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

VICH/21/086

PUBLIC STATEMENT

VICH progress acknowledged

Brussels, 19 November 2021.

Notwithstanding the continuing pandemic and its complications, the work program of VICH has progressed, as was acknowledged by the VICH Steering Committee members who met for the second year in on-line virtual meetings to review and guide the VICH activities.

VICH promotes the establishment of safe and effective veterinary medicinal products across the world through wider international harmonisation of technical requirements for the registration of veterinary medicinal products. The 40th VICH Steering Committee, chaired by the European Medicines Agency, and 14th VICH Outreach Forum (VOF) annual meetings took place by videoconference from 15 to 18 November 2021.

Over 70 participants representing 18 national regulatory agencies or animal health industry organisations from six continents took part in the 14th meeting of the VOF, chaired by the OIE. The VOF members took note of updates on VICH activities and related OIE activities, and received an on-line overview of the regulatory control of autogenous vaccines in the VICH regions.

VOF members were offered access to several training presentations on Environmental Impact Assessment (EIA) for Veterinary Medicinal Products and the implementation of VICH Guidelines (GLs) on EIAs for Veterinary Medicinal Products (GL 6 and GL38). The trainings were prepared by the EU, Japan and the USA. A follow up virtual meeting with VICH experts to address technical questions from VOF members will be organised in early 2022. This training material has been added to the training section available on the VICH website www.vichsec.org.

The VICH Steering Committee reviewed at step 3 of the VICH process the draft second revision of VICH GL18 (Quality) *Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients)* which will shortly be released for a 6 months consultation period at step 4.

Existing VICH GLs are reviewed every five years. In line with the ongoing VICH monitoring process, the Steering Committee reviewed 18 GLs. No GLs were considered for immediate revision, but the Steering Committee noted several GLs where future revision may be warranted when space will be available in the workplan.

The VICH Steering Committee adopted the Concept Paper *for the adoption of ICH Q8: Pharmaceutical Development* and mandated the Expert Working Group on Quality to begin the work on a new draft VICH Guideline.

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The Steering Committee monitored the progress of the Expert Working Groups on Biologicals, Pharmacovigilance, Safety, Metabolism and Residue Kinetics, Combination Products, Bioequivalence, Anthelmintics and Medicated Premixes.

The Steering Committee extended thanks to Dr. Xu from China, who will be stepping down from his role as Chair of the Combination Products EWG. Similarly, the Steering Committee commended the Expert Working Groups for their continued tenacity and work on these important harmonization efforts.

The Steering Committee is discussing how to make the VICH process more inclusive and transparent. A dedicated Task Force will reflect on the next steps and feed back to the Steering Committee. Switzerland will be invited as a guest to the 41st VICH meeting.

The 41st VICH Steering Committee and 15th VOF meetings are scheduled for 14 - 17 November 2022 in the USA, planned to be held as in-person meeting again.

About VICH:

VICH is a trilateral cooperation programme among the European Union, Japan and the United States of America driving the harmonisation of technical requirements for the registration of Veterinary Medicinal Products.

All VICH draft and final Guidelines are available on the VICH website. The translations of several VICH Guidelines are available on the website of OIE at: https://www.oie.int/scientific-expertise/veterinary-products/vich-outreach-forum/.

MEMBERS OF THE STEERING COMMITTEE
EU: European Commission - European Medicines Agency (EMA)
Japan: Ministry of Agriculture, Forestry and Fisheries (JMAFF)
USA: US Food & Drug Administration (FDA) – Center for Veterinary Medicine (CVM) and US Department of Agriculture (USDA) – Center for Veterinary Biologics (CVB)
AHI: US Animal Health Institute
AnimalhealthEurope: representing the European Animal Health Industry
JVPA: Japan Veterinary Products Association

OBSERVERS
Australia: Australian Pesticides and Veterinary Medicines Authority (APVMA)
AMA: Animal Medicines Australia
New Zealand: Ministry for Primary Industries (MPI)
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 South African Health Products Regulatory Authority (SAHPRA)
SAAHA: South African Animal Health Association
VMD: Veterinary Medicines Directorate – the UK
NOAH: National Office of Animal Health **-** representing the UK Animal Health Industry

ASSOCIATE MEMBER
OIE: World Organisation for Animal Health

INTERESTED PARTY
AVBC: Association of Veterinary Biologics Companies, USA

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