VICH/06020
1 June 2006

PRESS RELEASE

Significant progress on key Guidelines reported from the 18th VICH Steering Committee

The VICH Steering Committee at its 18th meeting on 31 May to 1 June 2006 in London, Europe, signed-off at step 3, Draft GL 30 (*Pharmacovigilance – Controlled List of Terms)* which was released for a 6 month public consultation period in the VICH regions, and at step 6, GL 29 (*Pharmacovigilance – Management of Periodic Summary Update Reports)* which will be transmitted to the regions for implementation by May 2007.

Two Target Animal Safety Guidelines will be signed-off by written procedure within a few weeks: Draft GL 43 *(Target Animal Safety - Target Animal Safety for Pharmaceuticals)* will be adopted at step 3 and released for public consultation at step 4 and Draft GL 41 *(Target Animal Safety - Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence)* will be adopted at step 6 for implementation by the VICH regions.

The Steering Committee mandated the newly formed Expert Working Group on Metabolism and Residue Kinetics to develop harmonised VICH Guidelines on the following 5 topics:

1. Study requirements to identify the nature and quantity of residues,
2. Study requirements to demonstrate comparative metabolism,
3. Study requirements to demonstrate residue depletion and to establish the withdrawal periods,
4. Validation requirements for analytical methods used in residue trials,
5. Harmonisation of scientific model assumptions.

These topics are important for the international harmonisation of testing requirements for veterinary medicines used in food producing animals.

The Steering Committee also discussed guidance on the monitoring and maintenance of VICH Guidelines which have been implemented for more than 3 years. Guidelines will either be updated through the full 7 step procedure for major changes, or through a simplified procedure should the review require minor changes only. The Steering Committee will decide which Guidelines should be updated as appropriate.

The Steering Committee also reviewed the progress of the work of the Expert Working Groups on Quality and Biologicals Quality Monitoring.

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The 19th meeting of the Steering Committee is scheduled for 24 and 25 January 2007, in Washington DC (USA).

MEMBERS OF THE STEERING COMMITTEE
EU: European Commission - European Medicines Agency
JMAFF: Japanese Ministry of Agriculture, Forestry and Fisheries
USA: US Food & Drug Administration (FDA) – Center for Veterinary Medicine (CVM) and US Department of Agriculture – Center for Veterinary Biologics (USDA/CVB)
AHI: US Animal Health Institute
IFAH-EUROPE: representing the European Animal Health Industry
JVPA: Japanese Veterinary Products Association

OBSERVERS
Australia/New Zealand: Australian Pesticides and Veterinary Medicines Authority (APVMA)/New Zealand Food Safety Authority (NZFSA)
The Alliance/AGCARM: National Association for Animal Health Products (Australia)/Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand
Canada: Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian Food Inspection Agency (CFIA) - Veterinary Biologics Section (VBS)
CAHI: Canadian Animal Health Institute

ASSOCIATE MEMBER
OIE: Office International des Epizooties/World Animal Health Organisation

INTERESTED PARTY
AVBC: Association of Veterinary Biologics Companies (USA)

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