EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

THE LATEST DEVELOPMENTS' IN SCIENTIFIC REVIEW, REGULATION AND MARKETING AUTHORISATION PROCEDURES

Scientific developments:
VICH update on work on biologicals

European Medicines Agency/IFAH-Europe Info Day 2016

Presented by Esther Werner - 17 March 2016

Content

- VICH Biologicals Quality Monitoring Expert Working Group
- Harmonisation of criteria to waive target animal batch safety test for vaccines for veterinary use
- Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use
- Discussion on extraneous viruses in veterinary vaccines

VICH Biologicals Quality Monitoring Expert Working Group

- 10th meeting, 25-27 Oct. 2015, TOKYO, (Japan)
- Discussion on harmonisation of criteria to waive TABST for live vaccines for veterinary use (GL 55) and as follow up consequences for GL 50 for inactivated vaccines.
- Discussion on harmonisation of criteria to waive LABST for vaccines for veterinary use.
- Discussion on extraneous agents testing for veterinary vaccines.

Harmonisation of criteria to waive TABST for live vaccines for veterinary use (VICH GL 55)

- Submission of batch safety test data from target or lab animals - requirement for batch release of veterinary vaccines in most regions participating in the VICH.
- Structure & content of the GL 55 – similar to GL 50.
- Addition of a paragraph on seed lot system (2.2.2.2)
  "The establishment of a seed lot system, subject to quality and manufacturing controls, provides further assurance of the consistent production of vaccine batches and resulting batch quality."
- Include paragraph on system for post-marketing re-examination of field safety data (2.3.1.3 Pharmacovigilance data)

Harmonisation of criteria to waive TABST for live vaccines for veterinary use (VICH GL 55)

2.3.1.2. Information available on the current batch safety test

- Number of batches: *"…, test data **of 10 batches (or a minimum of 5 batches if 10 batches are not manufactured within 3 years)** is likely to be sufficient for most products. The data should be obtained from consecutively tested batches from different vaccine bulks."*
- Combined vaccines: *"Generally, **data from TABST of combined vaccines** may be used to waive the TABST of vaccines containing fewer antigen and/or adjuvant components provided the remaining components are identical in each case and it is only the number of antigens and/or adjuvant which has decreased. …"*
- GL 55 signed off (step 3) for public consultation at VICH SC meeting

Harmonisation of criteria to waive TABST for inactivated vaccines for veterinary use (VICH GL 50)

- BQM-EWG also suggested that GL 50 should be revised to be in compliance with VICH GL 55, on the following points
  - update background of the GL (1.1.1)
  - change/update regional requirements, incl. legal basis for Japan
  - batch numbers necessary for waiving TABST
  - utilization of data from TABST of combined vaccines
  - include paragraph on seed lot system and on system for post-marketing re-examination of field safety data
- VICH SC decided to made in parallel minor changes to GL50 to bring it in line with GL55 - both GL circulated together for public consultation.

Harmonisation of criteria to waive TABST for live & inactivated vaccines for veterinary use (Draft VICH GL 50 & 55)

- Published for consultation 26 Feb 2016, deadline for comments: **1 Aug 2016**

  http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500202515&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc (Draft VICH GL55)

  http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500202514&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc (Draft VICH GL50)

Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use

- Review of proposed Concept Paper and discussion how to go on.
- Proposal to VICH SC to give the group the mandate of preparing a guideline on criteria for waiving of LABST (as a first step) for vaccines for veterinary use.
- The proposal to move forward would be categorisation of product classes based on risk and control measures as the preliminary step.
- To support this categorisation, data will be collected from previous or on-going LABST testing in collaboration with industry and regulators.
- VICH SC agreed for BQM-EWG to start work.
- Next step: EU to progress with development of a draft GL for discussion by EWG.

Discussion on extraneous viruses in veterinary vaccines

- EU presented the revised approach for extraneous agent testing recently developed.
- This revised approach moves away from prescribing specific tests and towards describing a general approach, starting with a lists of agents to consider, then continues with risk assessment to define which agents can be excluded for testing before starting actual testing, including the demonstration of suitability of tests applied to show freedom of the relevant substrate from specified EA.
- Step-wise approach supported by the BQM-EWG.

Discussion on extraneous viruses in veterinary vaccines

BQM-EWG agreed on 3 guidelines:

- Description of use of cell cultures for the detection of EAs, getting a full harmonisation across the 3 regions – narrow the scope of the already drafted proposal and focus on the use of cell cultures as a first step .
- List of EAs having a common list & if felt necessary additional regional lists to fit purely regional need – EU list will be looked at by the regions.
- General principles for detection of EAs & defining the testing – more guidance is expected from EU.

Discussion on extraneous viruses in veterinary vaccines

- VICH SC agreed on proposals.

Next steps:

- GL on the use of cell cultures for the detection of EAs – EU comments and proposal is under preparation.
  BQM-EWG to progress with development of draft GL.
- EU to develop Draft Concept Paper for two VICH Guidelines: (1) general principles for detection of extraneous agents in veterinary vaccines and defining the testing of seeds and materials of animal origin (2) a list of extraneous agents that need to be covered is under preparation.

Thank you for your attention