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

VICH/26/059

PUBLIC STATEMENT

Regulators and industry further advance VICH activities

Tsukuba, Japan, 19 November 2026.

Animal health regulatory experts from around the world came together in Tsukuba, Japan. VICH promotes safe and effective veterinary medicinal products worldwide by harmonising international technical registration requirements. The 45th VICH Steering Committee and the 19th VICH Forum (VF) annual meetings took place on 16 to 19 November with the Director General of the National Veterinary Assay Laboratory, Japanese Ministry of Agriculture, Forestry and Fisheries, chairing the Steering Committee and the World Organisation for Animal Health (WOAH) leading the Forum.

The Steering Committee meeting resulted in several notable milestones and accomplishments, including:

- **Adoption of the Concept Paper for the revision of VICH MRK GL 57** *(Residues in Fish - Studies to evaluate the Metabolism and Residue Kinetics of veterinary drugs in food-producing species: Marker residue depletion studies to establish product withdrawal periods in aquatic species)*
- **Adoption of the revised VICH Quality GL 8** (*Stability testing for medicated premixes*)
  This Guideline was released for implementation in the VICH regions by November 2027.
- **Review of 19 VICH Guidelines in accordance with the maintenance requirement ensuring that the VICH GLs remain up to date**.

The Steering Committee reviewed progress across nine Expert Working Groups (EWGs), including Quality, Biologicals, Bioproduct Safety, Pharmacovigilance, Metabolism and Residue Kinetics, Combination Products, Bioequivalence, Medicated Premixes and Global Regulatory Dossier Framework (GRDF) for veterinary medicinal products.

The Steering Committee noted that VICH revised GL 49 *(Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Validation of Analytical Methods used in Residue Depletion Studies)* was recently circulated for public consultation, and further noted that VICH GL 61 (*Pharmaceutical Development*) was recently released for implementation by the VICH regions.

The Steering Committee expressed strong appreciation and gratitude to the EWGs for their continued and efficient work in advancing global harmonisation.

The 19th VF meeting brought together 19 participants from 11 national regulatory agencies and one regional organisation representing 8 countries.

The participants in the VF pre-meeting noted that the implementation of VICH guidelines in the VF countries is challenging and variable. The ongoing development of the VICH Forum network was welcomed. The meeting was concluded by listing suggested subjects for discussion at the 20th VF meeting.

VF members received updates on VICH activities and on the progress of the VICH EWGs, as well as an overview of the status of VICH guidelines in development and under revision.

Regulators from the EU, Japan, USA and industry representatives provided an overview of their approaches to *in vitro* batch potency tests for veterinary vaccines and the VF members outlined the major regulatory challenges and barriers to implementation.

Regulators provided an overview of the existing regulatory pathways for innovation and new technologies, and industry provided its perspective on preparing for these products. The VF members shared knowledge and experiences on this topic.

The VICH Steering Committee decided to invite VF Partners' experts to join the VICH EWG on Metabolism and Residue Kinetics which will start reviewing VICH GL 57.

VF members were reminded that training materials and VICH resources are available online at www.vichsec.org.

The 46th VICH Steering Committee meeting and the 20th VF meeting will be held in Gent, Belgium, from 15 to 18 November 2027.

About VICH

VICH is an international cooperation programme 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 WOAH at: VICH Forum - WOAH - World Organisation for Animal Health.

Founding 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**: Animal Health Institute representing the United States animal health industry
- **AnimalhealthEurope**: Representing the European animal health industry
- **JVPA**: Japan Veterinary Products Association representing the Japanese animal health industry

Standing Members

- **Australia**: Australian Pesticides and Veterinary Medicines Authority (APVMA)
- **AMA**: Animal Medicines Australia, representing the Australian animal health industry
- **New Zealand**: Ministry for Primary Industries (MPI)
- **APHANZ**: Animal and Plant Health New Zealand representing the New Zealand animal health industry
- **Canada**: Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian Food Inspection Agency - Canadian Centre for Veterinary Biologics (CCVB)
- **CAHI**: Canadian Animal Health Institute representing the Canadian animal health industry
- **South Africa**: Department of Agriculture (DOA) and South African Health Products Regulatory Authority (SAHPRA)
- **SAAHA**: South African Animal Health Association representing the South African animal health industry
- **UK**: Veterinary Medicines Directorate (VMD)
- **NOAH**: National Office of Animal Health - representing the United Kingdom animal health Industry

Associate Member

- **WOAH**: World Organisation for Animal Health

Observer Member

- **Switzerland**: Swiss Agency for Therapeutic Products (Swissmedic)
- **Scienceindustries**: Business Association Chemistry Pharma Life Sciences, representing the Swiss animal health industry
- **Republic of Korea**
- **Brazil**

Interested Party

- **AVBC**: Association of Veterinary Biologics Companies, USA

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