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

VICH/11/022 24 February 2011

PRESS RELEASE

VICH adopts Strategy 2011 - 2015

The VICH Steering Committee held its 25th meeting in Washington DC on 23 and 24 February 2011.

The Steering Committee adopted a Strategy covering the next 5 years.

The Steering Committee further discussed ways forward to achieve wider international harmonisation of technical requirements for the registration of veterinary medicinal products and agreed to further develop proposals on how to address the needs and expectations of non-VICH countries. The short term objectives are:

- to improve information, communication and awareness on VICH
- to increase contributions of non-VICH countries in the consultation process of developing VICH guidelines and potential involvement in guideline development in the future.

As a next step, a meeting with certain non-VICH countries/regions will be organised before the next Steering Committee meeting in Tokyo.

The Steering Committee released for implementation in the regions the following VICH final Metabolism and Residue Kinetics Guidelines:

VICH Guideline 46 (*MRK* – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Metabolism Study to determine the Quantity and Identify the Nature of Residues),

VICH Guideline 47 (MRK – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Laboratory Animal Comparative Metabolism Studies),

VICH Guideline 48 (*MRK* – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Marker Residue Depletion Studies to establish Product Withdrawal Periods)

VICH Guideline 49 (MRK – Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Validation of Analytical Methods used in Residue Depletion Studies).

The Steering Committee also released for public consultation the draft revised VICH Safety Guideline 36 (*Safety – Studies to evaluate the safety of residues of veterinary drugs in human food: general approach to establish a microbiological ADI*). The public consultation period will be 6 months and comments can be sent to the VICH secretariat.

These Guidelines and the VICH strategy will be available on the VICH website (www.vichsec.org).

The Steering Committee reviewed and acknowledged the progress of the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation, Quality, Biologicals Quality Monitoring, Safety and Bioequivalence.

The 26th meeting of the Steering Committee is scheduled for 16 and 17 November 2011 in Tokyo, 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: 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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