EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update from the CVMP Efficacy Working Party (EWP-V)

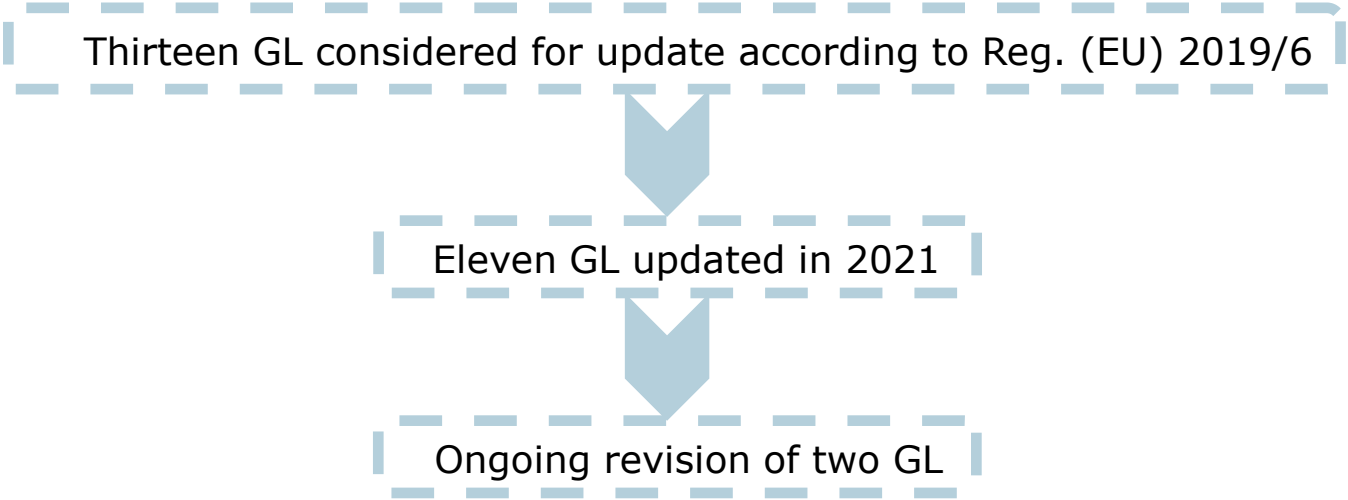
EMA Veterinary Medicines Info Day 2024

Presented by Cristina Muñoz Madero on 15 March 2024
Chair of the CVMP Efficacy Working Party

Content

Efficacy guidelines (GL) revision and update

Update in line with the provisions of Art. 107(3) and Art. 4 of Reg. (EU) 2019/6



Antiparasitic products

Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products - Rev.1

Adopted December 2021

Effective: 1 July 2022

Reflection paper on resistance in ectoparasites

Adopted January 2023

Guideline on data requirements for veterinary medicinal products intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats

Adopted June 2022

Effective: 1 January 2023

Guidelines revised

Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of Regulation (EU) 2019/6

Effective from 28 January 2022

Adopted by the Committee for Medicinal Products for Veterinary Use (CVMP) for release for consultation	17 February 2021
Start of public consultation	25 February 2021
End of consultation (deadline for comments)	15 May 2021
Adopted by CVMP	15 July 2021
Date for coming into effect	28 January 2022

Guideline on conduct of pharmacokinetic studies in target animal species – Rev.1

Date for coming into effect: 1 July 2024

Initial guideline adopted by CVMP	8 March 2000
Date of coming into effect	8 September 2000
Draft revised guideline (revision 1) agreed by Efficacy Working Party (EWP-V)	13 September 2017
Adopted by CVMP for release for consultation	9 November 2017
Start of public consultation	20 November 2017
End of consultation (deadline for comments)	31 May 2018
Agreed by EWP-V	October 2023
Adopted by CVMP	7 December 2023
Date for coming into effect	1 July 2024

Collaboration with other EMA working groups

AWP: Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances

ERAWP: Reflection paper on the environmental risk assessment of ectoparasiticidal VMPs used in cats and dogs

QWG: Guideline on investigation of chiral active substances

Training delivered

- **June 2022**
  - Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products
  - Guideline on the summary of product characteristics (SPC) for veterinary medicinal products containing antimicrobial substances (joint activity AWP & EWP-V)
- **March 2023:** Guideline on data requirements for VMPs intended to reduce the risk of transmission of vector-borne pathogens in dogs and cats

