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Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products (CVMP) Work Plan 2022

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

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Introduction

The Committee for Veterinary Medicinal Products (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 and Regulation (EU) 2019/6 of the European Parliament and of the Council, also referred to as 'the Regulation' in this document. 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 veterinary 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 2022, 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 CVMP workplan for 2022 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.

In 2022, as for 2020 and 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 Regulation (EU) 2019/6 up to, and beyond, 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. 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.

The activities outlined in the CVMP work plan for 2022 have been agreed taking into consideration the Agency's prioritisation set forth in the EMA multi-annual work programme 2022-2024.

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 (Commission Delegated Regulation (EU) 2021/805), 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. The newly established Novel Therapies and Technologies Working Party (NTWP) and its Operational Expert Groups (OEGs) are committed to foster innovation by facilitating authorisation of non-immunological biologicals and novel therapy VMPs.

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 Commission Delegated Regulation (EU) 2021/805 mostly in a general manner allowing flexibility on a case-by-case basis. Additional guidance on specific topics will support applicants and the efficient evaluation for timely marketing authorisation of novel veterinary treatments. Intensified horizon scanning activities will provide a better overview on emerging needs for targeted and efficient regulatory support.

CVMP topic lead: J. Poot, S. Casado; **EMA topic lead:** M. Goldammer

Key objective

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

Activities

No.	Specific activity[1]	Responsible group[2]	Prio[3]	Start date	Cons.[4]	Completion date
1.	Contribute to VICH[5] guidance on target animal safety evaluation for veterinary monoclonal antibody products.	NTWP	1	Ongoing	No	December 2023
2.	Develop guidance on efficacy of cell therapies: mechanism of action, potency and clinical effects.	NTWP	1	Ongoing	Yes	December 2023
3.	Develop guidance on quality, safety and efficacy of bacteriophages as veterinary medicines.	NTWP	1	Ongoing	Yes	December 2023
4.	With a view to determining where there is a need for future guidance, consult with national competent authorities (by way of survey) and Industry.	NTWP	2	Ongoing	Yes	June 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)
[5] VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

1.1.2. Limited markets

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 Regulation (EU) 2019/6 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' (LM) provision in the Regulation can best be implemented to increase availability of VMPs.

CVMP topic lead: C. Muñoz Madero; **EMA topic leads:** S. Thiele, A. Contreras

Key objective

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

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Practical implementation of the approach to classification as LM and consideration of eligibility for Article 23, with review and adapting of the approach based on experience and input from the CVMP 'LM oversight' group.	EMA/CVMP	1	Ongoing	No	December 2022
2.	Develop guidance for limited market products not deemed eligible for Article 23.	EWP/IWP/QWP /SWP	1	Ongoing	Yes	January 2023

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; **EMA topic lead:** V. Pucovský, E. Drury

Key objective

- Provide support for the development of new medicines.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Continue ongoing work of providing scientific advice.	SAWP-V	1	Ongoing	No	Ongoing
2.	Article 40(5) (Rules on data protection): Elaborate the overall concept and scientific criteria that need to be satisfied to support a reduction in antimicrobial or antiparasitic resistance and/or an improvement of the benefit-risk balance to justify application of the extended period of data protection.	Dedicated Expert group	1	Ongoing	Yes	May 2022

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
3.	Prepare for potential requests for scientific advice for variations qualifying for application of scientific criteria under Article 40(5).	SAWP-V	2	Q2 2021	No	2022

1.2. Authorisation activities

The CVMP is responsible for preparing the Agency's opinions on all questions concerning veterinary medicines, including evaluation of applications for marketing authorisation of new veterinary medicines. A critical element of the evaluation process is a robust and consistent approach to benefit/risk assessment.

