7 December 2017
EMA/CVMP/254946/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use (CVMP) Work Plan 2018

Chairpersons	**Status**
Chair: D. Murphy Vice-chair: H. Jukes	Adopted in December 2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Table of contents

Introduction

The Committee for Medicinal Products for Veterinary Use (CVMP) is responsible for preparing the Agency's opinions on all questions concerning veterinary medicines, in accordance with Regulation (EC) No. 726/2004 of the European Parliament and of the Council.

This work plan is not intended as an exhaustive description of the principal and specific activities of CVMP but is intended to highlight those specific areas which will be the subject of particular focus during 2018, taking as a guide the Network Strategy and the Agency's Work Programme. The Agency's Work Programme also provides workload forecasts for the various procedures managed by the Agency for Centralised Marketing Authorisations, Maximum Residue Limits and Referrals. For 2018, support for new product development, veterinary vaccine availability and addressing the public health threat associated with antimicrobial resistance are priority areas of activity.

The work plans for 2018 for the CVMP Working Parties on Scientific Advice, Safety, Environmental Risk Assessment, Efficacy, Immunologicals, Antimicrobials and Pharmacovigilance as well as for the Joint CHMP/CVMP Quality working party, the Ad-hoc veterinary Expert Group on Novel Therapies (ADVENT) and, the Joint CVMP/CHMP Working Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products (J3RsWG) are also available on the EMA website.

The activities outlined in the CVMP and its working parties work plans 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. Evaluation activities for veterinary medicines

1.1. Support for product development

1.1.1. Emerging therapies and technologies

Increasing the availability of veterinary medicines and promoting the development of innovative medicines and new technologies is one of the objectives of the Network Strategy to 2020. With this objective in mind, the CVMP Ad hoc group on Veterinary Novel Therapies (ADVENT) will continue to create guidance for Industry on selected priority topics relating to emerging therapies and technologies.

CVMP topic leader: J.-C. Rouby

Key objective

- Promote innovation and use of new approaches in the development of novel veterinary medicines.

Activities in 2018

- To adopt Question and Answer documents for priority topics based on proposals from ADVENT;
- Draft an explanatory document for publication on support provided for innovation (Innovation Task Force, MUMS, scientific advice, etc.) and including an explanation of related processes.

1.1.2. Minor use and minor species (MUMS)/limited markets

The MUMS policy is intended to stimulate development of new veterinary medicines for minor species and/or for rare diseases in major species. Products that are classified as MUMS/limited markets are eligible for incentives to encourage their development and the subsequent submission of marketing authorisation applications.

CVMP topic leader: C. Muñoz Madero

Key objective

- Provide support and incentives to develop new medicines for MUMS/limited markets.

Activity in 2018

- Implementation of the revised scientific guidelines on quality, safety, efficacy and immunological data requirements for veterinary medicinal products intended for MUMS/limited markets.

1.1.3. Scientific advice and support to product innovation

In order to facilitate development of new veterinary medicines, the CVMP provides scientific advice to applicants during the research and development phase of veterinary medicinal products on aspects relating to quality, safety or efficacy of these products, and on the establishment of maximum residue limits (MRLs).

CVMP topic leader: R. Breathnach

Key objective

- To provide support for the development of new medicines.

Activity in 2018

- Conduct a survey of potential and previous applicants for scientific advice and Innovation Task Force requests to better understand their needs and follow-up (i.e. implement process improvement, if and where necessary).

1.2. Quality of scientific output

The CVMP provides scientific opinions on applications for the authorisation of veterinary medicinal products following an evaluation of data submitted by applicants as to their quality, safety and efficacy. The assessment of benefits and risks of veterinary medicines includes an evaluation of their impact on animals, users, the environment and consumers of foodstuffs of animal origin.

CVMP topic leader: T. Høy/D. Murphy

Key objectives

- Ensure that guidance documents produced are appropriate in terms of recommendations for data requirements/generation and are proportionate;
- Strengthen the quality of the scientific review process and ensure consistency of CVMP assessment reports and other scientific outputs.

Activities in 2018

- Continue the development/updating and implementation of CVMP guidelines (see individual work plans for the CVMP Working Parties);
- Review assessment procedures with a view to identifying opportunities for process improvement, whilst maintaining the quality and scientific robustness of assessments.

1.3. Post-authorisation activities

1.3.1. Pharmacovigilance

Pharmacovigilance covers the science and activities relating to the detection, assessment, understanding and prevention of adverse events following use of veterinary medicinal products. Pharmacovigilance aims to ensure that post-authorisation safety monitoring and effective risk management are continuously applied to veterinary medicinal products throughout the EU.

CVMP topic leader: J. G. Beechinor

Key objectives

- Maintain and develop efficient and effective conduct of pharmacovigilance, including surveillance and signal management, by providing the necessary guidance and systems, and refining processes;
- Promotion of adverse event reporting relating to use of medicines in food producing animals and provision of feedback to reporters;
- Improve communication of urgent pharmacovigilance issues related to veterinary medicinal products and provide regular updates on emerging and topical issues.

Activities in 2018

- Evaluate the outcome of the pilot project on adverse events surveillance and, in light of the findings, revise the surveillance strategy for centrally authorised products to link signal detection and periodic safety update reports (PSURs) and ensure better use of pharmacovigilance resources;
- Support further development of principles for post-marketing surveillance based on signal detection for all veterinary medicinal products authorised in the EU;
- Obtain detailed insight from specialist veterinarians/healthcare professionals on practical experience with pharmacovigilance reporting;
- Develop overarching strategy on safety communication including pro-active public release of pharmacovigilance information.