Training activities

- **October 2023**
  - Bioequivalence - CVMP and VICH bioequivalence guidelines (joint activity EWP-V & QWP)
- **Q2-Q3 2024**
  - Guideline on efficacy and TAS data requirements for applications for VMPs for limited markets eligible for Art. 23 Guideline on the summary of product characteristics for antiparasitic veterinary medicinal products

2024 workplan for the CVMP EWP-V

Chairperson	Status
Chari: C. Muñoz Madero	Adopted by CVMP in January 2024

The activities outlined in the work plan for 2024 have been agreed considering the respective business priorities and may be subject to further review and reprioritisation in accordance with the business plan of the Agency

Status of EWP-V guidelines currently under development and/or revision

EWP-V workplan for 2024

1. Guidelines under development/revision at EWP-V level

To update the GLs in line with the provisions of Art. 107(3/4) and Art. 4 of Reg. (EU) 2019/6

- Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/627/2001 - Rev.1)
- Guideline on the conduct of efficacy studies for intramammary products for use in cattle (EMA/CVMP/344/1999 - Rev.2)

EWP-V workplan for 2024

2. EWP-V draft guidelines which have already been released for public consultation and the consultation period has finished

Guideline for the demonstration of efficacy for veterinary medicinal products containing anticoccidial substances (EMA/CVMP/EWP/755916/2016)

End of consultation: 31 August 2019*

Guideline on efficacy and target animal safety data requirements for applications for non-IVMPs intended for limited markets but not deemed eligible for authorisation under Art. 23 (EMA/CVMP/EWP/231668/2022)

End of consultation: 31 January 2024

**to be published for a 2nd public* consultation

EWP-V workplan for 2024

3. EWP-V draft guidelines currently published for public consultation

Guideline on data requirements for veterinary medicinal products for zootechnical purposes (EMA/CVMP/EWP/37280/2023)

Deadline: 31 May 2024

Guideline on data requirements for veterinary medicinal products for zootechnical purposes

Draft

First adoption of the guideline (7AE7a)	March 1992
Draft revised guideline agreed by Efficacy Working Party (EWP-V)	November 2023
Adopted by CVMP for release for consultation	18 January 2024
Start of public consultation	26 January 2024
End of consultation (deadline for comments)	31 May 2024

EWP-V workplan for 2024

4. Guidelines under development/revision at EWP-V level

Guideline on demonstration of efficacy of ectoparasiticides (7AE17A)

CP in 2023; GL to be revised 2024

Guideline on veterinary medicinal products controlling Varroa destructor parasitosis in bees (EMA/CVMP/EWP/459883/2008-Rev.1)

CP on the revision of the GL to be developed in 2024

Guideline on dossier requirements for anticancer medicinal products for dogs and cats (EMA/CVMP/28510/2008-Rev.1)

CP on the revision of the GL to be developed in 2024

Guideline on the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/2000-Rev.4)

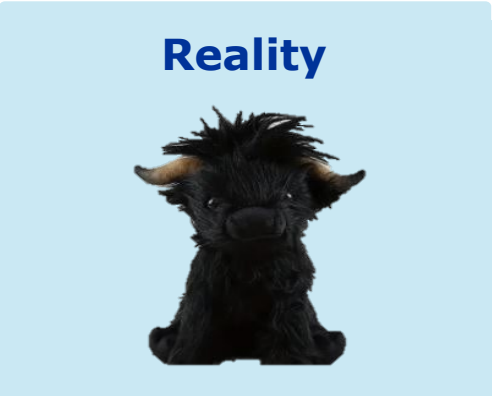
CP on the revision of the GL to be developed in 2024

EWP-V workplan for 2024

5. Collaboration with other groups

Develop an infographic on lack of expected efficacy for antiparasitic veterinary medicinal products - **New topic to be developed by EWP-V, PhVWP-V**

VS



EWP-V workplan for 2024

5. Collaboration with other groups

Guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6

New GL to be developed. Lead by AWP.

Develop an infographic on lack of expected efficacy for antiparasitic veterinary medicinal products

New topic to be developed by EWP-V and PhVWP-V.

EWP-V workplan for 2024

5. <u>Collaboration with other groups</u>

- Revision of VICH guidelines on efficacy of anthelmintics
- VICH guideline on fixed combination products (pharmaceuticals)
- VICH guideline on between strength biowaivers (lead by QWP)

Any questions?

Further information

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