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Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use (CVMP) Work Plan 2019

Chairpersons	**Status**
Chair: D. Murphy Vice-chair: H. Jukes	Adopted in December 2018

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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 2019, 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 2019, support for new product development, veterinary vaccine availability and addressing the public health threat associated with antimicrobial resistance continue to be priority areas of activity. In addition, with the adoption of the new Regulation on Veterinary Medicinal Products (NVR) expected before the end of 2018, it is anticipated that the CVMP and its working parties will be required to deliver on a number of tasks to facilitate implementation of the new legislation. The NVR contains numerous explicit requirements where the EMA will have to provide scientific advice on request as part of the consultation in drawing up various delegated and implementing acts specified in the regulation. Also, there will be a substantial number of consequential activities, in particular relating to the generation of new or revised regulatory and technical guidance. Given that the NVR will become applicable 36 months after adoption, the work preparing for its implementation will have to commence in 2019.

The activities outlined in the CxMP work plans for 2019 have been agreed taking into consideration the Agency's business continuity plans (BCP) due to the preparations for the consequences of the UK's exit from the EU, both in terms of impact on the Agency's operations and the physical relocation of the Agency's current premises in the UK to the new premises in the Netherlands.

The Agency is currently implementing its phase 3 BCP. This will be complemented with an additional set of temporary suspensions/reductions as of 1 January 2019, which will be launched as part of phase 4 of the BCP. Temporary scaling back of activities is currently scheduled to last until 30 June 2019, see enclosed link for additional information.

In that context, CxMP working party work plans will not be developed for 2019. In order to allow the Agency to gradually restore previously suspended/reduced activities, the situation will be reviewed in the second quarter of 2019 at which time the Agency will agree upon the priorities, the measures and the work to be undertaken in the second half of the year.

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.

CVMP topic leader: J.-C. Rouby

Key objective

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

Activity

- Provide a recommendation to the European Commission on the dossier structure and requirements for biological and novel therapy products as part of the revision of the technical annex to the new veterinary Regulation.

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

- Continue ongoing work on MUMS classification and applying reduced data requirements and financial incentives in accordance with the agreed policy.

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

- Following the 2018 survey of potential and previous applicants for scientific advice and Innovation Task Force requests to better understand their needs, 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, and take account of 3Rs principles;
- Strengthen the quality of the scientific review process and ensure consistency of CVMP assessment reports and other scientific outputs.

Activity

- 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/E. Dewaele

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;

- Improve communication of urgent pharmacovigilance issues related to veterinary medicinal products and provide regular updates on emerging and topical issues.

Activities in 2019

- Further develop the principles for post-marketing surveillance based on signal detection for all veterinary medicinal products authorised in the EU;
- Commence work on the drafting of new pharmacovigilance guidance (on Good Pharmacovigilance Practice and on the Pharmacovigilance System Master File) to take account of the changes introduced with the new veterinary regulation; in particular, focussing on adverse event reporting, signal detection, communication of safety information and pharmacovigilance inspections.

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: R. Carapeto Garcia

Key objective

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

Activity

- Continue cooperation with EC and EU Agencies; to discuss issues of mutual interest with regard to environmental risk assessment.

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: D. Murphy/S. Scheid

Key objective

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

Activity

- Develop guidance on the need 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

- Finalise the draft guideline on the risk assessment of antimicrobial veterinary medicinal products following the public consultation;
- Finalise the work of the antimicrobial advice ad hoc expert group on antimicrobials categorisation and development of a preliminary risk profiling;
- Prepare to address Commission requests to provide input on the NVR relating to various AMR topics, including defining criteria for restricting antimicrobial substances to use in man (i.e. not for use in animals).

2.2. 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

- Provide a recommendation to the European Commission on the dossier structure and requirements for immunological products to reflect scientific progress and experience in dossier assessment as part of the revision of the technical annex to the new veterinary Regulation.
- In the context of the revision to the technical annex to the NVR, give further consideration to incorporating the Vaccine Antigen Master File concept in the assessment of immunological veterinary medicinal products.

2.3. 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.

Activity

- In collaboration with EU network training centre, contribute to the training of assessors on regulatory scientific topics and guidelines for the network.

2.4. 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.

Activity

- Contribute to development of VICH guidelines.