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Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use (CVMP) Work Plan 2021

Chairpersons	**Status**
Chair: D. Murphy Vice-chair: G. J. Schefferlie	Adopted

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Introduction

The Committee for Medicinal Products for Veterinary Use (CVMP) is responsible for preparing the European Medicines Agency (EMA) opinions on all questions concerning veterinary medicines, in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council. This includes: evaluating applications for marketing authorisation of new veterinary medicines; supervising the quality, safety and efficacy of veterinary medicines following their introduction to the market; evaluating veterinary medicines authorised at national level that are referred to the EMA for a harmonised position across the EU; and, recommending safe limits for residues of veterinary medicines used in food-producing animals. In addition to the various product assessment-related activities, the CVMP together with a number of expert working groups supports medicinal product development through the provision of scientific advice to companies researching and developing new veterinary medicines and by generating technical guidance for the pharmaceutical industry.

This workplan is not intended to provide an exhaustive list of all activities of CVMP but is intended to highlight those specific areas which will be the subject of particular focus during 2021, taking as a guide network needs regarding the implementation of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products. The regulation contains numerous explicit requirements where the EMA has provided, or is in the process of providing, scientific advice on request of the European Commission in support of drawing up delegated and implementing acts impacting the work of the Agency. Also, there will be a substantial number of consequential activities, relating to the generation of new or revised regulatory and technical guidance.

The CVMP workplan for 2021 also takes into account:

- The recommendations of the EMA Regulatory Science to 2025 and the strategic goals for veterinary medicines;
- The European Medicines Agencies Network strategy to 2025.

Therefore, as for 2020, in 2021 the primary focus for the CVMP and its expert working groups will be to deliver on a number of tasks to facilitate implementation of the Regulation (EU) 2019/6 to be ready by the application date of 28 January 2022. As part of this work, the CVMP will take account of, and strive to realise, the primary objectives of the revision of the legislation, namely: to support new product development, improve veterinary medicines availability, reduce administrative burden and address the public health threat associated with antimicrobial resistance, while guaranteeing the highest level of public and animal health and environmental protection. Further, regarding the use of animals in product development and medicines testing, the CVMP will look to promote the appropriate application of the principles of reduction, replacement and refinement (3Rs), when implementing the new legislation. Some activities related to the implementation of the new legislation will require liaison with CMDv on common interest areas aiming at consistent approaches across the EU.

The Agency's work programme provides workload forecasts for the various procedures managed by the Agency for centralised marketing authorisations for veterinary medicinal products, maximum residue limits and referrals, which are the core activities of the CVMP. For these activities, the CVMP is committed to strengthening the quality of the scientific review process, and to ensuring consistency of CVMP assessment reports and other scientific outputs. While specific activities relating to this objective are not detailed in this work plan, the CVMP will continue to review assessment procedures with a view to identifying opportunities for process improvement, whilst maintaining the quality and scientific robustness of assessments.

While there has been substantial progress implementing the CVMP workplan for 2020, with most activities progressed and many finalised and delivered on time, it is acknowledged that the anticipated

completion date has not been achieved for some activities. There are several reasons for this, including the volume of Regulation (EU) 2019/6 related activity and the disruption to working party activity due to the COVID-19 pandemic. Those activities not completed in 2020 have been carried forward to the 2021 workplan.

The activities outlined in the CVMP workplan for 2021 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2021-2023.

1. Evaluation activities for veterinary medicines

1.1. Support for product development

1.1.1. Emerging therapies and technologies

One of the EMA's strategic goals is to promote development of innovative veterinary medicines and new technologies. In addition, stimulating innovation and promoting new product development is one of the main objectives of Regulation (EU) 2019/6.

When reviewing and updating the technical annex to the regulation (Annex II), the CVMP proposed new technical requirements for biological veterinary medicinal products (VMPs) other than immunologicals and for novel therapy VMPs, with the aim of providing predictability for the development of new products and thus promoting innovation. Reflecting the limited experience and the large range of novel therapy VMPs, as well as the uncertainty regarding types of products that may be developed in the future, the requirements for novel therapy products are presented in the Annex of the regulation mostly in a general manner allowing flexibility on a case-by-case basis. Further, it was acknowledged that additional guidance from the Agency on specific topics to complement some elements of the advice will be required.

