International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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Final

Implementation of VICH guidelines

How to use VICH guidelines?

VICH guidelines are documents that explain to companies/organisations interested in obtaining a marketing authorisation (also called registration) for veterinary medicines how to generate the experimental data necessary to support the application.

The VICH member countries / regions have the obligation to implement the adopted VICH guidelines as technical requirements for the authorisation of veterinary medicinal products in their country/region. The VICH Observer countries/regions are committed to implement the adopted VICH guidelines to the fullest extent possible.

The use of the VICH guidelines is not restricted to the countries and regions affiliated with VICH. Any country or regional organisation, any regulatory system that requires submission of experimental data in support of applications for the granting of marketing authorisation for veterinary medicines can make use of VICH guidelines. Indeed, countries and regions are invited to do so, as it would multiply the benefits in respect of reducing the use of animals in the generation of data for regulatory submissions and in respect of a reduction of duplication of work.

The VICH guidelines are publically available through the VICH website. They are also published on the websites of the regulatory authorities of the VICH members and observers.

There are different ways that technical guidelines such as the VICH guidelines can be implemented. It is the decision of the country or region and may depend on how the legislation in the country/region has been set up. Normally VICH countries and observers use them as separate technical guidelines in support of legislation without making them a part of the legislation (legally non-binding).

If a country or region considers implementing VICH guidelines, it should bear in mind that it is not necessary to implement all the guidelines as a package, but a country or region may choose to implement only selected guidelines, e.g. the most needed or suitable guidelines, or may consider a stepwise implementation process.

The VICH member countries and regions are obliged to implement the VICH guidelines as adopted, and it is encouraged that also other countries using VICH guidelines would use them unchanged.

It is however recognised that a country or region that was not part of the VICH process developing the guideline, may find that it can apply the main part of a VICH guideline, but specific required details may need to be adapted to the specificity of local conditions, such as the specific animal diseases or animal species relevant for that country /region. In such a case a VICH guideline can be implemented adapted, to the minimum extent necessary, to fit local conditions.

In the interest of promoting harmonisation of technical requirements for the registration of veterinary medicinal products, VICH would encourage the widest use possible of its guidelines, with the minimum changes only when absolutely necessary to adapt the guidelines to local conditions.

Feedback to VICH on which guidelines have been implemented in your region, and how they were implemented would be greatly appreciated.