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PRESS RELEASE

Japan successfully hosts progressive VICH meeting

The Steering Committee* of the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) held its 7th meeting on 14-15 June 2000 in Tokyo, Japan. Following the decision to rotate the chair, the meeting was chaired by Dr. Norio Hirayama, JMAFF.

The Steering Committee adopted 4 final VICH guidelines:

- GL6 - Environmental impact assessments (EIAs) for veterinary medicinal product (VMPs) Phase 1
- GL9 - Good Clinical Practices
- GL17 - Stability testing of biotechnological/ biological veterinary medicinal products
- GL18 - Impurities: residual solvents in new veterinary medicinal products, active substances and excipients

These guidelines are scheduled to enter into force by July 2001. However, implementation of GL6 will be postponed in Japan until the guidelines for Phase 2 is adopted.

It also signed off at step 3 on 5 guidelines which will be released for consultation at step 4:

- GL20 - Efficacy of anthelmintics: specific recommendations for feline
- GL21 - Efficacy of anthelmintics: specific recommendations for poultry
- GL22 - Safety studies for veterinary drug residues in human food: reproduction studies
- GL23 - Safety studies for veterinary drug residues in human food: genotoxicity studies
- GL24 - Pharmacovigilance of veterinary medicinal products: management of adverse event reports

The Steering Committee reviewed the progress of the Working Groups on Quality, Safety, Good Clinical Practices, Anthelmintics Efficacy Requirements, Environmental Impact Assessment, Biologicals Quality Monitoring, Pharmacovigilance and the Antimicrobial Resistance.

Formal approval was given for the Expert Working Group on the Target Animal Safety to initiate its activities.

The Steering Committee agreed to a change to its charter to allow affiliation to VICH by certain interested organisations. Such organisations will apply to attend at, but not participate in the Steering Committee meetings. Applicants will be considered on a case by case basis after receipt of written application.

The Steering Committee continues to consider ways of optimising the efficiency of the harmonisation process on an on-going basis.

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The 8th meeting of the Steering Committee was scheduled for 20 and 21 November 2000 in Washington, DC.

*** 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 – Center for Veterinary Medicine (CVM) and US Department of Agriculture – Center for Veterinary Biologics (USDA/CVB)
AHI: US Animal Health Institute
FEDESA: European Federation of Animal Health
JVPA-JAVB: Japanese Veterinary Pharmaceutical Association – Japanese Association of Veterinary Biologics
***Observers**
Australia/New Zealand: National Registration Authority (Australia)/Ministry of Agriculture and Forestry (New Zealand)
AVCARE/AGCARM: National Association for Crop Production & Animal Health (Australia)/Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand