



Concept Paper for the Creation of an Ad Hoc Working Group on Training Implementation

Introduction – background:

1. The issue of training non-member, non-observer countries regulatory authorities on VICH Guidelines (GLs) is a longstanding and evolving issue within the VICH Steering Committee (VICH SC). At the 26th Meeting of the VICH SC plans were made for the first VICH Outreach Forum (VOF) to be held in conjunction with the 27th meeting of the VICH SC in Brussels towards starting to address this issue.
2. At the 26th meeting, The VICH SC agreed that the objective of the VOF is “to provide a basis for wider international harmonization of registration requirements, improve information exchange and raise awareness of VICH and VICH GLs with non-VICH countries.” During the first VOF, the VICH SC asked Forum participants for feedback regarding their needs. Training was identified as a key need.
3. At the 27th VICH SC meeting, the members discussed the role of OIE, the use of focal point training opportunities and continuation of the VOF. OIE agreed to conduct a survey with the 16 VOF participants (13 countries and 3 international organizations) in order to identify priorities for training. The survey included questions on requests (that have been already expressed) for training on VICH GLs, on topics for discussion in next VOF meetings, on which VICH GLs are already used in their countries. The survey included questions on the prioritization of requests for translation of VICH GLs. OIE also mentioned that, funding permitting, a one-day training could be considered back to back with the VOF meeting as one input to the VOF activities.
4. At the 28th meeting of the VICH SC in Washington, DC, the VICH SC reviewed the results of the OIE survey and after discussion, decided to explain during the VOF meeting that the VICH SC is aware of the training needs and is examining ways of addressing them. The VICH SC agreed to set up an ad hoc Working group of VICH SC members and VOF participants to develop a strategy defining the priorities for training and the strategy for establishing the resources and funds needed for future VICH trainings of VOF participants. The strategy was to focus on priorities of VOF participants (e.g. Quality), seek funding (e.g; under the Food Security banner), and proposals for development of training modules based on a category of VICH GLs.
5. The ad hoc working group on Training Strategy convened and developed a draft strategy that was presented to the VICH SC at its 29th meeting of the VICH SC in Auckland. The VICH SC noted that the primary mandate of the ad hoc group was to propose a training strategy. Details of the financing and implementation still need to be elaborated.

6. The ad hoc group recommended a two-pronged approach for the implementation of the training strategy: a first level of intervention during the VOF meetings and a second level at VOF participating-country or regional level.

7. The first level proposed is high level training such as the introduction to VICH GLs, rather than training on technical details of a specific VICH GL technical details. The VICH SC confirmed that VICH does not have the capacity to train the assessors of dossiers.

8. The second level of intervention proposed is the development of (a) training course(s) composed of different modules. The ad hoc group recommended developing these modules with the support of VICH SC members and observers who were encouraged to provide existing material. For the second level, it was proposed that the countries which requesting the training should be able to provide the funding, if necessary by requesting support from larger international organizations that have the financial means to advance these activities.

9. The VICH SC took note that most of the content of the proposed modules is already available but it is spread among various organizations in the world. The existing material should therefore be gathered and updated. However, as very few funding resources are available, VICH should prioritize the needs.

10. It was recalled that the primary objective of the VOF initiative and the training was to create awareness that the VICH GLs exist and can be used by all countries, thus preventing duplications and repetitions of studies, including those studies that use animals. After discussion in the VOF, funding remained an issue.

11. The VICH SC recognized that there was an ongoing need to develop a high level communication on VICH work and on what are VICH GLs. This would include one or more presentations to be located on the website. The VICH SC noted that the VICH website will become an essential communication tool with the VOF members.

12. The VICH SC therefore agreed that the ad hoc working group on training strategy will consider the improvement of the communication tools within the first level of the training strategy. Existing material will primarily be used. The ad hoc working group on training will develop a draft recommendation document on the VICH communication strategy.

13. At the 30th meeting of the VICH SC in Brussels, the VICH SC meeting reiterated strong support for the proposed level 1 and level 2 approach to training, but expressed ongoing concerns regarding the resources needed for this two level training approach.

14. The ad hoc group presented an overall communication proposal, building on available elements and documents that were presented to the VICH SC for discussion. It recommended developing a “key messages” document supporting a communication strategy that included the existing VICH leaflet, a long and abbreviated VICH general presentation as well as a presentation on the VOF. The proposal also recommended increasing the VICH media engagement, to broaden the audience of the press release, to renew regularly the content of the website and to consider developing a regular electronic newsletter on VICH.

15. The VICH SC thanked the ad hoc group and welcomed these concrete proposals but noted that the resources are a key limiting factor to the implementation of these proposals. The proposals on extending communication activities should therefore be considered further as part of an overall strategy. It was further noted, as explained in the proposed strategy, that communication material in the form of documents and presentations on the role of VICH and VICH GLs at different levels are already available.

16. The VICH SC agreed to the message that should be conveyed to the VOF which needs to balance the high expectations of the VOF members against the reality of what VICH SC can deliver.

