International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

VICH/23/073

PUBLIC STATEMENT

VICH Advances Efforts to Harmonise Technical Requirements

Tokyo, Japan, 16 November 2023.

Animal health experts from around the world convened in Tokyo, Japan, to advance efforts to harmonise technical requirements for veterinary medicinal products by progressing VICH activities.

VICH promotes the establishment of safe and effective veterinary medicinal products across the world through wider international harmonisation of technical requirements for the registration of veterinary medicinal products. The 42nd VICH Steering Committee and the 16th VICH Forum (VF) annual meetings ran from 13 to 16 November. The Steering Committee was chaired by the Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF) and the VICH Forum was chaired by the World Organisation for Animal Health (WOAH).

The 16th VF meeting welcomed 16 participants representing 8 national regulatory agencies or animal health industry organisations from 5 continents and 1 international organisation representing 7 countries. 48 participants took part in the 2 days meeting. The VF featured a pre-meeting that focused on the benefits, the impact and the expectations of being a member of the VF and the challenges realised by regulatory agencies. The VF members took note of updates on VICH activities and related WOAH work streams. They were updated on the status of VICH guidelines either in development or under revision, and noted important resources and activities available to them through the WOAH. Representatives from the EU, Japan and the USA delivered presentations on how generic veterinary medicinal products are regulated in their country or region. All participants had the opportunity to engage in conversation about the review of applications for generic veterinary medicinal products and to elaborate on their efforts aimed at increasing the efficiency of regulatory reviews. VF members were reminded of important resources available online at www.vichsec.org including training materials and information about the VICH process and activities.

The VICH Steering Committee agreed to criteria for countries to progress along VICH membership categories. This effort was a continuation of work to modernise the organisation's structure and better align the VF with members' diverse expectations. In this frame, the Steering Committee welcomed the delegates from Switzerland, the new observer member to VICH. The Steering Committee also initiated two new activities related to (1) Global Regulatory Dossier Framework for Veterinary Medicinal Products and (2) principles for technical guidance for the transition to in-vitro methods for batch potency tests in veterinary immunologicals.

The Steering Committee took note of the progress of the Expert Working Groups (EWGs) on Anthelmintics, Quality, Biologicals, Pharmacovigilance, Safety, Metabolism and Residue

Kinetics, Combination Products, Bioequivalence and Medicated Premixes. The Steering Committee acknowledged that the consultation period of draft VICH Quality GL 60 (*GMP for API: Good Manufacturing Practice for Active Pharmaceutical Ingredients used in Veterinary Medicinal Products)* will shortly come to an end, and that, after the review of the comments by the experts, the final revised guideline will be circulated for implementation next year. Additionally, implementation of the 9 revised Anthelmintics guidelines is expected in the coming months.

The Steering Committee thanked the EWGs for efficiently continuing their work to progress harmonisation efforts.

The 43rd VICH Steering Committee meeting, together with the 17th VF meeting, and 7th VICH public conference will be held in Amsterdam, The Netherlands, from 10 to 15 November 2024. The public conference is open to all interested parties and will take place on Wednesday 13 and Thursday 14 November. The meetings will be in person.

About VICH:

VICH is an international cooperation programme driving the harmonisation of technical requirements for the registration of Veterinary Medicinal Products.

All VICH draft and final guidelines are available on the VICH website. The translations of several VICH guidelines are available on the website of WOAH at: VICH Forum - WOAH - World Organisation for Animal Health.

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

STANDING MEMBERS
Australia: Australian Pesticides and Veterinary Medicines Authority (APVMA)
AMA: Animal Medicines Australia
New Zealand: Ministry for Primary Industries (MPI)
APHANZ: Animal and Plant Health New Zealand
Canada: Health Canada (HC) - Veterinary Drugs Directorate (VDD) and Canadian Food Inspection Agency - Canadian Centre for Veterinary Biologics (CCVB)
CAHI: Canadian Animal Health Institute
South Africa: Department of Agriculture, Forestry and Fisheries (DAFF) and South African Health Products Regulatory Authority (SAHPRA)
SAAHA: South African Animal Health Association

VMD: Veterinary Medicines Directorate – the UK
NOAH: National Office of Animal Health **-** representing the UK Animal Health Industry

ASSOCIATE MEMBER
WOAH: World Organisation for Animal Health

OBSERVER MEMBER
Swissmedic: Swiss Agency for Therapeutic Products
Scienceindustries: Business Association Chemistry Pharma Life Sciences, representing the Swiss Animal Health Industry

INTERESTED PARTY
AVBC: Association of Veterinary Biologics Companies, USA

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