CVMP topic lead: D. Murphy, F. Hasslung Wikström

Key objective

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

Activity

No.	Specific activity[1]	Responsible group[2]	Prio[3]	Start date	Cons.[4]	Completion date
1.	Complete review of experience of ADVENT and implement outcome in the establishment of the Novel Therapies and Technologies Working Party (NTWP).	NTWP	1	Ongoing	No	June 2021
2.	Annex II (Novel therapies): consider what, if any, new guidance is required to support Annex II. - Guidance on the classification of novel therapies; - Guidance on data requirements or generation for specific types of novel therapy.	NTWP NTWP	2	June 2021	No	January 2022

[1] Activities that are directly related to implementation of Regulation (EU) 2019/6 are preceded by the relevant Article(s) in the Regulation (e.g. Art. 23-24 (limited markets)) or by 'Annex II' (referring to the technical annex).
[2] Group to support the CVMP in delivering on the specific activity.
[3] Prio = priority. Activities are prioritised (1 – high; 2 – medium; 3 – low) taking account of the date for completion, the extent of work required and criticality of activity (for example, issues not considered essential and/or for which existing guidance can be applied (temporarily) have been given lower priority taking into account the scale of the overall work required).
[4] Cons. = stakeholder consultation required? (yes or no)

No.	Specific activity[1]	Responsible group[2]	Prio[3]	Start date	Cons.[4]	Completion date
3.	Finalise (post-consultation) the reflection paper on 'Promoting the authorisation of alternatives to antimicrobials in the EU'. Prioritise recommendations and select actions to pursue.	CVMP	2	Ongoing	No	June 2021

1.1.2. Limited markets

The existing minor use, minor species (MUMS)/limited markets 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 (MAAs).

For the first time, Regulation (EU) 2019/6 provides a legal basis for authorisation of such products. In order to promote the availability of VMPs within the Union for minor species or for the treatment or prevention of diseases that occur infrequently or in limited geographical areas, recital 30 of the Regulation acknowledges that, in some cases, it should be possible to grant marketing authorisations without a complete application dossier (*reduced safety and efficacy dataset)* having been submitted, on the basis of a benefit-risk assessment of the situation and, where necessary, subject to specific obligations. The EMA/CVMP will consider how the 'limited markets' provision in the Regulation can best be implemented to increase availability of VMPs.

CVMP topic lead: C. Muñoz Madero

Key objective

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

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Continue ongoing work on MUMS classification and applying reduced data requirements and financial incentives in accordance with the agreed policy.	CVMP	1	Ongoing	No	December 2021
2.	Art. 23-24 (Authorisation for limited markets): Review approach for eligibility for 'limited market' product (establish objective criteria) to ensure that it is aligned with the intentions of the Regulation (EU) 2019/6.	EMA/CVMP	1	Ongoing	Yes	July 2021
3.	Art. 23-24 (Authorisation for limited markets): Review and update existing technical guidance on reduced data requirements.	Dedicated Expert group(s)	1	Ongoing	Yes	July 2021

1.1.3. Scientific advice and support to product innovation

In order to facilitate the development of new veterinary medicines, the Scientific Advice Working Party (SAWP-V) of the CVMP provides scientific advice (SA) to applicants on aspects relating to quality, safety or efficacy of these products, on the establishment of maximum residue limits (MRLs) or on bioequivalence of generic VMPs, as well as preliminary risk profile assessments of new antimicrobial substances for veterinary use or new antimicrobial veterinary medicinal products.

CVMP topic lead: F. Hasslung Wikström

Key objective

- To provide support for the development of new medicines.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Continue ongoing work of providing scientific advice.	SAWP-V	1	Ongoing	No	All 2021
2.	Art. 40(5) (Rules on data protection): Elaborate the overall concept and scientific criteria that need to be satisfied in respect of improvement of the benefit-risk balance to justify application of the extended period of data protection.	SAWP-V/CVMP	1	Ongoing	Yes	July 2021
3.	Prepare for potential requests for scientific advice for variations qualifying for application of scientific criteria under Article 40(5) of Regulation (EU) 2019/6.	SAWP-V	2	Q2 2021	No	Jan 2022

1.2. Authorisation activities

The CVMP is responsible for preparing the Agency's opinions on all questions concerning veterinary medicines, in accordance with Regulation (EC) No 726/2004, including evaluation of applications for marketing authorisation of new veterinary medicines.

