EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Review and approval of VICH guidelines and related documents by CVMP and its working parties		
Status: **PUBLIC**		Document no.: SOP/V/4047
Lead author	Approver	Effective date: 21-AUG-15
Name: Kornelia Grein	Name: David Mackay	Review date: 21-AUG-18
Signature: on file	Signature: on file	Supersedes: SOP/V/4047 (10-OCT-12)
Date: 20-AUG-15	Date: 20-AUG-15	TrackWise record no.: 4614

1. Purpose

This SOP aims to facilitate the consultation process of the CVMP and its working parties in the drafting of CVMP-VICH guidelines and related documents on behalf of the EU.

2. Scope

The SOP applies to all guidelines being prepared under the VICH initiative to be adopted by CVMP for veterinary medicines in the EU.

3. Responsibilities

It is the responsibility of the Head of Veterinary Medicines department to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of 9. Procedure.

Responsibilities of the EU expert

The EU expert represents the CVMP in the VICH Expert Working Groups developing VICH guidelines. In preparation of each EWG or TF meeting, the EU expert must ensure that a clear EU mandate for negotiation has been established. The same principle applies for discussions via email or teleconferences.

It is incumbent of the EU expert to inform the CVMP through the EU coordinator and secretary of the responsible CVMP working party of any difficulties or contentious issues which could result in a guideline which is not in accordance with EU principles.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Reporting (EU experts and EU coordinator)

After each meeting of the EWG, the EU expert must:

- Prepare a summary of the key discussion points after each EWG meeting and send to EU coordinator (and WP Secretariat) including any relevant document(s) that were discussed, if applicable. The same principle applies for discussions via email or teleconferences, as appropriate.
- Send to EU coordinator (and relevant WP Secretariat, if applicable) the minutes of all EWG meetings, as soon as available.

After each SC meeting, the EU coordinator should:

- Send the mission report to CVMP, CMDv, EU experts and WP secretariats, as well as any relevant meeting document(s) that were discussed, if applicable. Present in verbal report to CVMP and CMDv.
- Send the minutes of the VICH Steering Committee to CVMP, EU experts and WP secretariats, as soon as available.
- Send update reports to all relevant EU experts and coordinate follow-up.

4. Changes since last revision

Routine review and minor changes to wording.

5. Documents needed for this SOP

n/a

6. Related documents

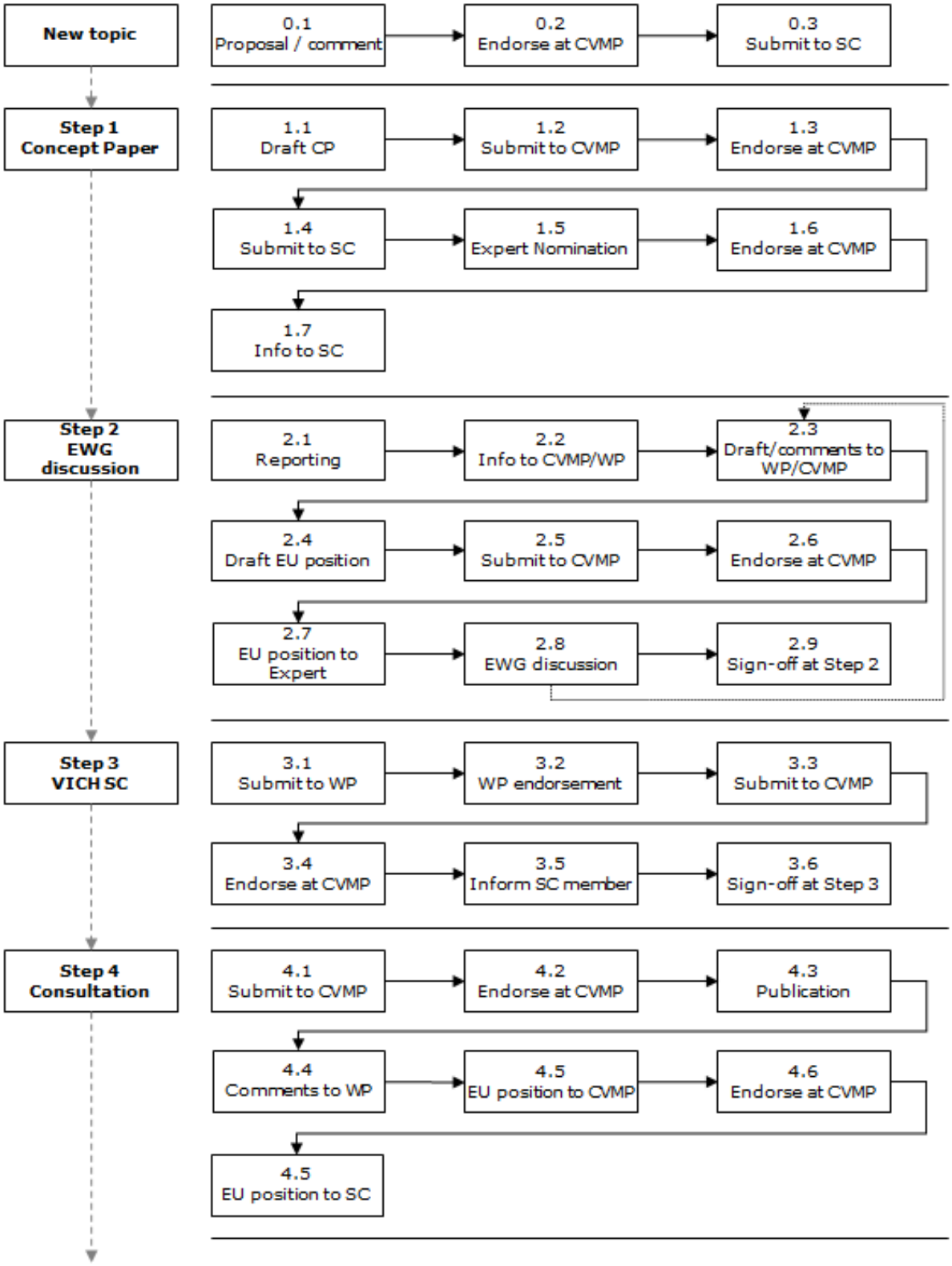
Procedural guidance: latest versions available in DREAM:

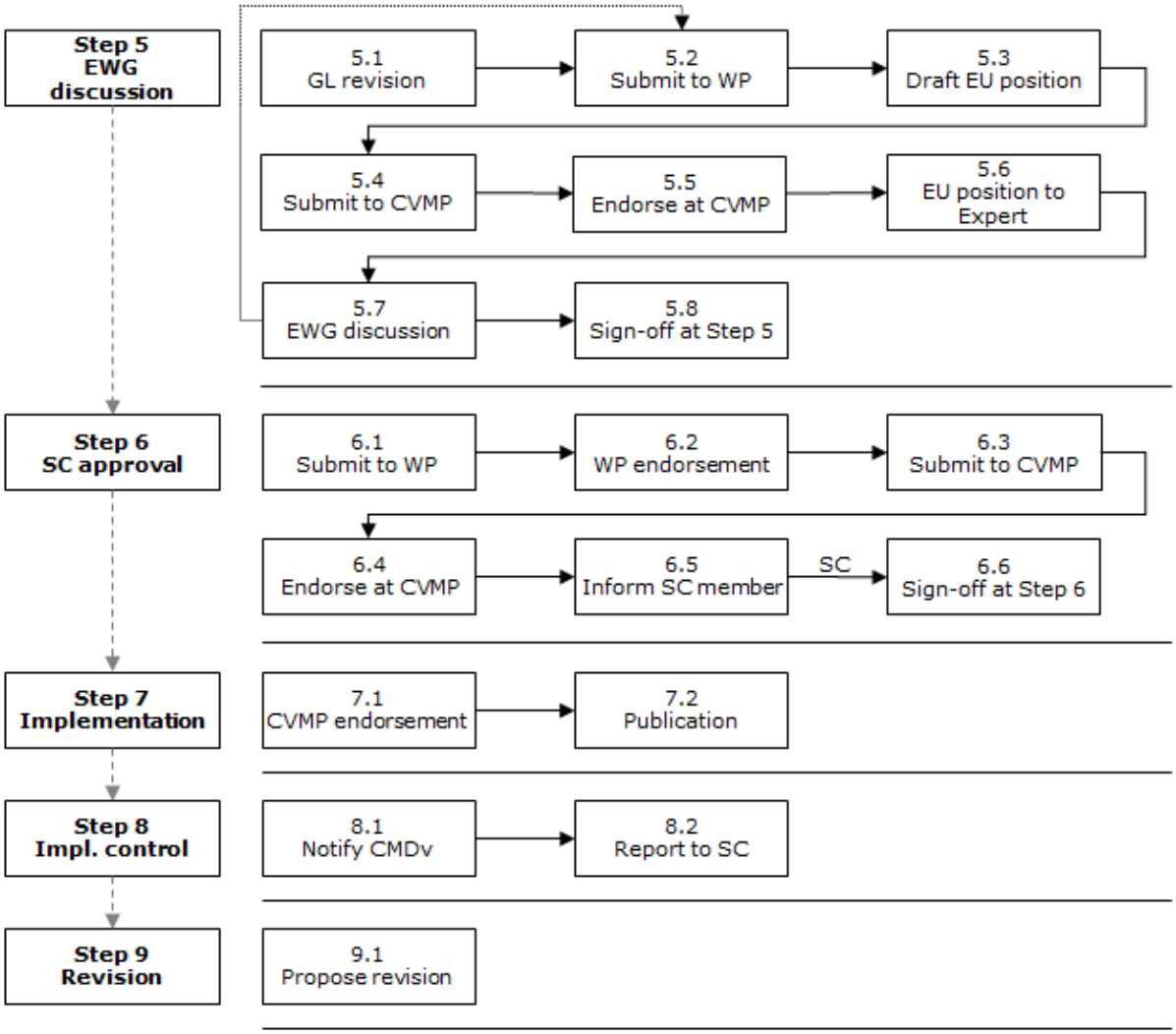
- Organisational Charter of VICH (VICH/96/002)
- Note to prepare a VICH Concept Paper (VICH/97/037)
- Note on format and style of VICH GLs (VICH/97/061)
- Clarification of VICH Step Procedure (VICH/00/008)
- Guidance for members of VICH Working Groups (VICH/00/150)
- SOP on VICH Procedures for the VICH Working Groups (VICH/00/151)
- Policy on Consultation at Step 4 (VICH/00/154)
- Monitoring and maintenance of existing VICH Guidelines (VICH/05/017)
- Review of VICH GLs at Step 9 (VICH/07/039)
- Categorisation of VICH Guidelines (VICH/07/061)
- Appointment of EWG Experts, Chairpersons and Topic Leaders (VICH/00/152)
- Policy for disbanding EWGs (VICH/00/153)
- Policy on appreciation and recognition of EWG Chair and Members (VICH/00/155)
- Framework for public disclosure of VICH Concept Papers (VICH/11/026)

