19 April 2018
EMA/CVMP/IWP/347865/2017-Rev.1
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the CVMP Immunologicals Working Party (IWP) 2018

Chairperson	Status
Chair: E. Werner	Adopted by CVMP in December 2017

The activities outlined in the work plan for 2018 have been agreed considering the respective business priorities, as well as Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

Plenary meetings:	2 (per meeting: 24 members, 1.5 days)
	28 February – 1 March 2018
	20 – 21 September 2018
Other meetings:	
Drafting / Expert groups	6 (approximately 6 participants)
Workshop / Focus group	None
Training	None

Virtual meetings are mainly regarded as complementary to plenary meetings. However, if feasible and depending on the workload, one or two of the plenary meetings could be replaced by virtual meetings.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

2. Product related issues

The following table provides the expected number per year of contributions (number of involvements in dossier) for scientific advice and product assessment, including pre- and post-authorisation issues.

Expected contribution in Scientific Advice	Expected contribution in Product Assessment
2	2

3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1 Guideline on data requirements for multi-strain dossiers for inactivated vaccines against Avian Influenza (AI), Blue Tongue (BT) and Foot and Mouth Disease (FMD) (EMA/CVMP/IWP/105506/2007)

Action: Consideration of the comments to be received on the draft revised guideline (EMA/CVMP/IWP/105506/2007-Rev.1) during the public consultation, for the finalisation of the guideline (Q3 2018).

Comments: None.

3.2. Guidance documents to be released for consultation

3.2.1 Guidance on requirements for the production and control of allergens products for use in animals (EMA/CVMP/IWP/170689/2016-Rev.1)

Action: Revised guideline to be released for public consultation (Q3 2018).

Comments: None.

3.2.2 Reflection paper on measures to promote availability of veterinary vaccines against emergency animal health diseases

Action: Reflection paper to be developed and released for public consultation (Q3 2018).

Comments: None.

3.2.3 Guidance on the use of adjuvanted veterinary vaccines (CVMP/IWP/043/97)

Action: Revised guideline to be released for public consultation (Q3 2018).

Comments: None.

3.3. New topics/concept papers to be prepared/other

3.3.1 CVMP reflection paper on methods found suitable within the EU for demonstrating freedom from extraneous agents of the seeds used for the production of immunological veterinary medicinal products (EMA/CVMP/IWP/251741/2015)

Action: Initiation of revision of the annex to the reflection paper.

Comments: Revision of existing information and addition of new with respect to viruses and/or species and suitable methods for the detection of extraneous agents, to support availability of vaccines and to provide predictability.

4. VICH guidelines and activities

4.1. Draft VICH guideline on the harmonisation of criteria to waive laboratory animal batch safety testing

Action: Contribution to EU position.

Comments: Current status of guideline: Step 2 of VICH process.

4.2. Continued development of VICH guidelines on the subject of extraneous viruses

Action: Contribute to EU position

Comments: Current status of guidelines: development on hold; keep Steering Committee updated of relevant developments in the EU.

5. EU regulatory activities

5.1. Queries raised by CMDv

Action: Provide response to queries raised by CMDv via CVMP, as required.

Comments: None.

5.2. Collaboration with EFSA

Action: Provide contribution to EFSA opinions in accordance with Article 59 of Regulation (EC) No 726/2004, as required.

Comments: None.

5.3. Collaboration with EDQM

Action: Continue the collaboration with EDQM on guidance regarding the implementation of veterinary vaccine monographs.

Action: Continue the collaboration with EDQM on guidance regarding the implementation of veterinary vaccine monographs.

Comments: None.

5.4. Assessor training

Actions: Provide advice / active participation for training of assessors, as required.

Comments: None.

5.5. Joint EMA and HMA action plan on veterinary vaccine availability

Actions: Provide contributions to the CVMP on relevant actions of the action plan, as required.

Follow-up recommendations following the focus group meeting on field trials on how to improve predictability to applicants with respect to the requirements for field efficacy trials.

Comments: Review of the analysis of available field efficacy data and reflect on the need for additional or revision of existing guidance.

5.6. Other

Action: Provide contributions to guidelines and questions raised by other working parties and ad hoc expert groups, as required.

Comments: None.

6. Activities with external parties

6.1. Meeting with interested parties

None foreseen.

6.2. Regulatory authorities outside the EU

As required.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the CVMP Immunologicals Working Party (EMEA/CVMP/IWP/208689/2004-Rev.3)

7.2. List of organisational documents to be developed/revised in the forthcoming 2 years

Mandate, objectives and rules of procedure for the CVMP Immunologicals Working Party (EMEA/CVMP/IWP/208689/2004-Rev.3)

7.3. List of proposed scientific guidelines for the next work plan

Revision of the guidance on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use (EMEA/7/1998);

Revision of the guidance on statistical principles for clinical trials for immunological veterinary medicinal products;

Development of the vaccine antigen masterfile concept;

Revised guideline on indications for veterinary vaccines (EMA/CVMP/IWP/48720/2013).