CVMP topic lead: D. Murphy/G. J. Schefferlie; **EMA topic leads:** J. Torren, B. Mustafov

Key objectives

- Efficient procedures to support the authorisation of safe and effective veterinary medicines of good quality;
- Ensure a consistent approach to benefit/risk assessment and taking decisions on classification.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Article 42 (Scope of the centralised procedure): Ongoing review of procedures for the processing of generic applications submitted to the EMA to ensure efficiency of process.	EMA/CVMP	1	Ongoing	No	December 2022
2.	Revise the CVMP recommendation on the evaluation of the benefit-risk balance of VMPs (EMEA/CVMP/248499/2007).	CVMP	2	Ongoing	Yes	December 2023
3.	Article 34 (Classification of VMPs): guidance on the application of Article 34 establishing criteria for determining the prescription status of centrally-authorised marketing authorisations.	EMA/CVMP	2	Jan 2022	Yes	December 2022
4.	Article 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	Ongoing	Yes	June 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: E. Dewaele; **EMA topic lead:** R. Gopal

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.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	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
2.	Ongoing review of signal management work sharing to ensure efficiency of process.	PhVWP	1	Ongoing	No	December 2022

1.3.2. 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. Existing referral procedure documents need to be reviewed and updated to align with the new procedure as laid down in Article 83 of Regulation (EU) 2019/6.

CVMP topic lead: G. J. Schefferlie; **EMA topic lead:** K. Paterson, A. Azaceta

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.	Article 83 (Union Interest Referral): Referral procedure to be revised in line with the Regulation.	EMA	2	Ongoing	No	Q2 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[6]" outlines a set of actions addressing the multifaceted challenges that the release of pharmaceuticals poses to the environment.

CVMP topic leader: R. Carapeto Garcia; **EMA topic lead:** M. Empl

Key objective

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

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Elaboration of a reflection paper on the ERA of ectoparasiticidal VMPs used in companion animals — Considerations based on documented environmental concerns.	ERAWP	1	Ongoing	Yes	December 2022
2.	Development of a guideline on the environmental risk assessment of veterinary medicinal products used in aquaculture.	ERAWP	2	January 2022	Yes	December 2024
3.	Review of the "Reflection paper on risk mitigation measures related to the environmental risk assessment of veterinary medicinal products (EMA/CVMP/ERAWP/409328/2010)".	ERAWP	2	January 2022	Yes	March 2023
4.	Contribute to EC strategic approach for pharmaceuticals in the environment, as required.	ERAWP	3	Ongoing	N/a	2022

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 (Commission Delegated Regulation (EU) 2021/805), 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: C. Bergman; **EMA topic lead:** S. Girault

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

Key objective

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

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Finalise procedural and technical guidance on the need for MRL evaluation for biologicals.	EMA, SWP-V, NTWP	1	Ongoing	Yes	July 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	1	Ongoing	No	April 2023
4.	Revision of residues guidelines to align with the new definition of withdrawal period in Regulation (EU) 2019/6.	SWP-V	1	Sept 2021	Yes	March 2022
5.	Contribute to ongoing revision of VICH safety guidance: GL 22, GL 23 and GL 49.	SWP-V	1	Ongoing		Beyond 2022

1.4.3. Efficacy

The CVMP scientific guidelines on the efficacy of veterinary medicines help applicants prepare marketing authorisation applications. Guidelines reflect a harmonised approach of the EU Member States and the Agency on how to interpret and apply the requirements for the demonstration of efficacy set out in the Union legislation. Noting that Regulation (EU) 2019/6 places significant emphasis on addressing resistance, both antimicrobial resistance as well as antiparasitic resistance, a particular focus for 2022 will be on generating and/or revising existing efficacy guidance aimed at strengthening the prudent use of both antimicrobial and antiparasitic products, avoiding the routine prophylactic use of antimicrobials specifically and encouraging the development of alternatives to antimicrobials.

