VICH/11/026 June 2014 Revision 1 - FINAL

PROCEDURE FOR THE PUBLICATION OF VICH CONCEPT PAPERS

Background

One of the objectives of VICH is to provide a basis for wider international harmonisation of technical requirements for registration of veterinary medicinal products. Achieving this goal requires active participation of non-VICH countries and regional organisations in the harmonisation process. One way of stimulating participation of non-VICH countries/regions in the development and revision of VICH Guidelines is to publish the underlying finalised and approved concept papers as follows:

- publication on the VICH website and the OIE website:
- · circulation to the VICH Outreach Forum members; and
- circulation by the OIE to the OIE national focal points for veterinary products.

The objectives of publication of VICH Concept Papers

Publication of VICH Concept Papers will facilitate achieving the wider harmonisation objective of VICH by ensuring:

- a transparent approach to identification of potential new topics for harmonisation,
- that potential stakeholders worldwide are aware of new VICH topics, thus stimulating their interest to provide input in the development/revision of harmonised guidelines as appropriate,
- clarity and transparency on the expected outcomes of new harmonisation topics agreed by the VICH Steering Committee (SC).

Publication of finalised VICH Concept Papers

When a concept paper has been adopted by the VICH SC it will be published as mentioned above under "Background". There will be a passive information to the public via the VICH SC press release and a notification in the "What's New" section of the VICH public website. In addition there will be an active distribution of information via the OIE national focal points for veterinary products and through the VICH Outreach Forum.

Comments on published VICH Concept Papers

Comments should be submitted directly to the VICH Secretariat or indirectly via OIE within the specified deadline. Received comments will be considered by the VICH SC during its discussions leading to a decision to adopt or not adopt the topic.