1.4. Other specialised areas

1.4.1. Environmental risk assessment

CVMP routinely considers environmental risk assessment (ERA) as part of the regulatory assessment process for veterinary medicinal products.

CVMP topic leader: J. Weeks

Key objectives

- To ensure that potential risks to the environment associated with the use of veterinary medicinal products are evaluated in accordance with international best practice;

- Further consider environmental risk assessment of veterinary medicinal products in aquaculture.

Activities in 2018

- Development of a reflection paper focusing on the potential environmental risks associated with the use of veterinary medicinal products in aquaculture in the EU;
- Finalisation of the reflection paper on antibiotics and antimicrobial resistance in the environment.

1.4.2. Maximum Residue Limits (MRLs)

Safeguarding human health by establishing MRLs of veterinary medicines for food-producing animals continues to be a key task.

CVMP topic leader: E. Lander Persson

Key objective

- Ensure that the establishment of MRLs supports the safe use of veterinary medicines in regard to their impact on human health.

Activities

- Provide advice to the European Commission on the need for existing 'other provisions' entries in Commission Regulation (EU) 37/2010;
- Develop principles for the approach for MRLs for biologicals.

2. Horizontal activities and other areas

2.1. Antimicrobial resistance (AMR)

CVMP seeks to balance the continued need for antimicrobials to treat infectious diseases in animals with the need to minimise the risk of antimicrobial resistance arising from the use of these classes of products in veterinary medicine.

CVMP topic leader: H. Jukes

Key objectives

- Facilitate the prudent and responsible use of antimicrobials;
- Contribute to the minimisation of the risk to man and animals from AMR due to the use of antimicrobials in veterinary medicines.

Activities in 2018

- Foster implementation of the recommendations from the CVMP Strategy on Antimicrobials 2016-2020, including a focus group meeting to take forward the draft guideline on the risk assessment of antimicrobial veterinary medicinal products following the public consultation;

- Continue the antimicrobial advice ad hoc expert group work on the antimicrobials categorisation;
- Finalise the pilot project on dose optimisation in the context of SPC harmonisation of established veterinary antibiotics and, depending on the outcome of the pilot, provide guidance on the harmonisation of SPCs for 'established' antimicrobials.

2.2. Antiparasitic resistance

CVMP seeks to balance the continued need for use of antiparasitic substances in animals with the need to minimise the risk of (and the development of) antiparasitic resistance.

CVMP topic leader: C. Muñoz Madero

Key objective

- Facilitate the prudent and responsible use of antiparasitic substances.

Activity in 2018

- Finalise an action plan for CVMP on how to follow-up on the recommendations of the reflection paper on anthelmintic resistance.

2.3. Vaccine availability

The EU Network Strategy to 2020 recognises the need to promote the availability of veterinary vaccines in general and those that are needed to control incursions of emerging disease in particular.

CVMP topic leader: E. Werner

Key objective

- Support the development and availability of veterinary vaccines.

Activities in 2018

- CVMP review of recommendations from the CVMP ad hoc group on veterinary vaccine availability (CADVVA) and agreement on specific actions for CVMP and its working parties;
- Develop a reflection paper on measures to promote the availability of veterinary vaccines in emergency situations;
- Follow up from the focus group meeting held in 2017 in relation to field efficacy trial requirements for the authorisation of veterinary vaccines;
- Reflect on the feasibility of incorporating the Vaccine Antigen Master File concept in the assessment of immunological veterinary medicinal products.

2.4. Application of the 3Rs – Replacement, Reduction, Refinement - in regulatory testing of medicinal products

The EMA, through the CVMP, has a key role to play in advocating for minimised use of animals in medicines research and development and in ensuring that alternatives to the testing of animals are used wherever possible.

CVMP topic leader: E.-M. Vestergaard

Key objectives

- Improve and foster the application of 3Rs in the regulatory testing of medicinal products throughout their lifecycle;
- Provide support in implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes and the identification of improvements of the application of 3Rs for regulatory procedures.

Activities in 2018

- Finalise draft reflection paper providing an overview of the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs;
- Continue to review quality control tests for batch release of immunological veterinary medicinal products authorised via the centralised procedure for compliance with current best practice in 3Rs.

2.5. Reinforce the scientific and regulatory capacity and capability of the network

The EU Network Strategy to 2020 acknowledges the advances in science and technology that expand the possibilities for development of medicines and their use, increasing the demands on regulatory advice and assessment. In addition, efforts will continue to strengthen the quality of scientific review processes and outputs.

CVMP topic leader: D. Murphy

Key objectives

- Strengthen the quality of the scientific review process by developing available expertise;
- Ensure optimal organisation of the available expertise within the network for services provided to EMA.

Activities in 2018

- Assess needs and provide training for assessors on regulatory scientific topics and guidelines for the network through working parties and in collaboration with EU network training centre;
- Contribute to considerations for outreach for academic expertise for services provided to EMA, in particular as regards the innovation of veterinary medicines.

2.6. International cooperation harmonisation of requirements for authorisation

Authorisation of veterinary medicines now takes place within a global context and CVMP seeks to harmonise the requirements for authorisation at an international level, wherever possible.

CVMP topic leader: D. Murphy

Key objective

- Promote uptake of harmonised standards at international level.

Activities in 2018

- Continue dialogue with international risk assessment bodies with a view to increasing harmonisation of scientific approaches and methodologies for the establishment of MRLs;
- Seek further interaction with EFSA and ECHA in order to discuss issues of mutual interest with regard to environmental risk assessment;
- Contribute to development of VICH guidelines.