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SCIENCE MEDICINES HEALTH

CVMP workplan for 2023 and beyond

EMA Veterinary Medicines Info Day 2023

Johan Schefferlie on 16 February 2023
Chair of the Committee for Veterinary Medicinal Products (CVMP)

Introduction

Johan Schefferlie

Toxicologist / biologist

CVMP member since 2007

Vice-chair since July 2019

Chair since June 2022

Science as basis for assessment

Keep pace with scientific developments in the veterinary field

Support innovation

Role of the CVMP

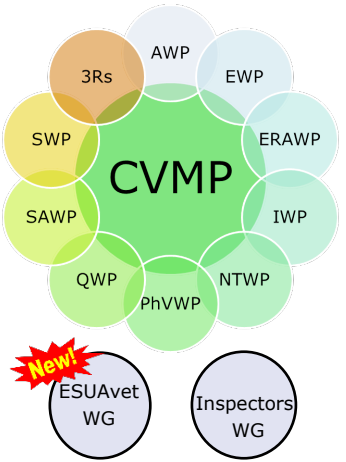
- Carry out the tasks conferred on it under Regulation 2019/6 and Regulation 726/2004.

➢ Assessment-related activities:

  - Assessment, and life-cycle management, of VMPs via the centralised procedure
  - Evaluates VMPs authorised at national level referred for a harmonised position
  - Establishment of maximum residue limits

➢ Contribute to the development of VMPs and VMP regulation, by:

  - providing scientific advice;
  - preparing scientific guidelines and regulatory guidance;
  - cooperating with international partners on the harmonisation of regulatory requirements.



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16 December 2022
EMA/CVMP/617330/2022
Committee for Veterinary Medicinal Products (CVMP)

Committee for Veterinary Medicinal Products (CVMP) Work Plan 2023

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Heads of Medicines Agencies

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7.1.2019 EN Official Journal of the European Union L 4/43

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

on veterinary medicinal products and repealing Directive 2001/82/EC

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 168(4)(b) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee (1),

After consulting the Committee of the Regions,

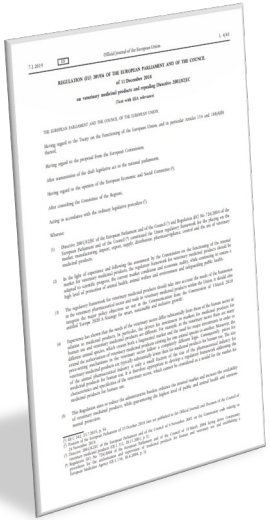
Acting in accordance with the ordinary legislative procedure (2),

Whereas:

(1) Directive 2001/82/EC of the European Parliament and of the Council (3) and Regulation (EC) No 726/2004 of the European Parliament and of the Council (4) constituted the Union regulatory framework for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and the use of veterinary medicinal products.

Regulation (EU) 2019/6 on veterinary medicinal products

Replaces Directive 2001/82/EC within the overall aim of achieving 'Better Regulation' in the EU



- *provides for a modern, innovative and fit for purpose legal framework*
- *gives incentives to stimulate innovation*
- *gives incentives to increase the availability of veterinary medicines*
- *strengthens the EU action to fight antimicrobial resistance*

Activities to support for product development and innovation

Novel Therapies and Technologies Working Party

Finalise GLs by Dec 2023

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18 November 2022
EMA/CVMP/NTWP/179287/2022
Committee for Veterinary Medicinal Products (CVMP)

Guideline on the development and data requirements of potency tests for veterinary cell-based therapy products and the relation to clinical efficacy

Consultation open until 28 February

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27 January 2023
EMA/CVMP/NTWP/32862/2022
Committee for Veterinary Medicinal Products (CVMP)

Guideline on quality, safety and efficacy of veterinary medicinal products specifically designed for phage therapy

Consultation open until 31 May

Activities to support for product development and innovation

Further activities

- Reflection Paper on article 40(5) – Consultation open until 28 February 2023
- **NEW** activity: Develop guidance on safety data requirements for VMPs containing non-degradable nanomaterials
- **NEW** activity: Guideline on requirements for quality, safety and efficacy of allergen products for use in horse dogs and cats
- DNA vaccines (GL revision)
- Live recombinant vector vaccines (GL revision)
- Contribute to VICH guidance on target animal safety evaluation for veterinary monoclonal antibody products
- Provide Scientific Advice

