VICH/98/021
2 March 1998

PRESS RELEASE

Third 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 third meeting at the OIE Central Bureau in Paris on February 26 – 27, 1998. The meeting was chaired by Dr. J. Boisseau, Head of the OIE Collaborating Centre for Veterinary Drugs.

The Steering Committee adopted the release for consultation of three draft VICH guidelines on the stability testing of veterinary pharmaceuticals (VICH GL3: stability testing of new drug substances and products; VICH GL4: stability testing for new dosage form; VICH GL5: stability testing : photostability testing of new drug substances and products). The Steering Committee reviewed the progress of the WGs on Quality, Safety, Good Clinical Practice, Anthelmintics Efficacy Requirements and Environmental Impact Assessment

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 order to improve the efficiency of the process, the Steering Committee agreed both short-term and long-term measures. Short-term measures involve an expanded role of the secretariat working with VICH co-ordinators in emphasising the importance of deadlines by VICH members and in a faster circulation of draft guidelines for consultation. The Steering Committee agreed on the need to develop a long-term strategy for VICH.

The Steering Committee decided to rotate the location of Steering Committee meetings in order to balance the resources spent by all VICH members and to improve the participation and the communication within each region. However, the SC agreed that OIE should chair the next Steering Committee meeting. It was agreed that further discussion on the chairmanship of the Steering Committee should take place at the next meeting.

To enhance public communication on VICH, the Steering Committee agreed to open a VICH web site in the 2nd quarter of 1998 and to organise a public conference in the second half 1999 in Europe.

With respect to the work on specific topics, these are the key aspects, as reviewed or agreed by the SC :

Quality

- the scope of the three stability guidelines released for consultation (see above) is limited to pharmaceuticals i.e. does not include biologicals and premixes for medicated feedstuffs.
- it was expected that two draft guidelines on impurities would be available as step 2 documents for the next Steering Committee meeting.
- Additional expertise will be added to the WG which will develop stability testing guidelines for biotechnological/biological products and for pre-mixes.
- the next meeting of the WG will take place in Washington in May 1998.

Safety

- with an amended composition of the WG, the WG was given the mandate to start working again (the next meeting is envisaged to be held in Europe, before the next SC meeting), along the lines of the revised mandate of the group agreed at the 2nd meeting of the Steering Committee.

Ecotoxicity/Environmental impact assessment

- the WG should finalise phase I guidelines at its next meeting scheduled for May in Japan, and begin work on phase II.
- the SC agreed that aquaculture medicinal products will be within the scope of ecotoxicity guidelines

Good Clinical Practice

- in a second phase, the Working Group, with modified expertise, should extend the scope of the guidelines or develop separate guidelines for veterinary biologicals.
- the next meeting will be held on March 9 in Washington, USA

Anthelmintics Efficacy Requirements

- work on the species-specific guidelines (bovine, ovine/caprine, equine, companion animals) should continue at the next meeting of the WG.
- the next meeting will be held in July and location will be confirmed by the end of March.

New topics

- The SC agreed that the two WGs on the new topics (biologicals quality monitoring, pharmacovigilance) should start working and preparing their meeting. They will hold their first meeting as soon as progress has been made on the original work programme of VICH.

The 4th meeting of the SC was scheduled for October 20 - 22, 1998 in Tokyo, Japan.

*** 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/National Registration Authority
AVCARE/AGCARM/VMDA : National Association for Crop Protection & Animal Health/Agricultural Chemicals & Animal Remedies Manufacturers'Association of New Zealand/Veterinary Manufacturers and Distributors Association
FILASA : Federación Latinoamericana de la Industria para la Salud Animal
MERCOSUR : Mercado Común Sudamericano (Argentina, Brazil, Paraguay, Uruguay)