



PRESS RELEASE

VICH Outreach initiative gains momentum

The 4th meeting of the VICH Outreach Forum, co-chaired by VICH and the OIE, was held, in conjunction with the 30th VICH Steering Committee meeting, in Brussels from 23 to 26 June 2014.

Representatives from 6 continents participated actively in the meeting. ASEAN (Association of Southeast Asian Nations), Morocco and Russia presented updates on their approach to the implementation of VICH guidelines. The positive feedback on the value of the VICH guidelines marked a milestone in the progress and momentum of the Outreach initiative. The Tanzania Food and Drug Authority attended as a guest and gave a presentation to the Forum on the East African Community Medicines Regulatory Harmonisation project.

The Steering Committee, the OIE and the Forum participants considered strategies to improve the implementation of VICH Guidelines in Outreach Forum member countries and regions. Extensive discussion focused on means of training and communication to enhance the VICH Outreach initiative.

The Steering Committee worked on the programme for the 5th VICH Public Conference that will take place in Tokyo, Japan on 28 & 29 October 2015. This public conference will focus on the VICH Outreach initiative, the activities of the Expert Working Groups as well as the future of VICH.

Based on the achievements of the VICH Phase III strategy, the Steering Committee initiated the development of the Phase IV strategy for the years 2016 to 2020.

The Steering Committee welcomed the progress of the Task Force on the revision of VICH Stability GL 3(R) (*Stability testing of new drug substances and products*), considering the addition of climatic zones. The Task Force on a VICH Guidance for Efficacy Studies for Combination Drug Products reported on the diversity of combination products in different regions of the world. The Steering Committee is expected to decide at the next meeting on the development of guidelines in these two areas. These Task Forces are composed of experts from both VICH and the Outreach Forum regions.

The SC took note of progress on the following VICH guidelines:

- Draft VICH GL 52 (*Bioequivalence: Blood Level Bioequivalence Study*) by the Bioequivalence Expert Working Group
- Draft VICH GL 53 (*Electronic File Format - Electronic Exchange of Documents: File Format Requirements*) by the Electronic File Format Expert Working Group

- Revision of VICH GL 23 (*Studies to evaluate the safety of residues of veterinary drugs in human food: genotoxicity testing*) by the Safety Expert Working Group.

All VICH Draft and Final guidelines are available on the VICH website (www.vichsec.org).

The Steering Committee also reviewed and acknowledged the progress of the work of the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation, Quality, Biologicals Quality Monitoring, and Metabolism and Residue Kinetics.

The 31st VICH Steering Committee meeting and the 5th VICH Outreach Forum meeting are scheduled to take place between 23 and 26 February 2015 in Washington DC, USA.

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: Japan Veterinary Products Association

OBSERVERS

Australia/New Zealand: Australian Pesticides and Veterinary Medicines Authority (APVMA)/New Zealand Ministry for Primary Industries

AMA/AGCARM: Animal Medicines Australia/Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand

Canada: Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian Centre for Veterinary Biologics (CCVB)

CAHI: Canadian Animal Health Institute

South Africa: Department of Agriculture, Forestry and Fisheries (DAFF) and Department of Health

SAAHA: South African Animal Health Association

ASSOCIATE MEMBER

OIE: World Organisation for Animal Health

INTERESTED PARTY

AVBC: Association of Veterinary Biologics Companies, USA

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