EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on VICH activities

European Medicines Agency/IFAH-Europe Info Day 2016

Presented by Nick Jarrett on 17 March 2016

25th to 30th October 2015

32nd VICH Steering Committee (SC) meeting

6th VICH Outreach Forum (VOF) meeting

VICH 5 Conference
“Reaching out to the world”

(Bilogicals Quality Monitoring EWG meeting)

32nd Steering Committee meeting

VICH priorities – Phase 4: 2016 – 2020

Include:

- Contribute to international efforts to minimise AMR: create/raise awareness of specific technical requirements for registration of antimicrobials, minimising factors that select for AMR
- Focus on wider international harmonisation: foster VOF activities; provide training focused on VICH guidance; consider needs of non-VICH countries when developing guidance; continue to work in close cooperation with OIE
- Consider need for guidance on novel therapies

Expert Working Groups and GLs

Biologicals Quality Monitoring EWG:

- GL 55 on Harmonisation of criteria to waive TABST for live vaccines: recently published for consultation (until 1 August 2016)
- GL 50 on Harmonisation of criteria to waive TABST for inactivated vaccines: recently published for consultation (until 1 August 2016)
- Extraneous agents testing:
  - EWG working on GL on use of cell culture for the detection of extraneous agents
  - CP for 2 further GLs: List of extraneous agents and General principles for detection of extraneous agents
- EWG working on GL on harmonisation of criteria to waive laboratory animal batch safety testing

Expert Working Groups and GLs

Quality EWG:

- 31st VICH SC gave EWG mandate to develop new GL on stability testing focusing on climatic zones III and IV (hot and dry/humid conditions).

  First draft of the GL under development.

Expert Working Groups and GLs

Electronic standards implementation EWG (PhVig reporting)

- Continues with routine maintenance of the GL30 vocabulary list, with particular focus on Species and Breeds lists
- Completion of GL42 and GL35 to finalise the validation procedures technical document and develop a common XML acknowledgment message
- Review of industry paper focusing on the impact of disharmonisation in pharmacovigilance. EWG to comment on where solutions might be achieved without guideline changes and identify areas where guideline changes would be needed.

Expert Working Groups and GLs

Metabolism and residue kinetics EWG:

- GL on study design recommendations for residue studies in honey for establishing MRLs and withdrawal periods
  Development of draft GL is advanced - hope it will be agreed by the EWG in the next 3 to 6 months
- GL on marker residue depletion studies to establish product withdrawal periods in aquatic species
  Development of draft GL is advanced - hope it will be agreed by the EWG in the next 6 to 9 months

Expert Working Groups and GLs

Safety EWG:

- Revision of GL23 (genotoxicity testing):

  Work ongoing to consider continued need for a default in vivo test.

- GL24 (General approach to establish an ARfD):

  EWG in process of finalising guideline following public consultation on the draft.

- GL22 (reproduction toxicity):

  EWG asked to look at the Extended One Generation Reproductive Toxicity Study and consider whether it would be appropriate to update GL 22 to allow use of the EOGRTS as an alternative to the standard 2 generation study and under what circumstances. No mandate to revise the GL at this stage.

Expert Working Groups and GLs

Bioequivalence EWG

- Final BE GL agreed by VICH in August 2015 with implementation date of August 2016

  No ongoing work

  IFAH-EU indicated that it is considering developing a concept paper proposing development of guidance focusing on dissolution testing and possibly on biowaivers (not covered by existing GL)

Expert Working Groups and GLs

Anthelmintics EWG

- A Task Force has reviewed the existing GLs and highlighted areas where there is general support for revision and other areas where further discussion is needed (as well as areas where there is not need for revision).

  EWG created to follow up on this, with mandate to begin revising guidelines where appropriate and hold further discussion where needed.

Expert Working Groups and GLs

Task Force on development of a general combination products GL

- A Task Force previously reviewed and summarised the types of combination products in existence. As a follow up the task force is now developing a concept paper proposing development of a general GL on combination products

Next meeting of VICH SC

20 to 23 June, Brussels

The VICH public website (http://www.vichsec.org)