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PRESS RELEASE

8th VICH makes further progress

At its 8th meeting on 20-21 November 2000 in Washington, the Steering Committee (SC)* of VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) approved its work plan and a list of potential future topics to be addressed. The Steering Committee's objective is to finalise its work in 2005. However, the action plan will be reviewed by the SC on a regular basis.

Good progress was reported from the seven active Working Groups: Safety, Anthelmintics Efficacy Requirements, Environmental Impact Assessment, Biologicals Quality Monitoring, Pharmacovigilance, Antimicrobial Resistance and the newly created Target Animal Safety. The Quality Working Group who had finalised its initial work will be reactivated to review the recently adopted ICH guideline Q6A (Specifications: test procedures and acceptance criteria for new drug substances and new drug products: chemical substances) and Q6B (Specifications: test procedures and acceptance criteria for biotechnological/biological products). The ICH is the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Step 4 guidelines on Testing of residual formaldehyde (GL25) and Testing of residual moisture (GL26) were released for a 6-months public consultation period. A corrigendum to GL7 (Efficacy of Anthelmintics: General Requirements) was adopted and released for immediate implementation in the 3 regions.

For the first time, Interested Parties attended the Steering Committee meeting in an effort to improve knowledge and awareness of VICH. The Steering Committee adopted criteria for the acceptance of Interested Parties and will proceed with formal granting of this status to the AVBC (Association of Veterinary Biologics Companies).

The Steering Committee agreed in principle on new policies and guidance documents to improve and optimise the efficiency of the harmonisation process and made plans for the Second Veterinary International Conference on Harmonisation (VICH 2). The conference will take place in Tokyo in October 2002. The VICH Steering Committee outlined the programme for this conference which will mainly focus on a review of progress made to date. The conference will also address the way forward and discuss possible future roles for VICH.

The 9th meeting of the Steering Committee was scheduled for 27-28 June 2001 in London.

*** 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