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VICH Training Strategy
(Proposal to VICH Steering Committee)

Introduction

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a collaboration instituted between the regulatory authorities and the animal health industries of the European Union, the United States of America and Japan as members; Australia, New Zealand, Canada, the UK and South Africa's regulatory authorities and animal health industries as observers and the World Organisation for Animal Health (WOAH) as associated member. The aim of VICH is to harmonise technical requirements for registration of Veterinary Medicinal Products (VMPs) as well as for post marketing surveillance (pharmacovigilance).

The objectives of VICH are to:

- Establish and implement harmonised technical requirements for VMPs in the VICH regions, which meet high quality, safety and efficacy standards and minimise the use of test animals and costs of product development
- Provide a basis for wider international harmonisation of registration requirements
- Monitor and maintain existing VICH guidelines, taking particular note of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use's (ICH) work programme and, where necessary, update these VICH guidelines
- Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following the implementation of VICH guidelines
- By means of a constructive dialogue between regulatory authorities and industry, provide technical guidance enabling response to significant emerging global issues and science that impact on technical requirements within the VICH regions

Background to the formation of the VICH Forum

The VICH Organisational Charter states that "over and above its mandate of establishing and implementing harmonised technical requirements for VMPs in the VICH regions, the VICH programme aims to work towards providing a basis for wider international harmonisation of registration requirements."

In realising this aim, VICH in close cooperation with the WOAH embarked on a "global outreach" initiative with the objectives of providing this basis for wider international harmonization of registration requirements, improving information exchange and raising awareness of VICH and VICH guidelines with non-VICH countries and regions. The global outreach initiative resulted in VICH and WOAH jointly hosting a contact meeting with selected non-VICH member countries and regional

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representations on wider harmonisation of VICH guidelines in Tokyo in November 2011. One of the outcomes of this meeting was the formation of the VICH Outreach Forum, now called VICH Forum.

Since the Tokyo contact meeting, regular formal meetings of the Forum have taken place in conjunction with the VICH Steering Committee meetings. From the discussions held and a survey carried out amongst Forum members, it was evident that there is a need for training in the understanding and application of VICH guidelines. Over and above this need, there was clear evidence of a need for comprehensive training of people working in the regulatory authorities in Forum member countries in all aspects of VMP registration dossier assessment.

In this context, it was decided to develop a VICH Training Strategy.

Mission of the VICH Training Strategy

The mission of VICH training strategy is to promote a better understanding of VICH guidelines and subsequently, their utilization in the context of a system for regulation of veterinary medicines and in order to facilitate the wider international harmonisation of registration requirements globally.

This mission will support building capacity of Veterinary Medicinal Product regulatory authorities and industry to ensure both animal and public health protection and ensure appropriate quality of veterinary medicines. In addition, these efforts can assist in minimizing fraud and ensure food safety.

Aim of the VICH Training Strategy

The aim of the proposed training strategy is to:

- Address where feasible, challenges faced by Forum participants with respect to the application of VICH guidelines within a fit for purpose registration process.
- Contribute to enhancing the ability of Forum participants to adequately assess technical studies and data generated and documented in registration dossiers in accordance with VICH guidelines

Scope of the VICH Training Strategy for Forum members

The scope of this Training Strategy is to provide training on the technical requirements for the registration of VMPs including general requirements, pre-approval (quality, safety and efficacy) and post-approval (pharmacovigilance).

Principles and approaches of the VICH Training Strategy for Forum members

Principles are proposed in order to make best use of resources, opportunities and technology, thereby ensuring that training activities directed through VICH are as effective and efficient as possible.

A two-pronged approach for the implementation of the training strategy is proposed:

First level of intervention:

Multiple overview training presentations regarding the VICH process and deployment of VICH adopted guidelines will be published on the VICH website for training purposes.

Presentations by Steering Committee members, who may be supported by experts, as appropriate, to the Forum and discussion of selected topics proposed by the Forum member country and region representatives in small group discussions and on the basis of question and answering sessions, with reporting back to plenary are proposed to address this level. Presentations to the Forum will not be detailed technical guideline presentations but address a higher level and general topics.