7. Definitions

VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
SC	(VICH) Steering Committee
EWG	(VICH) Expert Working Group; in this SOP the abbreviation applies equally to VICH Task Forces (TF)
EWG Chair	Chairperson of VICH Expert Working Group
TL	Topic leader; member of VICH EWG responsible for drafting of topic GL (often, but not necessarily, chair of EWG)
EU expert	Expert appointed by CVMP as member of VICH Expert Working Group representing the EU (regulatory)
EU coordinator	main contact point in EMA for SC mailings, distribution of documents, coordination of EU input, etc
VICH secretariat	main contact point for the organisation of VICH Steering Committee meetings and circulation of documents to the group
CMDv	Coordination group for mutual recognition and decentralised procedures (veterinary)
CVMP	Committee for Medicinal Products for Veterinary Use
WP	CVMP Working Party (incl. ad-hoc groups/scientific advisory groups)
WP secretariat	Scientific Administrator in charge of the organisation and preparation of respective WP meetings
Concept paper	a paper prepared by a member of the VICH Steering Committee proposing the adoption of a topic (area of testing) for which a guideline is required
GL	Guideline

8. Process map(s) / flow chart(s)




Step 5
EWG
discussion
5.1
GL revision
5.2
Submit to WP
5.3
Draft EU position
5.4
Submit to CVMP
5.5
Endorse at CVMP
5.6
EU position to
Expert
5.7
EWG discussion
5.8
Sign-off at Step 5
Step 6
SC approval
6.1
Submit to WP
6.2
WP endorsement
6.3
Submit to CVMP
6.4
Endorse at CVMP
6.5
Inform SC member
SC
6.6
Sign-off at Step 6
Step 7
Implementation
7.1
CVMP endorsement
7.2
Publication
Step 8
Impl. control
8.1
Notify CMDv
8.2
Report to SC
Step 9
Revision
9.1
Propose revision

