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

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Draft 3

VICH PRIORITIES
Phase 6: 2026-2030

1. History

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is an international program providing guidance on technical requirements for veterinary medicinal product registration. VICH was established in 1996 to facilitate collaboration between the regulatory authorities and animal health industry of the founding members, the EU, Japan, and USA. VICH continues to grow with active participation from regulatory authorities and animal health industry of the standing and observer members (https://vichsec.org/about/vich-structure/). VICH was created under the auspices of the World Organisation for Animal Health (WOAH) which continues to participate as an associate member to support and disseminate the VICH outcomes globally.

The VICH Forum provides a basis for wider international harmonisation of registration requirements beyond the VICH founding, standing, and observer members. The Forum enhances information exchange and awareness of VICH guidelines to facilitate their wider use. The VICH Forum currently includes regulatory representatives from more than 20 countries or regional organisations.

This document outlines VICH's Phase 6 priorities (2026 – 2030).

2. The scope of VICH

VICH covers veterinary medicinal products, including pharmaceuticals, biologicals (vaccines and other biological products) and medicated premixes. VICH guidelines establish harmonised technical requirements for registration of new veterinary medicinal products and post-marketing surveillance.

3. Drivers behind the priorities for VICH phase 6

The drivers for VICH phase 6 include:

- The need to develop new and maintain current VICH guidelines to establish internationally acceptable technical requirements for registration of veterinary medicinal products that ensure high standards of public health, animal health, and environmental safety, in line with "One Health" principles.
- The desire to expand VICH's geographical reach through fostering VICH Forum activities, increasing awareness of VICH, and encouraging use and reference to the guidelines in national registration systems.

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- The need to increase involvement of VICH Forum members and WOAH Member Countries in development of guidelines and concept papers.
- The desire to foster effective cooperation with WOAH, particularly supporting WOAH's strategic focus on good governance of veterinary medicinal products within which WOAH refers to VICH as the reference body for technical requirements for registration.
- The drive to internationally harmonize technical requirements for veterinary medicinal product regulation to minimize disease impact through availability of safe and effective veterinary medicinal products.
- The need to reduce animal use in veterinary medicinal product registration by eliminating duplicative studies in each region and promoting harmonized testing strategies that replace, refine, and reduce animal testing.
- The need to contribute to international efforts to address antimicrobial resistance by promoting access to effective antimicrobial agents and developing guidance on technical requirements for registration of veterinary medicinal products that prevent or minimize factors that select for antimicrobial resistance.
- The need for resource efficiency for both regulatory authorities and industry while ensuring effective regulatory systems for product registration through harmonized technical requirements, including globally aligned principles of pharmacovigilance, that increase consistency and predictability of requirements and outcomes, lower overall cost and delays, and facilitate acceptance of data and assessments between regulatory authorities.
- The desire to minimize registration costs to facilitate market entry and improve access to quality, effective, and safe veterinary medicinal products.
- The opportunity to leverage ICH[1] guidelines, procedures, and experience to develop VICH guidelines and processes whenever possible.

4. Priorities for the period 2026-2030

VICH will **continue** the following key activities:

- Establish guidelines on harmonised technical requirements for veterinary medicinal products considering need, feasibility and resources required.
- Update guidelines through periodic reviews to incorporate new scientific knowledge, experience, and other needs, where required.
- Foster collaboration with WOAH to support international harmonization and WOAH's strategic activities on good governance of veterinary medicinal products in WOAH member countries.
- Contribute to international efforts to minimize antimicrobial resistance risks by considering responsible/prudent use principles when developing and revising guidelines.
- Contribute to international efforts to promote application of the principles of Reduction, Replacement, and Refinement (3Rs) in veterinary medicinal product development by developing animal testing/alternative guidelines and sharing them with Forum members.

[1] ICH – International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human use

- Identify opportunities to leverage ICH experience to develop VICH guidelines and procedures, including emerging regulatory science areas such as real world evidence, big data, and artificial intelligence.
- Progress mutual understanding of evolving technical requirements and solutions for pharmacovigilance reporting to achieve greater harmonization and efficiency in global adverse event reporting and monitoring.

VICH will continue **expanding** activities in the following areas:

- Progress international harmonization of technical requirements by fostering VICH Forum activities and promoting wider dissemination and acceptance of VICH guidelines.
- Consider VICH Forum countries' needs and priorities for technical requirements for the registration of veterinary medicinal products and evaluate how VICH can best support them.
- Develop or adapt guidance on technical requirement for registration of veterinary novel therapy products of greatest strategic importance to VICH.
- Enhance collaboration between PIC/S veterinary working group and VICH to support international GMP alignment and efficiency.