

PRESS RELEASE

Tokyo Agreement - VICH reaches out to other countries

At the 26th VICH Steering Committee meeting held in Tokyo from 14 to 17 November 2011 a milestone was reached with the formation of the VICH Outreach Forum, in partnership with OIE. This Forum will enable further countries to participate in VICH activities and obtain in the future substantial benefits of wider harmonisation.

The Forum will be held in conjunction with future VICH Steering Committee meetings and offer opportunities for wider international harmonisation of regulatory requirements, improve information exchange and raise awareness of VICH Guidelines in other countries and regions.

VICH has been listening closely to the requests and needs of countries around the world and initiated a one day contact meeting on 15 November in Tokyo, supported by OIE. Delegates from 11 countries and 3 regional organisations (UEMOA, ASEAN and Camevet) discussed with the VICH Steering Committee the possibilities of extending VICH activities and Guidelines to other countries and regions. The Steering Committee consequently agreed to create the Outreach Forum.

Dr Sakai, chairman of the 26th Steering Committee meeting stated: “This major VICH initiative sends out a clear message that VICH has value to offer to the global community and the Outreach Forum now established will enable wider engagement in our activities. With OIE already offering tangible resources to countries for building their capacity on technical requirements for the regulation of Veterinary Medicinal Products, this new VICH Outreach Forum will complement the work of OIE by raising awareness on the options available for the use of existing and future VICH Guidelines.”

The Steering Committee released for public consultation the draft VICH Biologicals GL 50 (*Biologicals: TABST - Harmonization of criteria to waive target animal batch safety testing (TABST) for inactivated vaccines for veterinary use*) and draft VICH Quality GL 51 (*Quality: Statistical evaluation of stability data*) for a 6 months consultation period.

The draft VICH Biologicals GL 34 (*Biologicals: Mycoplasma - Test for the detection of Mycoplasma contamination*) was released for a second shorter public consultation period of 3 months.

These Guidelines will be available on the VICH website (www.vichsec.org) and comments can be sent to the VICH secretariat.

The Steering Committee noted further that the revision of VICH GL 36 (*Safety – microbiological ADI: Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI*) is near to finalisation and will be published for implementation in the regions in the near future.

The Steering Committee initiated the development of a VICH GL on Metabolism and Residue Kinetics in fish.

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

The 27th Steering Committee meeting and the inaugural Outreach Forum meeting are scheduled between 25 and 28 June 2012 in Brussels, Europe.

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 Ministry of Agriculture and Forestry

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 Centre for Veterinary Biologics (CCVB)

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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