Centre collaborateur de l'OIE
pour les Médicaments Vétérinaires
ANMV - AFSSA - Fougères

MEMORANDUM ON VICH PROGRAMME

(International Co-operation on Harmonisation of Technical
Requirements for Registration of Veterinary Medicinal Products)

Ten years of Harmonisation

Established under the auspices of the OIE, VICH was officially created in April 1996 when the VICH Steering Committee held its first Meeting. VICH is currently a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. VICH activities should, while maintaining the security of products, harmonise and thus facilitate and accelerate the registration of veterinary products within national and regional territories of countries participating in VICH. This objective is supported by the OIE through its mandate to "improve animal health worldwide".

1. The Birth of VICH

The preparatory work for the establishment of VICH was carried out by an OIE *ad hoc* Group on Harmonisation of Veterinary Medicinal Products. Two meetings were held in 1994 and in 1995 at which the scope of veterinary harmonisation of veterinary drug registration was discussed and the membership and objectives of the VICH proposed.

On the subject of food safety standards linked to the use of veterinary products, it was decided that the VICH should complement the work of Codex and JECFA (Joint FAO/WHO Expert Committee on Food Additives).

2. The Objectives of VICH

- To provide a forum for a constructive dialogue between regulatory authorities and the veterinary medicinal products industry on the real and perceived differences in the technical requirements for veterinary product registration in the EU, Japan and the USA, with the expectation that such a process may serve as a catalyst for broader international harmonisation;
- To identify areas where modifications to technical requirements or greater mutual acceptance of research and development procedures could lead to a more economical use of human, animal and material resources, without compromising safety;
- To make recommendations on practical ways of achieving harmonisation in technical requirements affecting registration of veterinary medicinal products (pharmaceuticals, biologicals, medicated premixes) and to implement these recommendations in the three regions or countries. Once adopted, the VICH recommendations will replace corresponding regional requirements. These recommendations should focus on the essential scientific requirements needed to address a topic and should eliminate unnecessary or redundant requirements;
- The VICH should work in a transparent, timely and cost-effective manner and should provide the opportunity for public comment on recommendations at the draft stage.

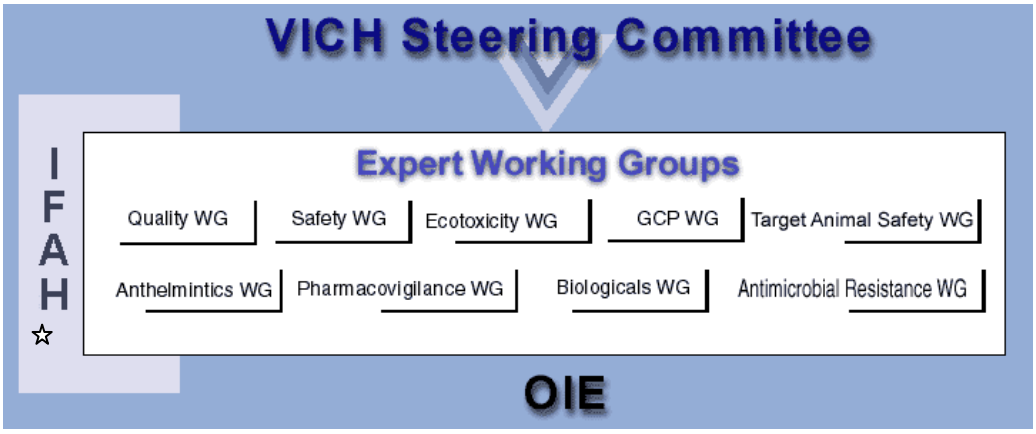
3. General organisation

- VICH activities are carried out under the auspices of the OIE

- ***A single steering committee (SC):***
  - determines the working procedures;
  - determines the priority items based on concept papers prepared by its members;
  - sets up the appropriate working groups and appoints topic leaders and WG chairpersons;
  - approves the draft recommendations issued by working groups before release for world-wide consultation and subsequently for approval by the competent authorities of the EU, Japan and the USA.

- ***Task-oriented working groups (WG):***
  - elaborate draft recommendations for the priority items determined by the SC;
  - submit these draft recommendations and the revised draft recommendations to the SC.

- ***International conferences:***
  - The scope, size, and location of these meetings are decided on a case by case basis by the SC.



☆ **IFAH:** International Federation of Animal Health industry (provides the secretariat for VICH activities)

4. The Work already performed

- 36 final guidelines have been adopted
- 11 draft guidelines are released for consultation

Three International conferences have been organised:

VICH 1
16-18 NOVEMBER 1999
BRUSSELS

VICH 2
10-11 October 2002
Tokyo, Japan

VICH 3
International Conference on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
25-27 May 2005
Washington, USA

5. Forthcoming events

Next meeting of the VICH Steering Committee: **20th meeting: 17–18 October 2007, Japan**

For more information please visit the VICH Web site at the following address:

www.vichsec.org/