



## ***PUBLIC STATEMENT***

---

### **Regulators & Industry convene to envision the future of VICH**

---

*Amsterdam, the Netherlands, 15 November 2024*

Over 179 representatives from regulatory agencies and industry convened in Amsterdam on 13–14 November for the 7<sup>th</sup> VICH public conference at the European Medicines Agency. The event theme, “VICH and a New Era,” brought together leaders to address pressing challenges and develop strategies aimed at enhancing global access to veterinary medicinal products. Key topics included regulatory convergence, international cooperation, and the need for efficient, streamlined registration processes to meet rising global demand and challenges for use of veterinary products.

The conference underscored VICH's commitment to harmonizing technical requirements, thus supporting the global availability of safe and effective veterinary medicinal products. This public event was held in parallel with the 43<sup>rd</sup> VICH Steering Committee and the 17<sup>th</sup> VICH Forum (VF) meetings. Chaired by the European Union, the Steering Committee welcomed the first visiting delegations from Botswana, the Republic of Korea, and Saudi Arabia, who joined the SC meeting as observers. Several notable milestones and actions were achieved during the meetings, including:

- **Recognition of the Anthelmintics Expert Working Group (EWG)** for successfully completing revisions of nine (9) Anthelmintics Guidelines (GLs). This EWG has now adjourned after completing its objectives.
- **Approval of the draft revision of VICH GL 8(R) (Stability Testing for Medicated Premixes)** at Step 3, initiating a six-month public consultation period.
- **Adoption of a concept paper** to establish a Global Regulatory Dossier Framework for veterinary medicinal products, leading to the formation of a new EWG focused on developing a VICH Guideline for this framework.
- **Acknowledgment of significant progress across multiple EWGs** working in areas such as Quality, Biologicals, Pharmacovigilance, Safety (Toxicology), Metabolism and Residue Kinetics, Combination Products, Bioequivalence, and Medicated Premixes.

Significant progress is expected to continue in the coming year. The consultation period for the draft VICH Quality GL 61 (*Pharmaceutical Development for Veterinary Medicinal Products*) has ended. Following a review by the experts, the finalized guideline will be prepared for implementation in the coming year. Additional draft guidelines are anticipated to progress to public consultation expected in the coming months. The Steering Committee extended its gratitude to the existing EWGs for their sustained dedication to advancing global harmonization.

The VF meeting, chaired by the World Organisation for Animal Health (WOAH), hosted 58 participants from 21 regulatory agencies across five continents and one international organization representing seven countries. VF members participated in a pre-meeting session focused on VICH Guideline implementation and broader challenges beyond VICH's current scope. Members received updates on a self-assessment tool for veterinary medicine regulators and the status of VICH guidelines in development or revision. Presentations from Australia, Canada, the EU, Japan, the USA, and industry highlighted strategies to meet unmet animal health needs, with discussions covering expedited processes for Minor Uses Minor Species (MUMS) treatments and the accessibility to Veterinary Medicinal Products.

The 44<sup>th</sup> VICH Steering Committee and the 18<sup>th</sup> VF meetings are scheduled for 10–13 November 2025 in Indianapolis, Indiana, USA.

---

### 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
- **VMD:** Veterinary Medicines Directorate – the UK
- **NOAH:** National Office of Animal Health - representing the United Kingdom animal health Industry

#### **Associate Member**

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

#### **Observer Member**

- **Swissmedic:** Swiss Agency for Therapeutic Products
- **Scienceindustries:** Business Association Chemistry Pharma Life Sciences, representing the Swiss animal health industry

#### **Interested Party**

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

For further information, please contact:

**VICH Secretariat (Hervé Marion, DVM)**

c/o HealthforAnimals, Rue d'Idalie 9–13, Box 5, B-1050 Brussels, Belgium

Email: [sec@vichsec.org](mailto:sec@vichsec.org)

Website: [www.vichsec.org](http://www.vichsec.org)