CVMP topic lead: C. Muñoz Madero; **EMA topic lead:** V. Nicorescu

Key objectives

- Support the continued availability of effective antimicrobial and antiparasitic veterinary medicines;
- Review and revise existing guidelines.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Review the intramammary and antimicrobials (AM) efficacy guidelines following finalisation of the RP on prophylactic use and revise as appropriate.	EWP (AWP)	2	January 2022	Yes	December 2022

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
2.	Contribute to ongoing revision of VICH anthelmintic GLs 7, 12, 13, 14, 15, 16, 19, 20 and 21.	EWP	1	Ongoing	No	2022
3.	Contribute to the ongoing development of a new VICH guideline on fixed combination products.	EWP	1	Ongoing	No	Beyond 2022
4.	Finalise the guideline on data requirements for veterinary medicinal products for the prevention of transmission of vector borne diseases in dogs and cats (EMA/CVMP/EWP/278031/2015).	EWP	1	January 2022	No	June 2022
5.	Develop a concept paper on data requirements and potential claims for alternatives to AMs.	EWP	2	January 2022	Yes	December 2022
6.	Revise the guideline on veterinary medicinal products for zootechnical purposes (NtA, Volume 7, 7AE7a).	EWP	2	January 2022	Yes	December 2023

1.4.4. Quality non-biologicals

The CVMP scientific guidelines on the quality of veterinary medicines help applicants prepare marketing authorisation applications. Guidelines reflect a harmonised approach of the EU Member States and the Agency on how to interpret and apply the requirements for the demonstration of quality set out in the Union legislation.

CVMP topic lead: M. O'Grady; **EMA topic lead:** I. Diaz Ugalde

Key objective

- Review and revise existing guidelines

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Revise the guideline on quality aspects of pharmaceutical veterinary medicines for administration via drinking water to include an Annex addressing biocides.	QWP	2	Ongoing	Yes	December 2023
2.	Review of existing guidelines and Q&A's to implement revisions required arising from changes to the variations requirements and Annex II in Regulation (EU) 2019/6.	QWP	2	Ongoing	No	December 2022
3.	Revise the reflection paper on risk management requirements for elemental impurities in veterinary medicinal products: release concept paper for consultation to convert into a guideline and to include IVMPs within its scope.	QWP/IWP	2	March 2022	Yes	December 2022
4.	Q&A on co-processed excipients.	QWP/GMDP IWG	3	Ongoing	No	Q4 2022
5.	Concept paper for guidance on synthetic peptides.	QWP	3	March 2022	Yes	Q4 2022
6.	Contribute to ongoing revision of VICH GL8 on stability testing of medicated premixes.	QWP	1	Ongoing	Yes	Beyond 2022
7.	Contribute to ongoing revision of VICH GL18 on residual solvents.	QWP	1	Ongoing	Yes	Beyond 2022
8.	Contribute to the development of VICH GL on in vitro dissolution.	QWP/EWP	1	Ongoing	Yes	Beyond 2022

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
9.	Contribute to the development of VICH GL on GMP for APIs.	QWP/GMDP IWG	1	Ongoing	Yes	Beyond 2022
10.	Contribute to ongoing VICH activities on the development of VICH guideline to parallel ICH Q8GL.	QWP	1	Ongoing	Yes	Beyond 2022
11.	Consider the ongoing work of the EMA on the risk of nitrosamine formation or presence during the manufacture of human medicines and the implications of this activity for the quality evaluation of VMPs.	Dedicated Expert group	2	Q1 2022	No	December 2022

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. This requires that antimicrobial VMPs should be used responsibly and surveillance of antimicrobial sales and use according to a harmonised and defined methodology is a valuable tool for monitoring progress in antimicrobial stewardship.