CVMP topic lead: D. Murphy

Key objective

- Efficient procedures to support the authorisation of safe and effective veterinary medicines of good quality.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Determine CVMP-related activities, if any, as a follow-up to the Article 106(6) advice on appropriate measures to ensure the effective and safe use of VMPs for oral administration.	CVMP and WPs	2	Ongoing	No	June 2021
2.	Art. 42 (Scope of the centralised procedure): Establish clear rules on eligibility for the centralised procedure and reflect on the enlarged scope of the centralised procedure.	EMA/CVMP	1	Ongoing	No	Sept 2021

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
3.	Art. 4 (Definitions): Review and update of benefit-risk guidance (EMEA/CVMP/248499/2007) + assessment report templates to align with revised definition of benefit-risk balance.	EMA/CVMP	2	June 2021	Yes	Jan 2022
4.	Contribute to any tasks arising from revision of the QRD template (linked to Regulation (EU) 2019/6), as requested.	All WPs	2	Ongoing	No	May 2021
5.	Art. 37(2) (Decisions refusing marketing authorisations): Establish principles to demonstrate that a PBT (persistent, bioaccumulative and toxic) substance is essential to prevent or control a serious risk to animal health.	Dedicated expert group	1	January 2021	Yes	January 2022

1.3. Post-authorisation activities

1.3.1. Pharmacovigilance

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse events following use of VMPs, or any other problem related to a medicinal product. It aims to ensure that post-authorisation safety monitoring and effective risk management are continuously applied to VMPs throughout the EU.

Regulation (EU) 2019/6 includes several provisions aimed at improving the operation of the pharmacovigilance system. Chief amongst those is the move towards the 'signal management process' (consists of tasks of signal detection, validation, confirmation, analysis and prioritisation, assessment and recommendation for action) as the 'gold standard' for post-authorisation safety monitoring and the continuous evaluation of the benefit-risk balance. In addition, the Regulation requires that a pharmacovigilance database is established to record and integrate information of suspected adverse events for all VMPs authorised in the Union, noting that this database should facilitate pharmacovigilance surveillance, improve the detection of product-related adverse events, allow for effective work-sharing and communication between the competent authorities, and ensure that information on the safety of authorised VMPs is available to the general public.

CVMP topic leads: H. Bergendahl, E. Dewaele

Key objectives

- Maintain efficient and effective conduct of pharmacovigilance, including surveillance and signal management, while preparing for the future system by providing the necessary guidance, systems, and refining processes;
- Improve communication of urgent pharmacovigilance issues related to VMPs and provide regular updates on emerging and topical issues.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Develop guidance following on from the scientific recommendations on the implementing acts, with a focus on the following topics: - Signal management process; - PSMF and PhV inspections; - Communication on post-authorisation safety issues.	PhVWP	1	Ongoing	Yes	July 2021
2.	Establish processes for work sharing procedures for post-marketing surveillance based on signal detection for all VMPs authorised in the EU.	Dedicated Expert group in consultation with EMA and CMDv/HMA	1	Ongoing	No	Jan 2022

1.3.2. Variations

One of the primary objectives of Regulation (EU) 2019/6 is to reduce administrative burden, while guaranteeing the highest level of public and animal health and environmental protection. Simplification of the procedures for variations of existing marketing authorisations is one of the aspects considered as part of the objective of reducing administrative burden. Article 60(1) of Regulation (EU) 2019/6 requires that the European Commission shall, by means of implementing acts, establish a list of variations to marketing authorisations of VMPs that do not require assessment. In order to apply the Implementing Act, further guidance may need to be developed and procedures relating to the processing of both non-assessed and assessed variations will have to be established.

CVMP topic lead: M. O'Grady

Key objective

- To ensure that practical guidance and efficient procedures are developed that will allow the objective of reducing administrative burden to be achieved.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Art. 60-68 (Variations requiring assessment): Creation of a classification guideline for variations requiring assessment.	Joint EMA/CVMP and CMDv	2	Ongoing	No	June 2021
2.	Art. 60-68 (Procedures for variations): Procedures for variations requiring and not requiring assessment to be developed.	EMA/CVMP in liaison with CMDv	2	Ongoing	No	January 2022

1.3.3. Other post-authorisation activities

Where the interests of the Union are involved, and in particular the interests of public or animal health or of the environment related to the quality, safety or efficacy of VMPs, the marketing authorisation holder, Member States or the Commission may refer its concern to the Agency for an opinion. The new provisions in Regulation (EU) 2019/6 impact the existing referral procedures, which will need to be revised.