9. Procedure

Step	Action	Responsibility
	Proposal for new topic	
0.1	Prepare initial proposal, in agreement with CVMP Working Party, if applicable; submit to CVMP for agreement. Submit any proposal introduced by other SC members and sent in advance of the SC meeting to CVMP (and relevant CVMP Working Party, if applicable) for establishing EU position.	EU coordinator/EU SC member/WP secretariat/EU expert (as appropriate)
0.2	*At CVMP meeting:* Endorse new topic(s) and/or EU position(s).	CVMP
0.3	Submit proposal to measure interest/acceptance of proposal for new topic and/or submit EU position for other proposals in advance of SC meeting.	EU coordinator
Step 1	**Start of work (concept paper)**	
1.1	*Once a topic is supported in principle:* Draft concept paper, in consultation with relevant CVMP Working Party, if applicable.	EU coordinator / EU expert (WP secretariat)
1.2	The draft concept paper is submitted to CVMP for endorsement. Submit any concept papers submitted by other SC members in advance of the SC meeting to CVMP for agreement of EU position.	EU coordinator EU coordinator
1.3	*At CVMP meeting:* Endorse concept paper(s) and/or EU position(s).	CVMP
1.4	The concept paper(s) and/or EU position(s) are submitted to VICH secretariat for distribution for discussion at next SC meeting.	EU coordinator
1.5	In case the SC decided to establish a new EWG for this topic, nominate a member for EWG (and chairperson if EU is topic leader) at a CVMP meeting following the SC meeting at which the concept paper was discussed (or following the SC decision to establish an EWG).	CVMP
1.6	*At CVMP meeting:* Formally nominate EU member (and/or EWG chairperson, if applicable) for the EWG.	CVMP
1.7	Communicate nominated member/topic leader to VICH Secretariat in due course after CVMP meeting. Send information pack and organise briefing in case EU expert was not involved in VICH work before.	EU coordinator
Step 2	**Scientific Consensus (Expert Working Group) – drafting guideline**	
2.1	Submit reports (summary of discussions/mission report) and any relevant document(s) to EU coordinator (and WP secretariat, if applicable)[1]. The report should flag up any major problems or difficulties in EWG discussions so that the CVMP can consider in future EU position.	EU expert
2.2	Send reports (summary of discussions/mission report) and any relevant document(s) to the CVMP and relevant WP at their next meeting(s) respectively, for information or discussion.	EU coordinator / WP secretariat

[1] See reporting requirements under heading *3. Responsibilities* of this SOP

Step	Action	Responsibility
2.3	*Once a draft guideline has been prepared and/or comments that require consultation have been received from the regions:*	
	Submit draft guideline to EU coordinator and WP secretariat.	EU expert
	Send draft guideline and comments from the regions to the relevant CVMP WP and/or CVMP[2].	WP secretariat/ EU coordinator
2.4	Consider draft guideline and comments from regions and draft EU comments to be discussed and endorsed by WP (if applicable) and/or CVMP[2].	EU expert/ CVMP WP
2.5	*Following endorsement by CVMP WP:* Send draft guideline and draft EU comments to CVMP for endorsement at the next meeting.	WP secretariat / EU coordinator
	Inform CVMP of any major problems or difficulties in EWG so CVMP can consider for EU position.	EU expert/ EU coordinator
2.6	*At CVMP meeting:* Endorsement of EU position based on draft prepared by EU expert/WP.	CVMP
2.7	Send endorsed EU position to EU expert for submission to EWG.	WP secretariat
	EU expert sends EU position to EWG.	EU expert
2.8	Repeat *steps 2.3-2.7* as necessary while EWG discussions progress.	
2.9	Following the preparation of the draft VICH guideline for sign-off by EWG, sign-off of the final draft VICH GL at Step 2 in line with the EU position.	EU expert
Step 3	**Release for consultation (VICH Steering Committee)**	
3.1	Following receipt of draft VICH guideline by VICH SC members at step 2, send to relevant WP secretariat.	EU coordinator
3.2	Send to the relevant WP for endorsement.	WP secretariat
3.3	After WP endorsement, submit to CVMP for endorsement prior to sign-off by the SC.	WP secretariat
3.4	*At CVMP meeting:* Endorse draft guideline and/or any EU comments.	CVMP
3.5	Inform EU regulatory SC members of CVMP endorsement and/or any comments, if appropriate.	EU coordinator
3.6	Sign-off of the draft VICH GL by VICH SC at step 3 and/or submission of any comments, if appropriate (at SC meeting or by written procedure).	EU SC member
Step 4	**Consultation**	
4.1	Following receipt of draft Step 4 VICH GL for consultation and publication of GL on VICH website, submit draft GL to CVMP for formal adoption for release for consultation in the EU.	EU coordinator / WP secretariat
4.2	*At CVMP meeting:* Approve formally the draft guideline for release for consultation with a deadline for comments (normally 6 months, or same as VICH).	CVMP
4.3	Publication of draft VICH GL for consultation on EMA website.	CVMP secretariat

[2] In general the CVMP WP should be consulted prior to the consideration by the CVMP. However, if the position of the WP has been already obtained it may not always be necessary to consult the WP again for subsequent decisions on proposals or comments received. In any case, the WP should be informed of developments.

