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# *PRESS RELEASE*

## Second meeting of the VICH Steering Committee

The Steering Committee of the VICH (International Cooperation on Harmonisation of technical requirements for registration of veterinary medicinal products) held its second meeting at the OIE Central Bureau in Paris on August 20-21, 1997.

Chaired by Dr. J. Boisseau, Head of the OIE Collaborating Centre for Veterinary Drugs, the VICH Steering Committee (SC) reviewed its organisational charter, clarifying specific aspects of the operation of the Steering Committee, Working Groups (WGs) and communication.

The Steering Committee reviewed the progress of the WGs on Quality, Safety, GCP, Anthelmintics Efficacy Requirements and Environmental Impact Assessment on the basis of reports by the WG chairpersons.

The first two draft guidelines VICH GL1 (validation of analytical procedures : definition and terminology), and VICH GL2 (validation of analytical procedures : methodology), elaborated on the basis of ICH guidelines Q2A and Q2B, were adopted at step 3 to be released for consultation.

In reviewing the progress reports of the different WGs and the proposals for new topics, the following work programme was agreed :

- **Quality WG**

  The SC recommended to the WG to adopt, where appropriate, a more flexible approach to evaluate and, if necessary, modify ICH guidelines with respect to their applicability for veterinary medicinal products. The SC recommended that the WG should evaluate the ICH GL on biotechnology/biological stability (Q5C) and the ICH guidelines on Impurities : residual solvents (Q3C) for their applicability to veterinary medicinal products and develop separate guidelines on the stability of medicated premixes. The SC agreed that the work on the evaluation of ICH guidelines on stability and on impurities should continue. The SC approved the next meeting of the Quality WG which will take place in London on September 29-30, 1997.

- **Safety WG**

  The SC agreed to modify the mandate of the Safety WG and recommended that it should focus its activities towards defining food safety requirements. In line with this recommendation, the SC agreed on the mandate for the WG.

- **Environmental Impact Assessment (EIA) WG**

  The SC recommended that the WG should endeavour to adopt a step 2 recommendation regarding the Phase I of the EIA by the end of 1997. The SC agreed to extend the time line to the end of 1998 for the preparation of a step 2 recommendation for Phase II. The SC approved the 2nd meeting of the WG which will take place on September 1-3, 1997 in London.

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- **Good Clinical Practice WG**

  The SC recommended that the WG should endeavour to adopt a step 2 recommendation regarding GCP by the end of 1997. The SC approved the 2nd meeting of the WG which should take place in the 4th quarter of 1997. The United States offered to host this meeting.

- **Efficacy of Anthelmintics WG**

  The SC recommended that the WG should endeavour to adopt a step 2 recommendation regarding the general principles for efficacy requirements for anthelmintics by the end of 1997. Additionally, if feasible, the WG should attempt to adopt guidelines for bovine anthelmintics and guidelines for equine anthelmintics as step 2 VICH recommendations. The SC approved the 2nd meeting of the WG which will take place on September 28-30, 1997 in Bethesda, MD.

- **Pharmacovigilance WG**

  Pending final decision by the end of September 1997, the SC decided to establish a WG on pharmacovigilance chaired by the FDA. The scope of its work should cover both pharmaceuticals and biologicals. The WG should cover two topics :

  1. Veterinary pharmacovigilance framework and terminology - Topic leader : EU
  2. Electronic standards for the transfer of information - Topic leader : AHI

- **Biologicals WG**

  Pending final decision by the end of September 1997, the SC decided to establish a WG on quality monitoring or biologicals chaired by JMAFF. The WG should cover three topics :

  1. Mycoplasma testing - Topic leader : USA
  2. Formaldehyde and moisture testing - Topic leader : AHI
  3. Extraneous agents - Topic leader : Fedesa

The SC agreed that the results of VICH should be publicised and discussed at a VICH public conference. In order to prepare the first VICH public conference, the SC decided to prepare proposals regarding the organisation and issues of the conference by the end of 1997.

The 3rd meeting of the SC was scheduled for February 24-26, 1998.

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*** Members of the Steering Committee**
EU : European Commission, European Agency for the Evaluation of Medicinal Products
JMAFF : Japanese Ministry of Agriculture, Forestry and Fisheries
USA : US Food & Drug Administration (CVM) and Department of Agriculture (APHIS)
AHI : US Animal Health Institute
FEDESA : European Federation of Animal Health
JVPA : Japanese Veterinary Pharmaceutical Association
***Observers**
Australia/New Zealand : Ministry of Agriculture
AVCARE/AGCARM : National Association for Crop Protection & Animal Health/Agricultural Chemicals & Animal Remedies Manufacturers'Association of New Zealand
FILASA : Federación Latinoamericana de la Industria para la Salud Animal
MERCOSUR : Mercado Común Sudamericano (Argentina, Brazil, Paraguay, Uruguay)