CVMP topic lead: G. J. Schefferlie

Key objective

- To ensure that practical guidance and efficient procedures are developed.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Art. 83 (Union Interest Referral): Referral procedure to be revised in line with the regulation.	EMA	2	Ongoing	No	January 2022

1.4. Specialised areas

1.4.1. Environmental risk assessment (ERA)

Regulation (EU) 2019/6 includes several provisions with the specific objective of ensuring the highest level of environmental protection. In addition, the EC "Strategic Approach to Pharmaceuticals in the Environment[5]" outlines a set of actions addressing the multifaceted challenges that the release of pharmaceuticals poses to the environment.

CVMP topic leader: R. Carapeto García

Key objective

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

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Art. 18(7) (Generic VMPs): Establish criteria for requesting ERA data for generic applications (or exempting the requirement for ERA data).	ERAWP	1	Ongoing	Yes	December 2021
2.	Elaboration of a reflection paper on the ERA of ectoparasiticidal VMPs used in companion animals – considerations based on documented environmental concerns.	ERAWP	2	Ongoing	Yes	March 2022
3.	Art. 72 (SPC harmonisation) – Establish criteria for identifying products potentially harmful to the environment.	ERAWP	2	March 2021	Yes	December 2021
4.	Elaboration of a concept paper for the development of a guideline on the environmental risk assessment of veterinary medicinal products used in aquaculture.	ERAWP	2	March 2021	Yes	December 2021
5.	Finalise (post-consultation) the reflection paper on antimicrobial resistance due to presence of veterinary antimicrobials in the environment.	Dedicated expert group	2	Ongoing	No	February 2021
6.	Finalise the reflection paper on investigating the environmental impacts of parasiticides on dung fauna.	ERAWP	2	Ongoing	No	July 2021
7.	Contribute to EC strategic approach for pharmaceuticals in the environment, as required.	ERAWP	3	Ongoing	N/a	All 2021

[5] https://ec.europa.eu/environment/water/water-dangersub/pdf/strategic_approach_pharmaceuticals_env.PDF

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. While the consumer safety evaluation of conventional pharmaceutics is well established and the methodology currently used by the EMA/CVMP is considered adequate to ensure consumer safety, alternative methodologies or approaches are used by other EU/International agencies and, consequently, it is appropriate to consider the need to harmonise approaches. Further, when reviewing and updating the technical annex to the regulation (Annex II), the CVMP proposed new technical requirements for biological VMPs other than immunologicals and for novel therapy VMPs. According to Commission Regulation (EU) 2018/782, evaluations of "chemical-unlike" biologicals shall be conducted on a case-by-case basis. The respective procedures have not yet been developed.

CVMP topic leads: G. J. Schefferlie, S. Scheid

Key objective

- Ensure that the establishment of MRLs support the safe use of veterinary medicines in regard to their potential impact on consumer health.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Finalise procedural and technical guidance on MRLs for biologicals.	EMA, SWP-V, NTWP	1	Ongoing	Yes	March 2022
2.	Further to a request from the Commission, finalise a recommendation for a joint EMA/EFSA approach on exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides residues in food of animal origin.	Dedicated Expert group	1	Ongoing	Yes	November 2022
3.	Assess the possible impact of any change in approach to consumer exposure estimation on CVMP guidance, approach to MRL assessment and existing MRLs and initiate the necessary preparatory and follow-up work.	SWP-V	3	January 2021	No	All 2021
4.	Review relevant safety or residue guidelines and revise, as appropriate, to align with the new definition of withdrawal period in Regulation (EU) 2019/6.	SWP-V	1	April 2021	Yes	January 2022

1.4.3. Efficacy

CVMP topic lead: C. Muñoz Madero

Key objective

- Review and revise existing guidelines

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Art. 4 (Definitions): Review and revise existing efficacy guidelines and Q&A's in line with the definitions provided by Regulation (EU) 2019/6.	EWP	2	February 2021	Yes	January 2022

1.4.4. Quality pharmaceuticals

CVMP topic lead: M. O'Grady

Key objective

- Review and revise existing guidelines

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Finalise (post-consultation) the guideline on the manufacture of dosage forms.	QWP	2	February 2021	No	September 2021
2.	Review of existing guidelines and Q&A's to identify revisions required arising from changes to the variations requirements and Annex II in Regulation (EU) 2019/6.	QWP	3	February 2021	No	September 2021

