VICH/02/061
12 October 2002

PRESS RELEASE

International Conference moves forward global standards for Animal Health Products

About 200 delegates, from Japan, the USA and EU member States and accession countries, as well as from Australia, New Zealand, Canada and many other countries in the world met in Tokyo this week at the second VICH conference. VICH is an international cooperation programme set up between Japan, EU and the USA to develop international guidelines for the registration of veterinary medicinal products.

Dr Toshikazu Ijichi, Director of the Animal Health Division in the Japanese Ministry of Agriculture, Forestry and Fisheries, acknowledged in his welcome address that the public interest in Animal Health and Veterinary Medicinal Products is growing globally, thus the increasing significance of a steady and speedy progress of International Harmonisation, through VICH.

Dr Jim Pearson, representing OIE Director General Bernard Vallat, "believes that the expected benefits from VICH are realistic and that they will improve animal health" and confirmed OIE's commitment to continuing to support VICH.

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)/ New Zealand Food Safety Authority - Environmental Risk Management Authority (New Zealand)
Avcare/AGCARM: National Association for Crop Production & Animal Health (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: International Office of Epizootics

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Since the start of VICH in 1996, more than 100 of the world's leading experts have negotiated and prepared numerous draft and final guidelines in the different fields of product Safety, Quality and Efficacy. 25 guidelines have already been adopted and mostly implemented in the 3 regions, whilst 5 are at the end of the consultation period and 4 under consultation. Further documents are being prepared within the 6 currently active Expert Working Groups

The VICH2 conference breakout sessions provided an opportunity for the participants to meet with numerous experts and discuss the scope and the requirements of VICH Guidelines in the fields of Quality, Safety, Ecotoxicity, Biologicals Quality Monitoring, Efficacy of Anthelmintics, Pharmacovigilance, Antimicrobial Resistance and Target Animal Safety.

Participants agreed that VICH is today more important than ever before in order to facilitate the global registration of Veterinary Medicinal Products, whilst establishing and maintaining consumer confidence in the Quality, Safety and Efficacy of these products. Animal welfare and consumer safety are of paramount importance to modern society at the beginning of the 21st century.

Keynote speaker Dr Bill Jolly, New Zealand Ministry of Agriculture and Forestries, called for a harmonised, risk-based and outcome-focused registration system, in which mutual recognition of the equivalence of regulatory systems and increased cooperation and sharing of assessments are the keys to success.

In closing the conference, Dr Stephen Sundlof, Director of the Center for Veterinary Medicines of the US Food and Drug Administration, congratulated VICH for the progress achieved within a few years, and invited all the participants to attend the VICH3 conference in the USA in Spring 2005. Dr Sundlof encouraged the participants to address the remaining challenges.

JVPA, JAVB and JMAFF were praised for the outstanding organisation of this successful event.

The VICH Steering Committee held its 11th meeting in Tokyo around the Conference and signed-off four Guidelines at step 6:

- VICH GL 28 - Safety of Residues of Veterinary Drugs in Human Food – Carcinogenicity Testing,
- VICH GL 31- Safety of Residues of Veterinary Drugs in Human Food – Repeat-Dose (90 days) Toxicity Testing,
- GL 32 - Safety of Residues of Veterinary Drugs in Human Food – Developmental Toxicity Testing,
- GL 33 - Safety of Residues of Veterinary Drugs in Human Food – General Approach to Testing.

These Guidelines were released for implementation in the 3 regions by October 2003, with the exception EU implementing GL 32 at a later date.

The 12th meeting of the Steering Committee is scheduled for 7 and 8 May 2003 in London, Europe.

For further information, please contact the VICH Secretariat:
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