7 December 2017
EMA/CVMP/EWP/222886/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the CVMP Efficacy Working Party (EWP-V) 2018

Chairperson:	**Status**
Chair: C. Muñoz Vice-chair: N. Bridoux	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 the 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:	3 (per meeting: 26 members, 2 days) 20-21 February 2018 29-30 May 2018 23-24 October 2018
Other meetings:	
Drafting / Expert groups	8-10 virtual meetings (approximately 5 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.

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

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3. CVMP guidance documents

3.1. Guidance documents to be finalised after the consultation period

3.1.1. Guideline for the conduct of bioequivalence studies for veterinary medicinal products (EMEA/CVMP/016/00-Rev.2)

Action: Draft revised guideline to be finalised following public consultation (Q2-Q3 2018)
Comments: Multidisciplinary topic led by EWP-V and involving QWP.

3.1.2. Guideline on DNA reactive impurities in veterinary medicinal products (EMA/CVMP/SWP/377245/2016)

Action: Draft guideline to be finalised following public consultation (Q4 2018).
Comments: Multidisciplinary topic led by SWP-V and involving QWP and EWP-V (target animal safety).

3.2. Guidance documents to be released for consultation

3.2.1. Reflection paper on resistance in ectoparasites (EMA/CVMP/EWP/310225/2014)

Action: Draft reflection paper to be released for public consultation (Q2 2018).
Comments: None.

3.2.2. Guideline on data requirements regarding veterinary medicinal products for the prevention of transmission of canine and feline vector-borne diseases (EMA/CVMP/EWP/278031/2015)

Action: Draft guideline to be released for public consultation (Q2 2018).
Comments: None.

3.2.3. Guideline on anticoccidials used for the therapy of coccidiosis (NtA Vol 7, 7AE15a)

Action: Draft revised guideline to be released for public consultation (Q2 2018).
Comments: None.

3.2.4. Veterinary medicinal products for fluid therapy (NtA Vol 7, 7AE14a)

Action: Draft revised guideline to be released for public consultation (Q3 2018).
Comments: None.

3.2.5. SPC guideline for antimicrobial products (EMEA/CVMP/SAGAM/383441/2005)

Action: Draft revised guideline to be released for public consultation (Q1 2018)
Comments: Multidisciplinary topic led by AWP, and involving EWP-V.

3.3. New topics/concept papers to be prepared

None foreseen.

4. VICH guidelines and activities

4.1. Revision guidelines on efficacy of anthelmintics: General requirements (VICH GL 7) and species-specific recommendations (VICH GLs12-16, 19-21)

Action: Contribute to EU position.
Comments: Current status of guideline: Step 2 of VICH process.

4.2. New guideline on fixed combination products (pharmaceuticals)

Action: Contribute to EU position.
Comments: Current status of guideline: Step 2 of VICH process.

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 Art. 59 of Regulation (EC) No 726/2004, as required.
Comments: None.

5.3. Assessor training

Actions: Contribute to the evaluation of veterinary training curriculum.
Provide advice / active participation for training of assessors, as required.
Comments: None.

5.4. Other

Action: Develop an action plan for CVMP to implement "recommendations for the CVMP" outlined in the CVMP Reflection Paper on anthelmintic resistance (EMA/CVMP/EWP/573536/2013)

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. Meetings with interested parties

None foreseen.

6.2. Regulatory authorities outside the EU

None foreseen.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the CVMP Efficacy Working Party (EWP-V) (EMEA/CVMP/EWP/208686/2004-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 Efficacy Working Party (EWP-V) (EMA/CVMP/EWP/222886/2017-Rev.3).

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

Revision of guideline for the conduct of pharmacokinetic studies in target animal species (EMEA/CVMP/133/99).

Revision of guideline on the SPC for anthelmintics (EMEA/CVMP/EWP/170208/2005).

Revision of guideline for veterinary medicinal products for zootechnical purposes (NtA, AE7a).

Revision of the guideline for veterinary medicinal products controlling Varroa destructor parasitosis in bees (CVMP/EWP/81976/2010).