

PRESS RELEASE

First meeting of the VICH Steering Committee

The International Cooperation on Harmonisation of technical requirements for registration of veterinary medicinal products (VICH) was officially launched at the OIE headquarters in Paris on April 10-11, 1996.

Inaugurated by Dr. Blancou, Director-General of OIE and chaired by Dr. J. Boisseau, Head of the OIE Collaborating Center for Veterinary Drugs, the VICH Steering Committee meeting recognised the preparatory work carried out by the OIE Ad Hoc Group.

The Steering Committee agreed on its composition*, the objectives of VICH, the role of observers, the role of the secretariat by COMISA, and the working procedures.

The Steering Committee also agreed on a multi-annual work programme. Within this work programme five topics have been selected for initiating in 1996 the harmonisation discussion in expert working groups. These are :

- ICH quality guidelines Q1A, Q2A, Q3A and other guidelines related to Q1 (stability), Q2 (analytical validation) and Q3 (impurities) depending on their stage of advancement (ICH step 4 or higher)
- ICH safety guidelines S2A, S5A and other guidelines related to S2 (genotoxicity) and S5 (reproduction toxicity) depending on their stage of advancement (ICH step 4 or higher)
- Good Clinical Practice
- Efficacy requirements for anthelmintics
- Ecotoxicity/environmental impact assessment

Progress on these topics is expected to be reported at the next meeting of the Steering Committee which is to be scheduled for the end of 1996 taking account of progress on the different topics.

April 11, 1996

*** 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)