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

VICH/20/093

PUBLIC STATEMENT

VICH program continues unabated

Brussels, 20 November 2020.

The current global pandemic did not stop the VICH work program from continuing, with VICH Expert Working Groups and Steering Committee members continuing their discussions in on-line virtual meetings. In fact, as result of this year's meetings, the VICH work program will be expanded to new topics. The VICH Outreach Forum program, designed to give non-VICH countries access to VICH work, also continued unabated with record attendance on-line, and is further expanded to include on-line webinars.

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. Now in its third decade of activity, the 39th VICH Steering Committee and 13th VICH Outreach Forum (VOF) annual meetings took place by on-line video-conference from 16 to 19 November 2020.

The 13th meeting of the VOF, chaired by the OIE, drew over 90 participants representing 22 national regulatory agencies or animal health industry organisations from six continents. Following updates on VICH activities and related OIE activities, the VOF members took the advantage of an open Q&A session. An on-line training webinar aiming at a better understanding of VICH GL 27 (*Antimicrobial Resistance - Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance*) has been offered to the VOF members. A follow up virtual meeting with VICH experts to address technical questions from VOF members will be organised in early 2021. This training material will be added to the training section available on the VICH website www.vichsec.org.

The VICH Steering Committee formally adopted VICH GL59 (Biologicals) *LABST – Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use* for implementation in the VICH regions by November 2021. This Guideline completes the series of three VICH biologicals Guidelines on harmonising the criteria to waive target and laboratory animal batch safety testing, with the aim of reducing the need for these tests and improving animal welfare.

The Expert Working Group on Quality will begin to work on a new draft Guideline, following the adoption of the Concept Paper *for the adoption of ICH Q7: Good Manufacturing Practice for Active Pharmaceutical Ingredients* by the Steering Committee.

The Steering Committee took note of the initiation of work by the new Expert Working Group on Medicated Premixes following the adoption of the Concept Paper *on further guidance around medicated premixes*.

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The Steering Committee also monitored the progress of the Expert Working Groups on Biologicals, Pharmacovigilance, Safety, Metabolism and Residue Kinetics, Combination Products, Bioequivalence and Anthelmintics.
The Steering Committee finalised the VICH Priorities for Phase 5 (2021 to 2025).

The 40th VICH Steering Committee and 14th VOF meetings are scheduled for 15 - 18 November 2021 in Amsterdam, the Netherlands, Europe, possibly in a combined face to face and on-line format.

About VICH:

VICH is a trilateral cooperation programme among the European Union, Japan and the United States of America 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 OIE at: https://www.oie.int/scientific-expertise/veterinary-products/vich-outreach-forum/.

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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

OBSERVERS
Australia: Australian Pesticides and Veterinary Medicines Authority (APVMA)
AMA: Animal Medicines Australia
New Zealand: Ministry for Primary Industries (MPI)
AGCARM: Agricultural Chemicals & Animal Remedies Manufacturers' Association of New Zealand
Canada: Health Canada (HC) - Veterinary Drugs Directorate (VDD) and 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

ASSOCIATE MEMBER
OIE: World Organisation for Animal Health

INTERESTED PARTY
AVBC: Association of Veterinary Biologics Companies, USA

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

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