7 December 2017
EMA/CVMP/ADVENT/573725/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Work plan for the CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) 2018

Chairperson	**Status**
Chair: J-C. Rouby	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 of the core group:

3 (per meeting: 6 members, 0.5 day)

15 February 2018

25 May 2018

13 September 2018

For each new area of therapy on which the group provides advice, at least one physical meeting can take place between the core group and the respective group of specialised experts (topic groups), when applicable.

Other meetings:

Topic groups 12 (approximately 6 participants per meeting)

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. If needed, ad hoc physical meetings can be organised in the margins of CVMP meetings.

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2. Advice on the requirements for authorisation of therapies that are new to the veterinary domain to be completed by ADVENT

2.1. Topics as current priority

ADVENT will continue to work with Question and Answer documents and other guidance for the current priority topics.

The work plan may be updated considering the progress made with the assigned tasks and in light of new topics that have been identified as priority topics.

2.1.1 Cell-based products

Action: Questions and Answers on stem cell-based products for veterinary use: specific questions on target animal safety (EMA/CVMP/ADVENT/791717/2016) – (Q2 2018).

Comments: Reflect the need of new guidance topics based on questions raised and lines taken by CVMP during recent scientific advice and marketing authorisation assessment procedures of cell-based products.

2.1.2. Classification and dossier structure of novel therapy products

Action: Reflect principles in classification of products to pharmaceutical or immunological veterinary medicinal product and consider the most appropriate format of dossier structure for novel therapy products reflecting initially stem cell or monoclonal antibody products.

Comments: Linked to adoption of the new veterinary regulation.

2.1.3. MRLs for biological products

Action: Review the pharmacodynamic, pharmacokinetic and toxicological properties of biological substances relevant in the field of veterinary medicines including in the first phase cytokines, stem cells and monoclonal antibodies and considering how they impact on whether or not MRL evaluations would be necessary for substances that fall into those classes.

Comments: SWP-V will be consulted. Progress pending on availability of expert resources.

3. CVMP Guidance documents

None foreseen.

4. VICH Guidelines and activities

None foreseen.

5. EU Regulatory Activities

None foreseen.

6. Activities with external parties

- Exchanges with the US Food and Drug Administration (FDA), when appropriate, in the context of the confidentiality arrangement that exists between the EMA and FDA, and/or other regulatory authorities outside the EU.
- Contact on an advisory basis with parties concerned with the manufacture and control of veterinary novel therapies.
- When considered appropriate, oral or written presentations by interested parties can be made or may be invited during the development of advice.

7. Organisational matters

7.1. List of adopted organisational documents

Mandate, objectives and rules of procedure for the CVMP Ad Hoc Group on Novel Veterinary Therapies (EMA/CVMP/ADVENT/630299/2014-Rev.1).

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

Mandate, objectives and rules of procedure for the CVMP Ad Hoc Expert Group on Veterinary Novel Therapies (EMA/CVMP/ADVENT/630299/2014-Rev.2).

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

Consideration of regulatory and data requirements of bacteriophage products.