



VICH PRIORITIES **Phase 5: 2021-2025**

1. History

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is an international program to provide guidance on technical requirements for registration of veterinary medicinal products. VICH was established in 1996 as a means of collaboration primarily between the regulatory authorities and the animal health industry of the EU, Japan and the USA. The regulatory authorities and animal health industry of Australia, New Zealand, Canada and South Africa also participate actively as VICH observer members. The World Organisation for Animal Health (OIE) participates as an associate member in the VICH process aiming to support and disseminate the outcomes at a worldwide level.

The VICH Outreach Forum provides a basis for wider international harmonisation of registration requirements beyond the VICH member and observer regions and countries. The Forum aims to improve information exchange and raise awareness of VICH and understanding of VICH guidelines, thereby facilitating their wider use. The VICH Outreach Forum currently includes representatives from the regulatory authorities of 20 countries or regional organisations.

This document sets out VICH's priorities for its 5th phase (2021 – 2025).

2. The scope of VICH

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

3. Drivers behind the priorities for VICH phase 5

The drivers for VICH phase 5 include:

- The need to produce new, and to monitor and keep up-to-date existing, VICH guidelines by establishing internationally acceptable technical requirements for registration of veterinary medicinal products that ensure high standards of public and animal health as well as environmental safety, in line with “One Health” principles wherever appropriate.
- The desire to expand the geographical reach of VICH through fostering the activities of the VICH Outreach Forum thereby extending awareness of VICH, promoting uptake of its guidelines and encouraging reference to them in national systems of registration.

- The need to involve more closely the VICH Outreach Forum members, including the OIE Member Countries' representatives and their respective national Focal Points for Veterinary Products, in the development of Guidelines and Concept Papers for new topics.
- The desire to foster effective cooperation with the OIE, particularly with regard to the OIE's strategic focus on promoting good governance of veterinary medicinal products which provides the framework within which OIE member countries can apply the technical requirements established in VICH guidelines. In this context, the OIE refers to VICH as the reference body regarding the technical requirements for registration of veterinary medicinal products and related scientific aspects.
- The drive to harmonise technical requirements for the regulatory control of veterinary medicinal products at an international level so as to minimise the impact of diseases that can be controlled through appropriate treatment with safe and effective veterinary medicines.
- The need to reduce the use of animals in the registration of veterinary medicinal products by eliminating the need for repetition of studies in each region and fostering the uptake of harmonised testing strategies that are accepted in all regions and that replace, refine and reduce animal testing.
- The need to recognise that antimicrobial resistance is a global human and animal health threat and that VICH can contribute to the international efforts to combat antimicrobial resistance by promoting access to effective antimicrobial agents and by producing guidance on technical requirements for the registration of veterinary medicinal products that aim to prevent or minimise factors that select for antimicrobial resistance in humans and animals.
- The need for efficient use of resources, within both regulatory authorities and the veterinary medicinal products industry, while ensuring the effectiveness of regulatory systems. In this context harmonised technical requirements and study protocols facilitate the registration process across different countries and/or regions by increasing the consistency of data requirements and the predictability of applied technical requirements and reduce variability of outcome, the occurrence of delays and overall costs of the process. Furthermore, harmonised technical requirements and study protocols facilitate the comparison and acceptance of data and assessments between national or regional regulatory authorities.
- The desire to minimise the cost of gaining registration and thereby facilitating new veterinary medicines entering the market and improving access to quality assured, effective and safe veterinary medicinal products.
- The opportunity to benefit from ICH¹ guidelines and procedures, using ICH experience in the development of VICH guidelines and processes whenever possible.

4. Priorities for the period 2021-2025

VICH will **continue** the following key activities

- Establish guidelines on harmonised technical requirements for veterinary medicinal products considering need, feasibility and resources required.

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

- Update or revise guidelines, where required, in light of new scientific knowledge, experience gained or other needs arising following a systematic and periodic review process.
- Foster the already close collaboration with OIE as a pre-requisite to successful implementation of the wider objective of international harmonisation. VICH will support the strategic activities of OIE that are targeted at good governance of veterinary medicinal products in OIE member countries.
- Contribute to the international efforts to minimise the risks of antimicrobial resistance by generally considering the principle of responsible / prudent use of veterinary antimicrobial agents when developing / revising technical guidelines for the registration of veterinary medicinal products.
- Contribute to the international efforts to promote the appropriate application of the principles of Reduction, Replacement and Refinement (3Rs) in the use of animals for veterinary medicinal product development and testing by further developing animal testing / alternative guidelines in accordance with the 3R principles and conveying them along with the present VICH guidelines to Outreach Forum members through VICH training initiative.
- Identify opportunities to benefit from ICH experience in the development of the VICH guidelines and procedures.
- Progress the mutual understanding of the evolution of the technical requirements and technical solutions for pharmacovigilance reporting to achieve greater harmonisation and efficiency in global reporting and monitoring of adverse events.

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

- Progress the objective of wider international harmonisation of technical requirements, in particular to foster the VICH Outreach Forum activities, and to promote wider dissemination and acceptance of VICH guidelines.
- Consider the needs and priorities of non-VICH countries in relation to technical requirements for the registration of veterinary medicinal products and evaluate how VICH can best support those needs.
- Progress the development of, or adapt, guidance on registration requirements for veterinary novel therapy products considered of greatest strategic importance to VICH.