



Guidance on how to manage topics drawing a strong interest by the VOF members, which are currently outside the scope of VICH

Background

In preparing the agenda for VICH Outreach Forum (VOF) meetings and in reflecting on past meetings, the VICH Steering Committee (SC) noted that VOF members sometimes proposed topics for discussion and harmonisation, which fall “out of the scope” of VICH.

Recognising the importance of providing answers to the questions and interests received from VOF members, the VICH SC at its 36th meeting held in Bruges, Belgium, in July 2018, has decided to establish and publish an overview of topics for harmonisation of technical requirements raised to VICH, but considered as not falling within the scope of this international body.

At the same time the VICH SC confirmed that in order to progress its objective of providing a basis for wider international harmonisation of technical requirements, it was essential that VOF members continued to attend and actively participated to the VOF meetings. This is viewed as one key condition to successfully achieving the aim of wider dissemination and acceptance of VICH guidelines and of co-operation on a more global level. To continue to attract interest, the VICH SC needs to ensure that the topics on the VOF meeting agenda meet the needs and expectations of the participants.

Following on from the above, the purpose of this VICH guidance document is twofold:

1. Define the approach for maintaining and publishing an overview of topics drawing a strong interest by the VOF members, which are currently outside the scope of VICH.
2. Bring clarity as to the topics which may be discussed at VOF meetings and avoid out of scope topics being repeatedly proposed.

1. Topics drawing a strong interest by the VOF members, but currently outside the scope of VICH

The VICH SC, supported by the Secretariat, maintains a list of information on topics raised by VOF members to VICH, but considered to be currently out of the scope of the VICH objectives. For each topic the rationale for the VICH SC to conclude an “out of scope” status is explained. Moreover, the document includes advice as to the organisation through which further information on the topic could be gathered or inform, as appropriate, where those topics have been discussed in the past and through which mechanism they could be taken forward.

Process for maintaining the list of “out of the scope” topics:

- The format of the list is shown in table 1 of VICH document *List of information on topics drawing a strong interest by the VOF members, which are currently outside the scope of VICH (VICH/19/078-final)*. It includes all VICH “Out of scope” topics covered in the past.
- The VICH Secretariat will ensure that the list of information on those topics is routinely:

- reviewed and amended if needed, e.g. to reflect evolving views of the VICH SC,
- updated by the VICH Secretariat after each VOF meeting/receipt of requests from third parties and subsequent discussion at VICH SC,
- recirculated for comment and approval by VICH SC, and
- sent to VOF members prior to the next VOF meeting.
- The latest version of the *List of information on topics drawing a strong interest by the VOF members, which are currently outside the scope of VICH* will be made publicly consultable via the VICH website (www.vichsec.org).

2. Topics which may be covered at VICH Outreach Forum (VOF) meetings

Introduction:

The VOF was originally established with the following main objectives in mind:

- a) to provide a basis for wider international harmonization of registration requirements
- b) to improve information exchange and raise awareness of VICH and VICH guidelines with non-VICH countries/regions

The Terms of Reference for the VOF (VICH/11/010) describe, among other aspects, in more detail the kind of topics that will typically be addressed during the meetings, i.e.:

- How to participate in VICH, including submitting comments on concept papers and draft guidelines
- Discussing practical issues related to VICH guidelines arising in the participants' countries/regions and providing feedback to the Forum
- Collaborating and sharing of translations of guidelines
- Providing feedback on acceptance of existing guidelines
- Detailed review of selected topics covered by VICH guidelines

Over the past years the VICH SC was able to gather a lot of experience thanks to the VOF meetings that have taken place since June 2012. This has demonstrated a strong need for VOF members to additionally learn and understand about elements, which by definition are out of scope of the VICH objectives and are typically regulatory activities of national competent authorities and governments, e.g.:

- Establishing safety standards
- Regulatory requirements, including understanding the different approaches and perspectives as to how a certain subject is regulated in the VICH regions
- Establishment of regulatory systems and regulation for marketing authorisations
- Legal definitions (e.g. generic vs. new products) and topics
- Procedural regulatory topics
- Enforcement of legislation (e.g. monitoring and control in the field such as for product quality, residue violation, antimicrobial resistance)

VICH SC position:

With a view to the original objectives for the VOF, there is consensus at VICH SC level that VOF members should be encouraged to continue their active involvement in the annual meetings.

To stimulate that, the VICH SC agrees that some flexibility exists to consider an exchange and discussion on topics “out of the scope” for VICH GL developments during regular VOF meetings.

VICH SC agreement on which VICH “out of scope” topics should be treated during VOF meetings is part of the standard drafting and approval process for VOF meeting agendas.

This kind of information is not only useful to promote active communication between VOF and VICH members, but also amongst VICH SC members for better understanding the differences in VMP regulation leading to further harmonisation in the future.