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PRESS RELEASE

4th 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 fourth meeting in Tokyo on October 20 – 22, 1998. The meeting was chaired by Dr. J. Boisseau, Head of the OIE Collaborating Centre for Veterinary Drugs.

As a first concrete result, the Steering Committee adopted the first two final VICH guidelines:

* GL1 - Validation of analytical procedures: definition and terminology
* GL2 - Validation of analytical procedures: methodology

It also agreed to release for consultation 6 new draft VICH guidelines:

* GL6 - Environmental impact assessments (EIAs) for veterinary medicinal products: Phase I
* GL7 - Efficacy of anthelmintics: general requirements
* GL8 - Stability testing for medicated premixes
* GL9 - Good Clinical Practices
* GL10 - Impurities in new veterinary drug substances
* GL11 - Impurities in new veterinary medicinal products

The Steering Committee reviewed the progress of the WGs on Quality, Safety, Good Clinical Practices, Anthelmintics Efficacy Requirements and Environmental Impact Assessment and the preparatory work of the recently created Biologicals Quality Monitoring WG and the Pharmacovigilance WG. By authorising the two new working groups to meet, the SC fully engaged in new work involving biological products. The Committee reaffirmed that the work of VICH would cover biologicals unless it specifies otherwise.

The Steering Committee reassessed the overall efficiency of the VICH process and stressed the need that WGs should achieve their mandate of arriving at consensus draft guidelines in a timely fashion. It also reaffirmed the leading role of regulatory authorities in the final adoption and implementation of those guidelines in their respective regions.

The Steering Committee decided that OIE should continue to chair the Steering Committee meetings until the end of 1999. After that, the chair would be rotated among the three regions.

To enhance public communication on VICH, the Steering Committee reviewed the VICH web site that was opened on October 14 (http://vich.eudra.org) and reaffirmed its decision to organise a public conference in November 1999 in Brussels. This first public conference will be the landmark of the first phase of VICH and an opportunity to engage interested parties in the communication and consultation on the harmonisation process.

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Recognising that initiatives are under way in the three regions to address the potential risk of the development of resistance from the use of antimicrobials in animals, the Steering Committee agreed to take on board work related to registration requirements for antimicrobials used in veterinary medicine. Specific proposal on how to address this work will be considered at the next SC meeting.

The 5th meeting of the SC was scheduled for May 18-20, 1999 in the Washington DC area, USA.

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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: National Registration Authority (Australia)/Ministry of Agriculture and Forestry (New Zealand)
AVCARE/AGCARM: National Association for Crop Protection & Animal Health (Australia)/Agricultural Chemicals & Animal Remedies Manufacturers'Association of New Zealand