Workshop for OIE National Focal Points on Veterinary Products

Casablanca, Morocco, 6-8 December 2011

VICH

Preparation of Guidelines

Barbara Freischem
Executive Director
IFAH

ORGANISATIONAL CHARTER OF VICH

8.Decision-Making Process and Procedures

Process

-Step 1: The SC agrees to start a topic.

-Step 2: The EWG elaborates a draft guideline (GL).

-Step 3: The SC approves the draft GL to release for consultation.

-Step 4: The draft GL is circulated to all interested parties.

-Step 5: The EWG prepares a revised GL.

-Step 6: The SC approves the revised draft GL.

-Step 7: The final GL is circulated to authorities of VICH region.

-Step 8: The final GL is implemented in VICH region.

-Step 9: The SC monitors, maintains and reviews the GL.

VICH Guidance Documents

- Note to prepare a VICH Topic Concept Paper (VICH/97/037_Revision 2_Final)
- Policy Paper for the acceptance of Interested Parties in VICH Steering Committee meeting (VICH/00/117-Fin)
- Guidance for Members of VICH Expert Working Groups (VICH/00/150-rev1-fin)
- SOP on VICH Procedure for the Expert Working Groups (VICH/00/151-rev2-fin-cons)
- Guidance for the Steering Committee and the Appointment of Experts and Chairpersons/Topic Leaders to Expert Working Groups (VICH/00/152-rev1-fin)

VICH Guidance Documents

- Policy on Consultation at Step 4 (VICH/00/154-rev-2-FINAL)
- Policy on Appreciation and Recognition of the Chairs and Expert Working Group Members (VICH/00/155-rev1-fin)
- Monitoring and Maintenance of existing VICH Guidelines (VICH/05/017-FIN-Rev)
- Methodology for a systematic Review of the VICH Guidelines at step 9 (VICH/07/039-FINAL)
- Categorisation of VICH Guidelines (VICH/07/061-FINAL)
- Framework for public disclosure of VICH Concept Papers (VICH/11/026-FINAL)

VICH Steering Committee (SC)

The SC drives the harmonisation process. The key tasks of the SC are to:

- determine the working procedures;
- determine the priority items based on concept papers prepared by its members;
- establish the appropriate Expert Working Groups (EWGs) and appoints topic leaders and EWG chairpersons;
- consider and resolve issues raised by the Expert Working Groups;
- approve the draft recommendations issued by EWGs before release for world-wide consultation and subsequently for approval by the regulatory authorities of the EU, Japan and the USA;
- implement a programme of monitoring maintenance and review of Guidelines.

Expert Working Groups (EWGs)

The EWGs are task-oriented and their aims are to:

- develop a comprehensive discussion paper based on the SC concept paper;
- elaborate recommendations and draft Guidelines based on a concept paper adopted by the SC for the priority items determined by the SC;
- report regularly on progress and issues for resolution to the SC;
- submit these recommendations and draft Guidelines to the SC;
- produce minutes in a timely fashion.

For efficient GL elaboration

- There are limited resources in all VICH regions, so it is very important to consider priority of making new GLs.
- Therefore, the SC spends much times for discussion of starting a new topic.

The 9-step procedure

Kick-Off:

- Prior to the launch of a new topic, the SC ensures that the pre-requisites laid down in the VICH Strategy have been fulfilled.
- If approved, the SC then launches the VICH 9-step procedure:

Step 1: SC

The SC:

- defines priority items from a detailed concept paper sponsored by one of its members;
- establishes an appropriate EWG, if needed, and designates a chairperson. A topic leader, in charge of drafting a GL, is appointed with a clear mandate to do the expected work;
- ensures that each expert is properly briefed and has a clear mandate enabling him/her to deliver the expected outcome in the timeframe defined by the SC, in accordance with established VICH guidance;
- ensures that each topic leader has the required competence and interpersonal skills to lead an EWG and achieve its objectives.

Concept paper template

- Introduction
- Problem statement, including references to existing technical and legislative requirements in the different regions
- Impact for public health, animal health and animal welfare
- Anticipated benefit to:
  - Industry and Other Interested Parties
  - Regulatory Authorities
- Discussion
- Recommendation (action plan, issues to be addressed, mandate, etc.)
- Timetable
- Milestones
- Impact assessment for Industry
- Impact assessment for Regulatory Authorities
- References to literature, existing relevant international guidelines or standards (e.g. ICH, OECD, CODEX, JECFA,..).

