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PRESS RELEASE

VICH1 participants applaud impressive progress in international harmonisation

Over 280 delegates, from countries as far a field as Saudi Arabia, South Africa, Mexico and New Zealand met in Brussels this week at the first 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. Australia and New Zealand also participate as observers.

The spokesman of HRH Prince Laurent of Belgium said at the welcome reception to the conference that VICH had an important contribution to offer in the worldwide reduction in the use of experimental animals. The conference was opened by Dr. Jean Blancou, Director-General of OIE. He commended VICH members on succeeding agreement on areas such as:

- Duration and condition for stability tests
- Levels and testing requirements for impurities
- Initial environmental impact assessment (phase 1), including thresholds for the need for more sophisticated fate and exposure studies
- A complete guide for integrating quality approach into clinical trials (GCP)
- Design of dose-determination and dose-confirmation studies for anthelmintics
- Requirements for testing the efficacy of anthelmintics in each animal species

These agreements are consigned in a set of 12 guidelines developed during the first three years of the VICH process.

This was echoed by Dr. Boisseau, Head of the OIE Collaborating Center for Veterinary Drugs, who chaired the VICH Steering Committee for the first 3 years of VICH. “The conference was a unique opportunity for everyone to have their say on priorities for future international work” stated Dr. Boisseau.

Among these priorities for future work, VICH will be discussing certain registration requirements of antibiotics through a new working party.

“Antibiotics and the potential transfer of resistant organisms to human is a very topical issue in all member countries” said Dr. Jacques Boisseau, Chair of the VICH Steering Committee. “The new working group will have a difficult but very important job to do in establishing new guidelines that are acceptable to regulatory authorities” he said.

Secretariat : c/o COMISA, rue Defacqz, 1 - B - 1000 Bruxelles (Belgium) - Tel. +32-2-541.01.11, Fax +32-2-541.01.19
e-mail : comisa@fedesa.be - Website : http://vich.eudra.org

Mr. Jörn Keck, Deputy Director-General of the Directorate-General for Enterprise at the European Commission, also welcomed the progress made in reaching this important milestone, which will “benefit consumers everywhere", and "looked forward with confidence to the next phase of VICH.”

Mr. Alex Thiermann, Senior Trade Coordinator from US Department of Agriculture, and recent past Chairman of the WTO SPS Committee, commented on the role that harmonisation initiatives, such as VICH, have in reducing potential barriers to trade.

Keynote speaker John Preston, Chairman of Merial, said that "international harmonisation was a tremendous opportunity to reinforce and restore confidence in science-based decisions and address the crisis of confidence in the safety of the animal food supply chain”.

Dr. Alison Turner, CEO of the Australian National Registration Authority, in her address, reflected that “VICH provided the opportunity to access the best experience in the world, leading to quality guidelines that minimised unnecessary animal testing and contribute to consistent product standards.”

The VICH conference provided an opportunity for participants to review progress and make comments on specific guidelines and the VICH process in general.

Interest was strong – many comments focussed on how non-VICH participants could comment on guidelines under development, recognising their potential international impact, and they encouraged even greater transparency in the VICH process.

In closing the conference, Mr. Norio Hirayama, the Chief of the Second Assay Division in Japanese MAFF, recognised “the achievements of VICH in bringing together industry and regulatory agencies from countries with different cultures, languages and customs.” Dr. Michael McGowan from the US Animal Health Institute acknowledged “the major benefits that will accrue to industry from common data requirements in the VICH regions, as well as facilitating the availability of new innovative veterinary products.“

FEDESA, the European Federation of Animal Health, was praised for organising this top-class event, facilitating contacts and interactions between all delegates.

Seven new guidelines adopted at 6th VICH Steering Committee

The Steering Committee* of the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products) held its 6th meeting in the margins of the VICH conference, on 15, 16 and 19 November. The meeting was chaired by Dr. J. Boisseau, Head of the OIE Collaborating Centre for Veterinary Drugs.

The Steering Committee adopted 7 final VICH guidelines:

- GL7 - Efficacy of anthelmintics: general requirements
- GL8 - Stability testing for medicated premixes
- GL10 - Impurities in new veterinary drug substances

- GL11 - Impurities in new veterinary medicinal products
- GL12 - Efficacy of anthelmintics: specific recommendations for bovines
- GL13 - Efficacy of anthelmintics: specific recommendations for ovines
- GL14 - Efficacy of anthelmintics: specific recommendations for caprines

These guidelines are scheduled to enter into force in November 2000, with a maximum possible extension of the implementation date until May 2001.

It also released 3 guidelines for consultation at step 4:
- GL15 - Efficacy of anthelmintics: specific recommendations for equines
- GL16 - Efficacy of anthelmintics: specific recommendations for swine
- GL19 - Efficacy of anthelmintics: specific recommendations for canine

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 and Pharmacovigilance.

Based on a strategic plan agreed at its last meeting, the Steering Committee discussed the working plan for 2000-2003 and agreed a number of fundamentals regarding its functioning and future work. As a short-term item, it endorsed the creation of 2 additional working groups on the following topics:

- Antimicrobial resistance (to be chaired by the EU)
- Target Animal Safety (to be chaired by JVPA/JAVB)

The mandate of the antimicrobial resistance Working Group is to elaborate requirements on pre-approval studies needed to predict the potential of antimicrobials to develop resistance, and on labelling requirements related to the prudent use of these products.

The 7th meeting of the Steering Committee was scheduled for 14-16 June 2000 in Tokyo, Japan.

*** 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