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PRESS RELEASE

VICH adopts its priorities for the next 5 years

At its 32nd meeting held in Tokyo on 25, 26 and 30 October 2015, the VICH Steering Committee adopted the new VICH priorities for the years 2016 through 2020, with particular focus on its global outreach strategy.

The meeting was held in conjunction with VICH 5 public Conference, 28 - 29 October; the theme was *Reaching Out to the World*. It was attended by 189 participants from 23 countries. During the Conference the debate focused on the benefits of VICH Guidelines for non-VICH member countries, the needs and priorities of non-VICH countries regarding the technical requirements for the registration of veterinary medicinal products, the contribution of VICH to the global One Health approach, to food security and to animal welfare. The importance of global regulatory convergence was highlighted. The presentations made at the Conference will be made publically available on the VICH website (www.vichsec.org).

The 6th meeting of the VICH Outreach Forum, held on 26 - 27 October, was co-chaired by VICH and the OIE, and took place in conjunction with the Steering Committee meeting. The Forum participants from 6 continents heard representatives from Thailand and Argentina report on their regulatory experience with fish medicines, whilst South Africa and Canada shared their experience with herbal medicines.

The Steering Committee, the OIE and the Forum participants discussed the development of VICH Guidelines on stability to address climatic zones III and IV (hot and dry/humid conditions) and on efficacy studies for combination products. Discussions focused also on pharmacovigilance, bioequivalence, microbial safety assessment and waiving of target animal batch safety testing. The Steering Committee agreed to provide more information to the Forum member countries at the next ASEAN focal points meeting.

The Steering Committee discussed and set a plan of actions for the training implementation strategy which includes the development of training materials, funding and logistics.

The Steering Committee established the Anthelmintics Expert Working Group with the mandate to start reviewing the existing VICH anthelmintics guidelines.

The Steering Committee reviewed the discussion paper prepared by the Task Force on combination products and asked the Task Force to develop a Concept Paper for further discussion at the next Steering Committee meeting.

The Steering Committee adopted the draft VICH Biologicals Guideline 55 (*Biologicals: TABST Live vaccines - Harmonization of criteria to waive target animal batch safety testing for live vaccines*). The public consultation period will be 6 months.

All VICH draft and final Guidelines are available on the VICH website (www.vichsec.org).

The Steering Committee also reviewed and acknowledged the progress of the work of the Expert Working Groups on Pharmacovigilance – Electronic Standards Implementation, Safety, Quality, Biologicals Quality Monitoring, and Metabolism and Residue Kinetics.

The 33rd VICH Steering Committee meeting and the 7th VICH Outreach Forum meeting are scheduled to take place between 20 and 23 June 2016 in Brussels, Europe.

MEMBERS OF THE **S**TEERING 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: Japan Veterinary Products Association

OBSERVERS

Australia/New Zealand: Australian Pesticides and Veterinary Medicines Authority (APVMA)/New Zealand Ministry for Primary Industries

AMA/AGCARM: Animal Medicines Australia/Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand

Canada: Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian Centre for Veterinary Biologics

CAHI: Canadian Animal Health Institute

South Africa: Department of Agriculture, Forestry and Fisheries (DAFF) and Department of Health

SAAHA: South African Animal Health Association

ASSOCIATE MEMBER

OIE: World Organisation for Animal Health

INTERESTED PARTY

AVBC: Association of Veterinary Biologics Companies, USA

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