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 lead: C. Schwarz; **EMA topic leads:** Z. Kunsagi, A. Vidal, 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 medicine.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Article 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	Dedicated Expert group	1	Ongoing	No	Q1 2022

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
	Articles 112, 113 and 114 subject to certain conditions.					
2.	Article 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	Q1 2022
3.	Finalise the draft guideline on the risk assessment of antimicrobial VMPs following the public consultation.	AWP	1	Ongoing	No	Q2 2022
4.	Article 107(3) (Use of antimicrobial VMPs): Elaborate guidance or criteria for determining 'exceptional cases' when antimicrobial administration for prophylaxis would be accepted.	AWP/EWP	1	Ongoing	No	June 2022
5.	Review indications for existing AM CAP products and determine the approach to ensuring that they are aligned with the guidance for determining 'exceptional cases' when antimicrobial administration for prophylaxis would be accepted.	CVMP/AWP/EWP	1	Q1 2022	No	June 2022
6.	Article 57: Establish governance to perform new activities conferred upon CVMP in relation to sales and use of antimicrobials.	EMA/CVMP	2	Q1 2022	No	March 2022
7.	Article 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	Yes (GLs only)	June 2022
8.	Revise the AWP's reflection paper on the use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union.	AWP	2	Q1 2022	Yes	Sept 2023
9.	Taking forward the recommendations of the reflection paper on dose review and adjustment of established veterinary antibiotics (EMA/CVMP/849775/2017), establish a list of priority candidate products for dose review/adjustment.	CVMP	2	Q1 2022	Yes	December 2022
10.	Article 36(2): Development of concept paper on post-authorisation studies for antimicrobial VMPs to ensure the B/R remains positive in case of development of AMR.	AWP	2	Q2 2022	Yes	July 2022

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; **EMA topic lead:** V. Nicorescu

Key objective

- Promote the responsible use of antiparasitic veterinary medicines.

Activity

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Finalise the reflection paper on resistance in ectoparasites (EMA/CVMP/EWP/310225/2014).	EWP	2	January 2022	No	December 2022

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 European Medicines Agencies Network strategy to 2025 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; **EMA topic lead:** J. Pozo Gonzalez

Key objective

- Support the development and availability of veterinary vaccines.

Activities

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
1.	Article 25-27 (Authorisation under exceptional circumstances): Establish criteria for accepting such applications and elaborate guidance on basic data requirements.	IWP	1	Ongoing	Yes	January 2022
2.	Annex II - Vaccine Antigen Master File (VAMF): Develop specific guidance for the submission and for evaluation of a VAMF.	IWP	1	Ongoing	Yes	January 2022
3.	Annex II - 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	1	Ongoing	Yes	January 2022

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
4.	Annex II (Platform Technology Master File): Develop specific guidance for the submission and for evaluation of a Platform Technology Master File.	IWP	1	Ongoing	Yes	January 2022
5.	Annex II - Develop further guidance on providing field efficacy studies in support of MAA for immunological VMPs (revision of existing guidance).	IWP	1	Ongoing	Yes	January 2022
6.	Revise guideline on requirements for the production and control of IVMPs (EMA/CVMP/IWP/206555/2010 Rev. 1).	IWP	2	Ongoing	Yes	June 2022
7.	Contribute to ongoing VICH activities relating to extraneous viruses.	IWP	1	Ongoing	Yes	Beyond 2022
8.	Continue the collaboration with EDQM on practical implementation of veterinary vaccine monographs, e.g. requirements for non-conventional veterinary vaccines.	IWP	2	Ongoing	No	
9.	Revise Note for guidance: DNA vaccines non-amplifiable in eukaryotic cells for veterinary use (EMA/CVMP/IWP/07/98).	IWP	2	December 2021	Yes	Q1 2023

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; **EMA topic lead:** V. Pucovský

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

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 Domain	1	Ongoing	No	All 2022

No.	Specific activity	Responsible group	Prio	Start date	Cons.	Completion date
2.	Implement the recommendations of the EMA Management Board Task Force on Working Parties with a focus on: - Establishment of ESECs, - Stakeholder engagement.	Veterinary Domain	2	Ongoing		All 2022

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; **EMA topic lead:** N. Jarrett, others as required

Key objective

- Promote uptake of harmonised standards at international level.

Activities

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 2022
2.	Engage with EDQM to discuss issues of mutual interest with regard to the quality of VMPs.	IWP/QWP	2	Ongoing	No	All 2022
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 2022