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PRESS RELEASE

Important breakthrough at the 17th VICH Steering Committee

The VICH Steering Committee applauded, during its 17th meeting on 1 and 2 November 2005 in Kyoto, Japan, the progress achieved by the Pharmacovigilance Expert Working Group. The Steering Committee endorsed the VICH Draft GL 24 (*Pharmacovigilance of veterinary medicinal products: management of Adverse Event Reports (AERs)),* and VICH Draft GL 42 (*Pharmacovigilance of Veterinary Medicinal Products – Data Elements for Submission of Adverse Event Reports).* The Steering Committee decided appropriate to hold a second public consultation considering the important changes made to these documents. The consultation period for these two Guidelines was set to a minimum 3-months period. These guidelines will be available at: http://vich.eudra.org.

The Steering Committee congratulated the newly formed Expert Working Group on Metabolism and Residue Kinetics for the excellent work achieved in a short time period to produce an interim report on the current situation in the regions and the opportunities for harmonisation. This Expert Working Group's activities will lead to improving consumer safety by harmonising aspects covering residue depletion studies and withdrawal time estimation.

The Steering Committee endorsed 2 further Quality Guidelines for implementation in the regions by November 2006: VICH GL 39 (*Quality (Specifications) - Test Procedures and Acceptance Criteria for new Veterinary Drug Substances and New medicinal Products: Chemical Substances*) and VICH GL 40 (*Quality (Specifications) - Test Procedures and Acceptance Criteria for new Biotechnological/Biological Veterinary Medicinal Products).*

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

The 18th meeting of the Steering Committee is scheduled for 31 May 2005 & 1st June 2006, in London (Europe), which will be the first meeting under Phase II of the VICH process.

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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)
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: Office International des Epizooties/World Animal Health Organisation

INTERESTED PARTY
AVBC: Association of Veterinary Biologics Companies (USA)

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