2. Horizontal activities and other areas

2.1. Antimicrobial resistance (AMR)

The preamble to Regulation (EU) 2019/6 acknowledges that antimicrobial resistance to medicinal products both for human and veterinary use has become a global public health concern that affects the whole of society and requires urgent and coordinated inter-sectoral action in accordance with the 'One Health' approach. Accordingly, the regulation includes provisions aimed at strengthening the prudent use of antimicrobials, avoiding their routine prophylactic use and limiting metaphylactic use, restricting the use in animals of antimicrobials that are of critical importance for preventing or treating life-threatening infections in humans and encouraging and incentivising the development of new antimicrobials. It is also stated that the rules for the authorisation requirements of antimicrobial VMPs should sufficiently address the risks and benefits of these products and, in particular, an application for an antimicrobial VMP should contain information about the potential risk that use of that medicinal product may lead to the development of antimicrobial resistance in humans or animals or in organisms associated with them. The preamble to Regulation (EU) 2019/6 also recognises that, given the limited innovation in developing new antimicrobials, it is essential that the efficacy of existing antimicrobials be maintained for as long as possible.

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 leads: D. Murphy, C. Schwarz

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 medicine.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Finalise (post-consultation) the CVMP strategy on antimicrobials 2021-2025.	CVMP	1	Ongoing	No	January 2021

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
2.	Art 107(6): Provide scientific advice to the Commission on a list of antimicrobials which: (a) shall not be used in accordance with Articles 112, 113 and 114; or (b) shall only be used in accordance with Articles 112, 113 and 114 subject to certain conditions.	Dedicated Expert group	1	Ongoing	No	After publication of the Delegated Act according to Art. 37(4) and the scientific advice on Art. 37(5)
3.	Art. 37(5): Provide scientific advice to the European Commission on antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans.	Dedicated Expert group	1	Ongoing	No	After publication of the Delegated Act according to Art. 37(4)
4.	Art. 4 (Definitions): Revise existing guidelines and Q&A in line with the definitions in the Regulation (EU) 2019/6 for AMR, antimicrobial, antibiotic, metaphylaxis and prophylaxis.	AWP (EWP)	2	February 2021	No	January 2022
5.	Finalise (post-consultation) the draft guideline on the risk assessment of antimicrobial VMPs following the public consultation.	AWP	1	Ongoing	No	April 2021
6.	Art. 40(5) (Rules on data protection): Elaborate criteria that need to be satisfied to support a reduction in resistance to justify an extension to the period of data protection.	Dedicated Expert group	1	Ongoing	Yes	July 2021
7.	Art. 8(2)(b): Consider the need for further guidance on risk management measures (to mitigate the risk of AMR).	AWP	2	Ongoing	Yes	January 2022
8.	Art. 107(3) (Use of antimicrobial VMPs): Elaborate guidance or criteria for determining 'exceptional cases' when antimicrobial administration for prophylaxis would be accepted. Elaborate a procedure for reviewing indications for existing products.	AWP, EWP	2	Ongoing	Yes	January 2022
9.	Finalise the revision of the draft SPC guideline for VMPs containing antimicrobial substances.	AWP, EWP	2	Ongoing	No	June 2021
10.	Finalise (post-consultation) reflection paper on antimicrobial resistance due to presence of veterinary antimicrobials in the environment (see activity 5 under section 1.4.1.).	Dedicated Expert group	2	Ongoing	No	February 2021
11.	Art. 57: Prepare for new activities conferred upon CVMP in relation to sales and use of antimicrobials – establish the governance of activities and approval of forthcoming JIACRA reports (Regulation (EU) 2019/5) and annual reports on sales and use per animal species.	CVMP	2	Q2 2021	No	January 2022
12.	Art. 57: Develop guidance, manuals, data reporting protocols and templates following the scientific recommendations on the implementing and delegated acts on collection of data on antimicrobial medicines used in animals.	Dedicated Expert group	2	Ongoing	Guidelines only	December 2021

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
13.	Finalise (post-consultation) reflection paper on the use of aminopenicillins and their beta-lactamase inhibitor combinations.	AWP	3	Ongoing	No	February 2021
14.	Development of a concept paper to revise the AWP's reflection paper on the use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union.	AWP	3	Q2 2021	Yes	December 2021

2.2. Antiparasitic resistance

Antiparasitic veterinary medicines are widely used in both livestock and companion animals to treat or prevent parasitic diseases in animals; furthermore, a number of these parasites also have zoonotic potential, and some pose a major health concern in humans. Veterinary antiparasitic medicines are extensively used, representing one of the largest financial markets for the animal health industry. With the wide (routine) use of antiparasitic substances, concern has been raised about an increase in the development of resistance in parasites. The frequent use of anthelmintics and the observed development of resistance have already resulted in the loss of efficacy of some substances in certain target animals in certain regions, giving rise to concerns about continued availability of effective antiparasitic medicines.