Establishment of EWG

- The SC shows mandate to EWG with the concept paper.
- SC establishes EWG.
  - Each SC full member and observer member has the right to appoint one expert.
  - If necessary, and unless otherwise specified by the SC, each expert may be accompanied by one advisor.
- Topic Leaders/Chairperson of EWGs
  - A Topic Leader is appointed for each EWG by the SC, on the basis of expertise and on geographical balance.
  - He/She normally chairs the specific EWG and is therefore accountable to the SC with respect to the mandate and time frame given by the SC. He/She is also responsible for preparing the appropriate discussion documents for the EWG meetings.
  - At step 5 of the procedure the topic leader must be a representative of the regulatory authorities.

Step 2: EWG

The appropriate EWG elaborates a draft Guideline, and submits it to the Secretariat with the signatures of all experts.

- The Topic Leader will write a **discussion document** and establish the meeting schedule and action plan.
- If a Chairperson is appointed, he/she will be responsible for establishing the meeting schedule and action plan and the Topic Leaders would prepare the discussion documents under the chairperson's direction.
- Expert Working Group (EWG) members invest significant effort in preparing guidelines. In many cases, this effort is undertaken by EWG Chairpersons and members in their own time. It is therefore appropriate that VICH has in place procedures that recognise the contribution of EWG members to the overall success of VICH.
- VICH does not provide any financial support for EWG members.

Step 3: SC

The draft Guideline is submitted to the SC for approving its release for consultation.

Step 4: All Interested Parties

Once adopted by the SC, the draft Guideline is circulated to all interested parties for consultation, applying an appropriate consultation period (normally 6 months).

- **Objectives:**

- Transparency: To allow any group or individual to express their views on the draft guidelines, or major revisions to existing guidelines and receive feedback that indicates that their views have been considered.

- Expertise: To support the expertise available to the EWGs in preparing the final guideline or revision.

Step 4: All Interested Parties

Consultation managed by SC active participants

- Each of the active participants to VICH, i.e. US, Japan, EU, Australia, New Zealand, Canada and OIE, must define its own consultation/public disclosure methods.

Worldwide consultation managed by the VICH Secretariat

The VICH Secretariat will:

- post the draft guidelines on the VICH web page within four weeks of Step 3 being completed (i.e. being signed by the SC)
- maintain a distribution list so that any organisation or individual that requests it is automatically sent an e-mail when a new guideline at Step 4 is posted on the VICH web page .

Step 5: EWG

- Comments received are directed to the EWG for consideration.

At this step, the topic leader must be a representative of a regulatory authority. The EWG prepares a revised draft and submits it to the Secretariat with the signature of all experts. The signatures of industry experts are clearly separated from those of experts representing regulatory authorities.

Step 6: SC

- The revised draft Guideline is submitted to the SC for approval.

Step 7: Circulation to VICH Region

- Once approved by the SC, the final GL and a proposed date for implementation are circulated to the regulatory authorities represented in the SC.

Step 8: *Implementation in* VICH Region

- The SC members report to the SC on the implementation of the Guidelines in their respective regions.

Step 9: SC

- Monitoring, maintenance and review of Guidelines:

  The necessity to review adopted Guidelines should be determined, at least every 3 years, following the implementation in order to take account of new developments. The secretariat will notify the SC of the three years deadlines.

Step 9:SC

"Major" and "Minor" harmonization activities

- A “major” topic concerns major amendments to a guideline, its extension and addition of further aspects or revision due to new scientific knowledge or regulatory requirements. Other changes are considered as "minor".
- “Major” maintenance topics will be handled under the full 7-step VICH Process. Proposals for "Minor" changes to existing VICH guidelines will be handled through the Abbreviated Maintenance Process.

Step 9: SC

Monitoring of existing guidelines

The systematic monitoring of existing guidelines in order to identify any need to change or update of a guideline is carried out with 3 year intervals starting 3 years after the implementation of a guideline. The review considers in particular the following aspects:

- consistency of interpretation,
- need for further clarification and guidance,
- need for consideration of new scientific knowledge
- review of ICH guidelines whether these require adaptation of VICH guidelines

Thank you very much for your attention.