17. After a thorough discussion of the VICH Communication Strategy document, the VICH SC agreed to focus first on delivering the key messaging and the communication of the role of VICH in regulatory systems and to reflect on ways to attract funding such as from Public Private Partnerships to develop the material necessary for the second level of training strategy. The VICH SC further agreed to finalize the training strategy document at the next VICH SC meeting with the explained caveats regarding resources. Regarding the level 2 training, the VICH SC informed the VOF that VICH does not have the resources for the time being to provide specific training material and sessions to VOF members.

18. The ad hoc Working Group on the Training Strategy recognized that securing funding for the necessary level of training was beyond the VICH Scope and ability of the working group. As such, the working group is proposing that as this working group concludes its activity, another ad hoc working group be convened to continue the work on training implementation.

19. At the 31st meeting of the VICH SC, the ad hoc Working Group on Training Strategy is presenting four documents: 1) The final Training Strategy Document, 2) the final VICH presentation and leaflet; 3) the Communication Document on Key Messages; and 4) this concept paper proposing the formation of an ad hoc Training Implementation Group.

Problem Statement

The VICH SC recognizes a clear need to provide a basis for wider international harmonization of registration requirements, improve information exchange and raise awareness of VICH and VICH GLs with non-VICH countries. In developing a strategy to meet this need, the VICH SC noted the need for additional resources to effectively implement a training strategy. For example, the VICH SC has suggested the formation of public-private partnerships as well as the solicitation of funding from a number of external sources. In order to fully implement a training strategy, these resources must be secured.

While government regulators are likely to be involved in conducting training sessions, the government regulators have restrictions and prohibitions against participating in funding solicitation. A training implementation group consisting of VICH SC members who may operate without these restrictions are likely to be in a better position to secure the necessary resources and partner with outside organizations to leverage available resources.

Impact for Public Health, Animal Health and Animal Welfare

The recognition and/or adoption of VICH Guidelines by national regulatory authorities ensures that veterinary medicinal products are evaluated based on accepted data standards created by international expert working groups. Properly trained regulatory officials using these standards ensure the safety, effectiveness, quality and monitoring of veterinary medicinal products providing the assurance of Public Health, Animal Health and Animal Welfare.

Anticipated Benefit to

The anticipated benefit would be for all countries properly using VICH guidelines to ensure animal health and animal welfare, appropriate standards for veterinary medicinal products, improved productivity and health of food-producing animals and food security and safety.

Recommendation

We propose that the VICH SC create an ad hoc Working Group on Training Implementation.

Concerning the level one training: this group would work closely with the OIE and in conjunction with the VOF.

Concerning the level two training: the primary focus of the Training Implementation Working Group would be to develop funding opportunities including forging partnerships with outside organizations; to explore potential training opportunities in conjunction with other international meetings such as the Global Animal Health Conference; to establish curriculum, and to secure experts as needed to deliver the needed training as outlined in the Training Strategy document.

Timetable

We recommend the creation of the ad hoc Working Group in Training Implementation at the 31st meeting of the VICH SC. The working group should remain until such time as the VICH SC concludes the working group has fulfilled its charge.

Milestones

As the charge to the ad hoc working group represents a substantial challenge requiring innovation, creativity and exploration, the milestones at this time would be to provide a report at each meeting of the VICH SC. Further, as specific targets and objectives are realized, the working group may propose additional milestones to the VICH SC.

Impact Assessment for industry

1. The animal health industry would benefit from further adoption and recognition of VICH Guidelines by more national authorities.
2. This harmonization would enable wider markets and veterinary medicinal products meeting the evidentiary requirements as outlined in the VICH guidelines.
3. In addition, better post-approval monitoring becomes possible with the implementation of the pharmacovigilance guidelines on a global basis.

Impact Assessment for Regulatory Authorities

1. When funding is secured and training sessions are scheduled, the regulatory authorities would likely be asked to provide experts to serve as the faculty for the training courses.
2. Regulatory Authorities in Member and Observer countries would benefit from improving the standards for approval of veterinary medicinal products in countries where animal derived-food is produced and exported to member and observer countries.
3. Moreover, the member and observer countries would be better informed about the challenges of veterinary medicinal product evaluation in non-member countries and the inherent challenges faced by those national authorities.
4. The national authorities in non-member/non-observer countries would benefit from using and relying on the VICH guidelines in establishing national standards for the approval and monitoring of veterinary medicinal products and by this way could increase the availability of veterinary medicinal products in their country.

References to literature, existing relevant guidelines, documents

Meeting minutes of the 26th VICH SC

Meeting minutes of the 27th VICH SC

Meeting minutes of the 28th VICH SC

Meeting minutes of the 29th VICH SC

Meeting minutes of the 30th VICH SC

Proposed Draft VICH SC Training Strategy Document

VICH Overview Presentation and Leaflet

VICH SC Communication and Key Message Documents