



VICH/01/051
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PRESS RELEASE

9th VICH Steering Committee launches VICH2 and approves more guidelines

The Steering Committee* of VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) met in London, UK on 27 and 28 June 2001 and reviewed the progress of the Expert Working Groups (EWGs).

The Steering Committee gave guidance to the Antimicrobial Resistance Expert Working Group on the elaboration of statements related to prudent use of antimicrobials which should be included as an appendix to the guideline (GL) on Pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance (GL27). It also agreed that the Task Force on Microbial Safety should meet two more times to finalise its recommendations to the Safety WG on testing methods for identifying and measuring the effects of antimicrobial drug residues on the human gut flora. The appropriate revision at step 9 of GL10 - Impurities in new veterinary drug substances and GL11 - Impurities in new veterinary medicinal products was taken on board as a new topic to be dealt with in writing by the existing Quality Working Group.

With the adoption by the Steering Committee of the guidelines on Efficacy of Anthelmintics for equines (GL15), porcines (GL16), canines (GL19), felines (GL20) and poultry (GL21), the Efficacy of Anthelmintics Working Group has successfully finalised its mandate. These guidelines were released for implementation by July 2002 and will be published in the near future.

Safety guidelines GL 22 (reproduction testing) and GL23 (genotoxicity testing) were adopted at step 6 pending final approval by the EU. These guidelines will be released for implementation by August

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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 – 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)

Avicare/AGCARM: National Association for Crop Production & Animal Health (Australia)/Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand

ASSOCIATE MEMBER

OIE: International Office of Epizootics

2002. They will be implemented in Japan when the guideline on the General Approach to Testing is finalised. The pharmacovigilance guidelines GL24 (management of Adverse Event Reports) was returned to the Working Group who is requested to further address some outstanding issues.

Step 4 guidelines were released for a 6-month public consultation period on: 1) pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance (GL27), 2) safety guidelines on carcinogenicity (GL28), 3) pharmacovigilance management of Periodic Summary Update Reports (GL29) and 4) pharmacovigilance controlled list of terms (GL30). The SC agreed that VEDDRA (Veterinary Medicinal Dictionary for Drug Regulatory Authorities) will form the basis for international terminology for pharmacovigilance reporting.

The Steering Committee discussed the programme of the VICH2 conference to take place in Tokyo, Japan on **10-11 October 2002**. The first announcement is due to be circulated in early autumn. VICH2 will focus on the progress achieved to date whilst evaluating the implementation of the final guidelines. The conference will also confirm the benefits of VICH and define the future programme.

The 10th meeting of the Steering Committee is scheduled for 28-29 November 2001 in Tokyo, Japan.

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