Second level of intervention: Provide more detailed training at Forum member country or regional level

For this level of intervention, the development of a training course composed of different modules with the structure described below is proposed. Resources and costs for this level of training must be developed and available before the activity can take place. VICH guidelines that **could** be part of each module are also listed. Each module could provide a general overview of relevant requirements, relevant VICH guidelines and principles of their application. In order to achieve comprehensive training on the regulation of veterinary medicines, data assessment and VICH guidelines, several modules would be necessary that should include practical exercises on basis of examples. Pre-reading requirements will be an integral part of the training. Examples of potential training modules are listed below

- ***MODULE #1 (0.5 days)***

  Content: General Overview on Registration Requirements

  Target Group: national competent authority, managers, administrators, assessors

- ***MODULE #2 (1.5 – 2 Days)***

  Content: Chemistry and Manufacturing / Quality Assessment (process/data)

  Target Group: assessors

  Guidelines that could be used:

  - Validation of analytical procedures : Definition and Terminology
    VICH GL1 (Validation definitions)
  - Validation of analytical procedures : Methodology
    VICH GL2 (Validation methods)
  - Stability testing of new drugs substances and products
    VICH GL3 (Stability drugs)
  - Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)
    VICH GL3 (Quality)
  - Stability Testing :Requirements for New Dosage Forms
    Annex to the VICH guidelines on Stability Testing for New Drugs and Products
    VICH GL4 (Stability products)
  - Stability Testing :Photostability Testing of New Drug Substances and Products
    VICH GL5 (Photostability)
  - Stability Testing for Medicated Premixes
    VICH GL8 (Stability premixes)
  - Impurities in New Veterinary Drug Substances (Revision)
    VICH GL10 10 (R) (Quality)
  - Impurities in New Veterinary Medicinal Products (Revision)
    VICH GL11 (R) (Quality) –
  - Impurities: Residual Solvents in new veterinary medicinal products, active substances and excipients (Revision)
    VICH GL18 (R) (Impurities: Residual Solvents)
  - Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances + Decision Trees
    VICH GL39 (Quality)
  - Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products
    VICH GL45 (Quality)
  - Statistical evaluation of stability data
    VICH GL51 (Quality: Stability Data)

- ***MODULE #3 (1.5 – 2 Days)***

Content: Human (Food) Safety and Environmental Risk assessment
Target Group: assessors
Guidelines that could be used to assess Human (Food) Safety
Note: Depending on the training audience, the guidelines listed in this section may be further subdivided into multiple modules.

- Studies to evaluate the safety of residues of veterinary drugs in human food: Reproduction Testing
  VICH GL22 (Safety: Reproduction)
- Studies to evaluate the safety of residues of veterinary drugs in human food: Genotoxicity Testing
  VICH GL23 (Safety: Genotoxicity)
- Pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance
  VICH GL27 (Antimicrobial resistance: pre-approval)
- Studies to evaluate the safety of residues of veterinary drug in human food: carcinogenicity testing
  VICH GL28 (Safety: Carcinogenicity)
- Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose (90 days) Toxicity Testing
  VICH GL31 (Safety: Repeat-dose Toxicity)
- Studies to evaluate the safety of residues of veterinary drugs in human food: Developmental Toxicity Testing
  VICH GL32 (Safety: Developmental Toxicity)
- Studies to evaluate the safety of residues of veterinary drugs in human food: General Approach to Testing
  VICH GL33 (Safety: General Approach)
- Studies to evaluate the safety of residues of veterinary drugs in human food: General approach to establish a microbiological ADI
  VICH GL36 (R) (Safety)
- Studies to evaluate the safety of residues of veterinary drugs in human food: Repeat-dose (chronic) toxicity testing
  VICH GL37 (Safety: Repeat-dose chronic toxicity)
- Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: Metabolism study to determine the quantity and identify the nature of residues
  VICH GL46 (MRK)
- Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: Comparative metabolism studies in laboratory animals
  VICH GL47 (MRK)
- Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: Marker residue depletion studies to establish product withdrawal periods
  VICH GL48 (MRK)
- Validation of analytical methods used in residue depletion studies
  VICH GL49 (MRK)

Guidelines for Environmental Risk Assessment

- Environmental Impact Assessment (EIAs) for veterinary medicinal products (VMPs) - Phase 1
  VICH GL6 (Ecotoxicity - Phase 1)

- Environmental Impact Assessment (EIAs) for Veterinary Medicinal Products (VMPs) - Phase II
  VICH GL38 (Ecotoxicity Phase II)

- ***MODULE #4 (1.5 – 2 Days)***

  Content: Target Animal Safety (TAS) and Efficacy/Effectiveness

  Target Group: assessors

  Guidelines that could be used for Target Animal Safety

  - Relevant human food safety assessment guidelines on toxicity endpoints
  - Target Animal Safety for Pharmaceuticals
    VICH GL43 (TAS Pharmaceuticals)

