting of 8 VICH Safety Guidelines and their commitment to this difficult task.

The Steering Committee also reviewed a proposal for amending VICH GL 28 (*Studies to evaluate the safety of residues of veterinary drugs in human food: Carcinogenicity testing*) and agreed to release this revised Guideline for a shortened 2 months consultation period at step 4, limited to the additional new text to the Guideline.

The Steering Committee confirmed the restart of the Quality Expert Working Group activities and reviewed the work of the Expert Working Groups on Target Animal Safety, Biologicals Quality Monitoring, Environmental Risk Assessment and Pharmacovigilance.

The Steering Committee agreed on the outline of the agenda for the VICH3 public conference to be held in Washington, D.C. on May 25-27, 2005. The conference will focus on the work of VICH and its accomplishments in achieving greater harmonisation of technical requirements for the registration of veterinary medicinal products in the participating regions: the EU, Japan, the USA, Australia/New Zealand and Canada. The conference will also address VICH's vision for future achievements in 2006-2010.

The 15th meeting of the Steering Committee is scheduled for October 2004 in Berlin, Europe.

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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