Step	Action	Responsibility
4.4	Following the end of the consultation period, compile all comments received in the EU. Send all comments received to EWG chair and EWG.	WP secretariat EU expert
4.5	Send draft GL and a compilation of all comments received during the consultation period to the relevant WP for discussion and agreement of draft EU position, and review of comments received in other regions sent by EWG chair/members from other regions.	WP secretariat / EU expert
4.6	Submit the guideline and draft EU position from the CVMP WP to CVMP for endorsement.	WP secretariat
4.7	*At CVMP meeting:* Endorsement of EU position based on draft prepared by EU expert/WP.	CVMP
4.8	Submit the EU position endorsed by CVMP to the VICH EWG.	EU expert
Step 5	**Scientific Consensus (Expert Working Group) – finalising guideline**	
5.1	At the end of the consultation period the VICH EWG takes into consideration all comments received during the said period and prepares a revised draft.	EU expert
5.2	*Once a revised draft guideline has been prepared and/or comments that require consultation have been received from the regions:* Submit draft guideline and/or comments to EU coordinator and WP secretariat. Send draft guideline and comments from the regions to the relevant CVMP WP and/or CVMP[2].	 EU expert WP secretariat/ EU coordinator
5.3	Consider revised draft guideline and comments from regions and draft EU comments to be proposed to CVMP WP and/or CVMP[2] for endorsement.	EU expert/ CVMP WP
5.4	*Following endorsement by CVMP WP:* Send revised draft guideline and draft EU comments to CVMP for endorsement at the next meeting. Inform CVMP of any major problems or difficulties in EWG so that the CVMP can consider for EU position.	WP secretariat / EU coordinator EU expert/ EU coordinator
5.5	*At CVMP meeting:* Endorsement of EU position based on draft prepared by EU expert/WP.	CVMP
5.6	Send endorsed EU comments to EU expert for submission to EWG. EU expert sends EU comments to EWG.	WP secretariat EU expert
5.7	Repeat *steps 5.2-5.6* as necessary while EWG discussions progress.	
5.8	Sign-off of final VICH guideline by EWG at step 5.	EU expert
Step 6	**Final approval (VICH Steering Committee)**	
6.1	Following receipt of final draft VICH guideline by VICH SC members at step 5, submit to relevant WP Secretariat.	EU coordinator
6.2	Send to the relevant WP for endorsement.	WP secretariat
6.3	After WP endorsement, submit the GL to CVMP for endorsement at the next meeting.	WP secretariat
6.4	*At CVMP meeting:* Endorsement of draft GL and/or any EU comments.	CVMP

Step	Action	Responsibility
6.5	Inform the EU SC member of endorsement and/or any comments, if appropriate. In case of comments requiring consideration by the VICH SC or EWG, send comments as appropriate.	EU coordinator
6.6	Sign off the final guideline at step 6 and/or submission of any comments, if appropriate (at SC meeting or by written procedure), and if supported by CVMP.	EU SC member
Step 7	**Implementation phase**	
7.1	Following receipt of the final VICH GL by VICH SC members for implementation in the regions and publication of Step 7 GL on VICH website, submit the GL to CVMP for formal adoption.	EU coordinator
7.2	Approve formally the guideline procedurally (no review) so it becomes henceforth a CVMP/VICH guideline with the implementation date set by VICH SC.	CVMP
	After CVMP adoption, publish GL on EMA website.	CVMP secretariat
Step 8	**Implementation control**	
8.1	Notify CMDv at the next meeting of the approval of the guideline and implementation date.	EU coordinator/ CMDv secretariat
8.2	Report on implementation status in relevant jurisdiction at the SC meeting following the implementation date.	EU coordinator
Step 9	**Revision**	
9.1	Propose revisions to GLs to SC, e. g. to take into account new scientific evidence, as needed, on ad-hoc basis or as part of systematic review[3] if topic leader for implemented guideline.	EU coordinator following request and/or consultation with CVMP/CVMP WP

10. Records

When completed, the retention of the hard and electronic copies will be the responsibility of the EMA secretariat.

Electronic archiving

All electronic documentation should be archived in the relevant sub-folders in DREAM.

Relevant sub-folders may be linked to the relevant CVMP WP folders in DREAM, but the main folder must always exist in the above mentioned VICH folder structure.

There is no retention of paper copies.

[3] 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

The guidelines are reviewed by the VICH partner who was the original topic leader.