

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

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## PRESS RELEASE

## 6<sup>th</sup> VICH public conference in February 2019

The VICH, a trilateral cooperation programme between the EU, Japan and the USA, came together for its 35<sup>th</sup> Steering Committee and 9<sup>th</sup> VICH Outreach Forum (VOF) meetings, to further the harmonisation of technical requirements for the registration of Veterinary Medicinal Products (VMPs). The meetings were held from 13 to 16 November 2017 in Tokyo, Japan.

The Steering Committee updated the programme for the 6<sup>th</sup> VICH Public Conference that will now be held on 27 & 28 February 2019 in Cape Town, South Africa, a VICH Observer member country. The public conference will showcase the work of VICH to delegates from all regions of the world, and will provide a particular opportunity to attract regulators and industry representatives from the African continent. It will provide insights into the VICH global outreach activities, as well as the current work achieved by the VICH Expert Working Groups.

The Steering Committee, the OIE and the VOF members participated in the 9<sup>th</sup> VICH Outreach Forum meeting. Harmonisation and collaboration were the key topics of this meeting where CAMEVET and ASEAN reported on their members' efforts to harmonise the technical requirements for the registration of VMPs, often based on the VICH requirements. The EU described how the 28 EU Member Countries collaborate for the evaluation of VMPs.

The participants received feedback from VOF members on the degree of implementation of pharmacovigilance systems in Outreach Forum member countries, and insights on plans to improve the reporting of adverse events in their countries.

Further discussions focused on antimicrobial resistance in relation to VICH Guideline 27 and Thailand introduced its processes for the regulation of autogenous vaccines.

Nigeria and Zimbabwe participated for the first time in the VOF and presented their national registration systems.

The participants also discussed extensively the registration requirements for vaccines and how the VICH Guidelines on biologicals are applied.

The Steering Committee noted that the draft Guideline on residues in aquatic species will soon be signed off by the Metabolism and Residue Kinetics Expert Working Group and ready for a 6 months public consultation period. The Steering Committee was also informed that the

new EWG on Combination products Guideline, chaired by the People's Republic of China VOF member, had started its work.

The Steering Committee reviewed and acknowledged the progress of the work of the Expert Working Groups on Electronic Standards Implementation (Pharmacovigilance), Safety, Quality, Biologicals Quality Monitoring and Anthelmintics.

All VICH draft and final Guidelines are available on the VICH website (www.vichsec.org).

The 36<sup>th</sup> VICH Steering Committee meeting and the 10<sup>th</sup> VOF meeting are scheduled to take place between 25 and 28 June 2018 in Bruges, Belgium.

The 37<sup>th</sup> VICH Steering Committee meeting and the 11<sup>th</sup> VOF meeting are scheduled to take place, in conjunction with the VICH 6 public conference, between 24 February and 1<sup>st</sup> March 2019 in Cape Town, South Africa.

JMAFF: Japanese Ministry of Agriculture, Forestry and Fisheries

AHI: US Animal Health Institute

ASSOCIATE MEMBER **OIE:** World Organisation for Animal Health

INTERESTED PARTY **AVBC:** Association of Veterinary Biologics Companies, USA

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MEMBERS OF THE STEERING COMMITTEE

EU: European Commission - European Medicines Agency

**USA:** US Food & Drug Administration (FDA) – Center for Veterinary Medicine (CVM) and US Department of Agriculture – Center for Veterinary Biologics (USDA/CVB)

AnimalhealthEurope: representing the European Animal Health Industry JVPA: Japan Veterinary Products Association

OBSERVERS

Australia: Australian Pesticides and Veterinary Medicines Authority (APVMA)
New Zealand: New Zealand Ministry for Primary Industries
AMA: Animal Medicines Australia
AGCARM: 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
SAHA: South African Animal Health Association