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PRESS RELEASE

VICH considers its strategy for the next 5 years

At its 24th meeting held in the OIE headquarters in Paris on 23 and 26 June 2010, the VICH Steering Committee laid the foundation for the VICH strategy for the years 2011 to 2015. The priority area that was identified for attention is its global outreach strategy.

The meeting was held around the VICH 4 public Conference during which much of the debate focussed on the wish to learn directly from non-VICH member countries what their needs and expectations are from VICH.

Building on the Conference's outcome, the Steering Committee discussed the proposal for a future strategy on extending the appreciation of VICH activities towards non-VICH countries and regions, "the global outreach strategy". Working closely with OIE, the strategy is directed at wider understanding of VICH standards as part of capacity building in the area of veterinary medicines regulation.

The Steering Committee adopted the draft VICH pharmacovigilance Guideline 35 (*Pharmacovigilance: ESTD - Electronic Standards for Transfer of Data*). The public consultation period will be 6 months.

The Steering Committee also adopted at step 6 and released at step 7 for implementation in the regions the following VICH final Guidelines: VICH GL 30 (*Pharmacovigilance of Veterinary Medicinal Products: controlled list of terms.*) and VICH GL 42 (*Pharmacovigilance: Data Elements for Submission of Adverse Events Reports*).

These three new Guidelines complete the package of Guidelines on pharmacovigilance requirements in the VICH regions, and mark the finalisation of the development of the pharmacovigilance Guidelines.

The Steering Committee agreed to the establishment of an Expert Working Group to develop a Guideline on requirements to establish bioequivalence of veterinary medicinal products.

The Steering Committee reviewed the progress of the Expert Working Groups on Quality, Biologicals Quality Monitoring, Metabolism and Residue Kinetics, Microbiological ADI and Safety.

The 25th meeting of the Steering Committee is scheduled for 23 and 24 February 2011 in Washington DC, USA.

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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)

The Álliance/ÁGCARM: Animal Health Alliance (Australia) Ltd./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: World Organisation for Animal Health

INTERESTED PARTY

AVBC: Association of Veterinary Biologics Companies (USA)

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