  Guidelines that could be used for Efficacy / Effectiveness assessment:

  - Efficacy of Anthelmintics: General Requirements
    VICH GL7 (Anthelmintics General)
  - Good Clinical Practices
    VICH GL9 (GCP)
  - Efficacy of Anthelmintics: Specific Recommendations for Bovines
    VICH GL12 (Anthelmintics: Bovines)
  - Efficacy of Anthelmintics: Specific Recommendations for Ovines
    VICH GL13 (Anthelmintics: Ovines)
  - Efficacy of Anthelmintics: Specific Recommendations for Caprines
    VICH GL14 (Anthelmintics: Caprines)
  - Efficacy of Anthelmintics: Specific Recommendations for Equine
    VICH GL15 (Anthelmintics: Equine)
  - Efficacy of Anthelmintics: Specific Recommendations for Swine
    VICH GL16 (Anthelmintics: Swine)
  - Efficacy of Anthelmintics: Specific Recommendations for Canine
    VICH GL19 (Anthelmintics: Canine)
  - Efficacy of Anthelmintics: Specific Recommendations for Feline
    VICH GL20 (Anthelmintics: Feline)
  - Efficacy of Anthelmintics: Specific Recommendations for Poultry
    VICH GL21 (Anthelmintics: Poultry)

MODULE #5 (1.5 – 2 Days)

Content: Pharmacovigilance (PV) and Adverse event reporting

Target Group: assessors

Guidelines that could be used:

- Pharmacovigilance of veterinary medicinal products: management of adverse event reports (AERs)
  VICH GL24 (Pharmacovigilance)
- Pharmacovigilance of Veterinary Medicinal Products - Management of Periodic Summary Update Reports
  GL29 (Pharmacovigilance)
- Controlled List of Terms (cover page)
  VICH GL30 (Pharmacovigilance)
- Pharmacovigilance: Electronic Standards for Transfer of data
  VICH GL35 (Pharmacovigilance: ESTD)
- Pharmacovigilance of Veterinary Medicinal Products - Data Elements for Submission of Adverse Event Reports
  VICH GL42 (Pharmacovigilance)

- ***MODULE #6 (1.5 – 2 Days)***

  Content: Biologicals/Immunologicals/Vaccines

  Target group: assessors

  Guidelines that could be used to assess biological/immunological veterinary medicinal products / veterinary vaccines:

  - Stability testing of new biotechnological/biological veterinary medicinal products
    VICH GL17 (Stability: biotechnologicals/biologicals)
  - Testing of residual formaldehyde
    VICH GL25 (Biologicals: Formaldehyde)
  - Testing of residual moisture
    VICH GL26 (Biologicals: Moisture)
  - Test for the detection of Mycoplasma contamination
    VICH GL34 (Biologicals)
  - Test Procedures and Acceptance Criteria for New Biotechnological/Biological Veterinary Medicinal Products
    VICH GL40 (Quality)
  - Target Animal Safety - Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence - Annexes
    VICH GL41 - July 2007
  - Target Animal Safety for Veterinary Live and Inactivated Vaccines
    VICH GL44 (TAS Biologicals)
  - Harmonization of criteria to waive Target Animal Batch Safety Testing (TABST) for inactivated vaccines for veterinary use
    VICH GL50 (Biologicals: TABST)

Points for Consideration:

Training Venues for level 2 training

While the *ad hoc* working group considered alternative training methods such as e-learning, web based learning, depositories of teaching materials made accessible to Forum members, it came to the conclusion that face-to–face training courses might, at this stage, be the preferred option as a first step.

Training Material Content for level 2 training

The ad hoc working group recommends that as each module is developed that it includes learning objectives, the identified target group, content and practical exercises and time allocation to theory and exercises.

Training modules should be prepared as presentations and organized in a way to allow for interactive training following initial presentation and where possible, practical applications. The presentations could be made available on the VICH website.

Training Faculty for level 2 training

The ad hoc working group recommends that the training be implemented by experts knowledgeable about the specific guidelines in the module and experienced in applying the guideline in assessing a dossier. The training faculty would most likely be experts from competent regulatory authorities.

Requesting level 2 training

Request for level 2 training may be made by countries and regions participating in the VICH Forum. Once the training faculty for level 2 training is established, request may be sent to the VICH secretariat at least 1 year in advance of the desired training, indicating:

- The target group (number of people and their positions)
- Desired time period of the training
- Proposed training location and venue

A budget estimate and proposed sources of funding should also be indicated.