



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

VICH/15/030  
26 February 2015

## ***PRESS RELEASE***

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### **5<sup>th</sup> VICH Public Conference - Reaching Out to the World**

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The programme of the 5<sup>th</sup> VICH Public Conference, which will be held in Tokyo, Japan on 28 & 29 October 2015, was finalized during the 31<sup>st</sup> VICH Steering Committee meeting. Under the theme, *Reaching Out to the World*, the following key topics of the programme include: the contribution of VICH to the global One Health approach, the contribution of VICH to animal welfare in tests for veterinary medicinal products and the benefits of the VICH Outreach Forum to all countries.

The 5<sup>th</sup> meeting of the VICH Outreach Forum, co-chaired by VICH and the OIE, took place in conjunction with the Steering Committee meeting from 23 to 26 February in Washington DC. The Forum members from 6 continents participated actively in the meeting, where the OIE reported on their activities concerning veterinary medicinal products since the last VICH Outreach Forum, and representatives from ASEAN, CAMEVET and China reported on the application of VICH guidelines in their regions.

The Steering Committee, the OIE and the Forum participants considered strategies to improve the application of VICH guidelines in Outreach Forum member countries and regions. Extensive discussions focused on pharmacovigilance, bioequivalence and waiving of target animal batch safety testing as well as GLP/GCP guidance.

The Steering Committee finalized the training and communication strategy which outlines the training on VICH guidelines in two levels: level 1 covers the general understanding of VICH and the guidelines, level 2 will consider training modules on specific guidelines. The material on the first level training will be placed on the VICH website. The Steering Committee continues to work on the challenges posed by implementation of the second level.

The Steering Committee mandated the Quality Expert Working Group to develop guidance on stability testing in the climatic zones III and IV.

The Steering Committee reviewed the discussion papers prepared by the Task Forces on combination products and on the revision of the VICH anthelmintic guidelines, and will consider driving these topics forward at the next Steering Committee meeting.

The Steering Committee adopted final VICH GL 53 (*Electronic File Format - Electronic Exchange of Documents: File Format Requirements*) for implementation in the VICH regions by February 2016.

All VICH draft and final guidelines are available on the VICH website ([www.vichsec.org](http://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, Safety, Bioequivalence, Biologicals Quality Monitoring, and Metabolism and Residue Kinetics.

The 32<sup>nd</sup> VICH Steering Committee meeting and the 6<sup>th</sup> VICH Outreach Forum meeting are scheduled to take place between 25 and 30 October 2015 in Tokyo, Japan in conjunction with the 5<sup>th</sup> VICH Public Conference.

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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:** 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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