CVMP topic lead: C. Muñoz Madero

Key objective

- Support the continued availability of effective antiparasitic veterinary medicines.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Art 40(5) (Rules on data protection): Elaborate criteria that need to be satisfied to support a reduction in resistance to justify an extension to the period of data protection	Dedicated Expert group	1	Ongoing	Yes	July 2021
2.	Develop a Concept paper for the revision of the Guideline on the summary of product characteristics for anthelmintics in order to also address ectoparasiticides. Update the guideline accordingly.	EWP	2	February 2021	Yes	December 2021

2.3. Vaccine availability

Vaccination is one of the most effective tools for preventing animal diseases and for promoting animal health and welfare, safe food production and public health. In addition, veterinary vaccines can be an efficient tool in reducing the need to use antimicrobials in animals, thereby contributing to the fight against antimicrobial resistance. Despite their importance, there are often challenges to ensuring that suitable veterinary vaccines are available in a timely manner on the EU market.

The EU Network Strategy to 2020 identifies increasing the availability of veterinary medicines in general, and those that are needed to control incursions of emerging disease in particular, as a priority area for action by the European medicines regulatory network.

Increasing availability of veterinary medicines is also a key intent of Regulation (EU) 2019/6.

CVMP topic lead: E. Werner

Key objective

- Support the development and availability of veterinary vaccines.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Art. 23-24 (Limited markets): Guidance for limited markets for immunological VMPs to be published. See activity 3 under section 1.1.2.	Dedicated Expert group	1	Ongoing	Yes	July 2021
2.	Art. 25-27 (Authorisation under exceptional circumstances): Establish criteria for accepting such applications and elaborate guidance on basic data requirements.	IWP	2	Ongoing	Yes	January 2022
3.	Finalise (post-consultation) the guideline on the use of adjuvanted veterinary vaccines.	IWP	2	Ongoing	No	July 2021
4.	Annex II - Vaccine Antigen Master File (VAMF): Develop specific guidance for the submission and for evaluation of a VAMF.	IWP	2	Ongoing	Yes	January 2022
5.	Revision of the guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), blue tongue (BT) and foot-and-mouth disease (FMD) in line with the new scope of multi-strain dossier concept in the NVR. Guidance on submission of applications and eligibility criteria to be developed in parallel.	IWP	2	Ongoing	Yes	January 2022
6.	Annex II (Platform Technology Master File): Develop specific guidance for the submission and for evaluation of a Platform Technology Master File.	IWP	2	Ongoing	Yes	January 2022
7.	Develop further guidance on providing field efficacy studies in support of MAA for immunological VMPs (revision of existing guidance).	IWP	2	Ongoing	Yes	January 2022

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

The European medicines agencies network strategy to 2025 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 to having the capacity to deal with these increasing demands, it is recognised that there is a need to continue to strengthen the quality of the scientific review process and outputs and to acquire the necessary skills/competencies to support the development of, and appropriately regulate, novel products/technological innovations. An important tool in building regulatory capacity and capability is the provision of training. Much of the training in the Network is facilitated by the 'EU Network Training Centre' (EU NTC), a joint HMA & EMA initiative with the mission to ensure the exchange of good scientific and regulatory practices across the EU

regulatory network, by harmonising training standards and offering high quality and relevant training opportunities.

CVMP topic lead: 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

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	In collaboration with EU network training centre, contribute to the training of assessors on regulatory scientific topics and guidelines for the network (with a focus on training updates relating to the Regulation (EU) 2019/6).	Veterinary training coordination group	1	Ongoing	No	All 2021
2.	Implement the recommendations of the EMA Management Board Task Force on Working Parties	Veterinary Domain (SPG)	1	Ongoing	No	All 2021

2.5. International cooperation and harmonisation of requirements for authorisation

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

CVMP topic lead: D. Murphy

Key objective

- Promote uptake of harmonised standards at international level.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Contribute to development of VICH guidelines.	Relevant working party	1	Ongoing	No	All 2021
2.	Engage with EDQM to discuss issues of mutual interest with regard to the quality of VMPs.	IWP/QWP	2	Ongoing	No	All 2021
3.	Continue cooperation with EC, EU Agencies, other international agencies/organisations to discuss issues of mutual interest in particular but not limited to environmental risk assessment.	EMA	3	Ongoing	No	All 2021