



PUBLIC STATEMENT

Regulators and industry further advance VICH activities

Indianapolis, Indiana, USA, 13 November 2025.

Animal health regulatory experts from around the world gathered in Indianapolis, Indiana, USA.

VICH promotes safe and effective veterinary medicinal products worldwide by harmonising international technical registration requirements. The 44th VICH Steering Committee and the 18th VICH Forum (VF) annual meetings took place on 10-13 November with the U.S. Food and Drug Administration (FDA) 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 47**
(Comparative Metabolism Studies - Studies to evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-producing Animals: Comparative Metabolism Studies in Laboratory Animals)
- **Adoption of changes to VICH Safety GL 33** *(General approach to testing - Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to testing)* and to **VICH Biologicals GL 34** *(Mycoplasma - Testing for the Detection of Mycoplasma Contamination)*
- **Adoption of the VICH Priorities for the next 5 years** (2026 to 2030).

The Steering Committee reviewed progress across nine Expert Working Groups (EWGs), including Quality, Biologicals, Pharmacovigilance, Safety, Metabolism and Residue Kinetics, Combination Products, Bioequivalence, Medicated Premixes and Global Regulatory Dossier Framework (GRDF) for veterinary medicinal products. Three VICH draft guidelines were recently circulated for public review: VICH Quality GL 60 (*GMP for API: Good Manufacturing Practice for Active Pharmaceutical Ingredients used in Veterinary Medicinal Products*), VICH Quality GL 61 (*Pharmaceutical Development for veterinary medicinal products*), and VICH Biologicals GL 62 (*Biologicals: Target Animal Safety Evaluation for Veterinary Monoclonal Antibody Products*). The Steering Committee noted that the experts are reviewing the public comments received and that this work is nearing completion, with the final revised guidelines expected to be circulated and implemented next year. The Steering Committee also noted that revised VICH GL 22 and 23 were released for implementation.

The Steering Committee expressed appreciation to the EWGs for their continued efficient work advancing harmonisation efforts.

The 18th VF meeting brought together 20 participants from 11 national regulatory agencies or animal health industry organisations across 5 continents, plus one international organisation representing 7 countries.

The VF pre-meeting agreed to establish an active network to encourage member interaction, discussed the challenges linked to the implementation of the VICH guidelines and received feedback from the WOAHA Wildlife Group on veterinary medicine availability and appropriate use of VMPs in wildlife, an important One Health topic. The meeting was concluded listing potential subjects for discussion at the 19th VF meeting.

VF members received updates on VICH activities, WOAHA work streams, and the status of VICH guidelines in development and under revision. The meeting featured detailed bioequivalence training from the VICH Bioequivalence EWG Chairperson and regulatory process overviews from the EU, Japan and the USA representatives concerning veterinary biological products. Participants discussed challenges linked to the registration of biological and immunological veterinary products. VF members were reminded that training materials and VICH resources are available online at www.vichsec.org.

The VICH Steering Committee invited VF Partners' experts to join the newly created VICH EWG on GRDF for veterinary medicinal products which has recently begun its work.

The 45th VICH Steering Committee meeting and the 19th VF meeting will be held in Japan from 16 to 19 November 2026.

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 WOAHA at: [VICH Forum - WOAHA - 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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