Activities to support availability – limited markets

Further develop and implement the criteria for eligibility for limited markets

- Art 23: Benefit availability:
  - Serious/life threatening disease/condition
  - Unmet medical need

Assess the need to revise the Reflection Paper on limited markets

Develop guidance for limited market products not deemed eligible for Article 23

Finalise Q2 2023

Activities to support availability – limited markets

Outcome of Requests for classification as limited market under article 4(29) and eligibility under article 23	**2021**	**2022**	**2023** (January – February)
Limited market under art.4(29) and eligible under art.23	-	13	2
Limited market under art.4(29) and not eligible under art.23	3	8	1
Not limited market under art.4(29)	-	-	-

- 15 products have been considered eligible under Article 23:
  - 3 chemicals
  - 12 biologicals (10 vaccines)
- 12 products have been classified as limited market according to art.4(29) and not eligible under art.23:
  - 7 chemicals
  - 5 vaccines

Activities to support product authorisation

Guidance on article 34 (POM – non-POM) – **Finalised**

Revise the CVMP recommendation on the evaluation of the benefit-risk balance of VMPs

Develop a Q & A document on classification of VMPs as biological other than immunological, immunological or other than biological

Activities relating to antimicrobial resistance

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20 January 2021
EMA/CVMP/179874/2020
Committee for Medicinal Products for Veterinary Use (CVMP)

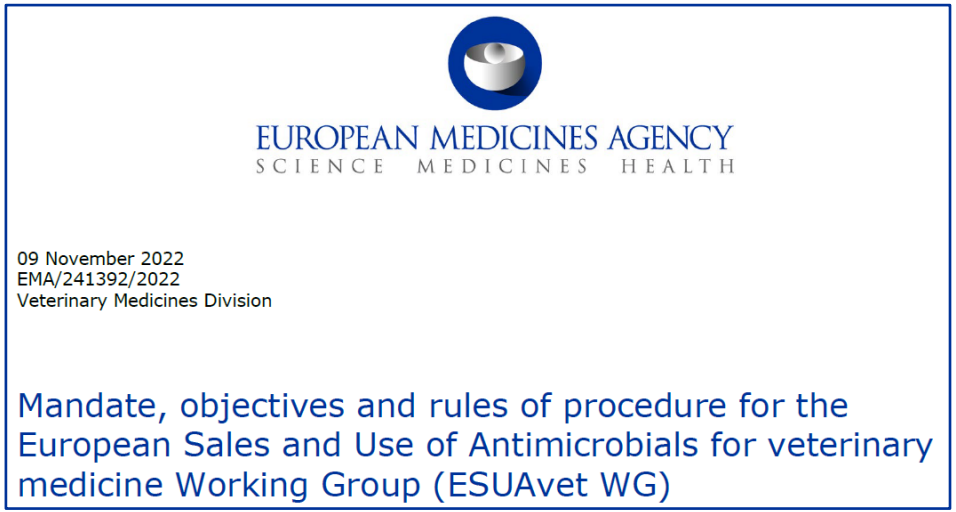
CVMP strategy on antimicrobials 2021-2025

Adopted by CVMP for release for consultation	18 June 2020
Start of public consultation	1 July 2020
End of consultation (deadline for comments)	30 September 2020
Adoption by CVMP	20 January 2021

Mission statement on antimicrobials

The CVMP's mission is to ensure the availability of effective antimicrobial medicines for the treatment of infectious diseases of animals while, at the same time, minimising the risks to animals, humans and the environment arising from their use.

Activities relating to antimicrobial resistance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09 November 2022
EMA/241392/2022
Veterinary Medicines Division

Mandate, objectives and rules of procedure for the European Sales and Use of Antimicrobials for veterinary medicine Working Group (ESUAvet WG)

ESUAvet WG

- Collect data on sales and use of AM
- Contribute to JIACRA
- Advice EMA and CVMP on related matters
- Call for members in progress

Activities relating to antimicrobial resistance

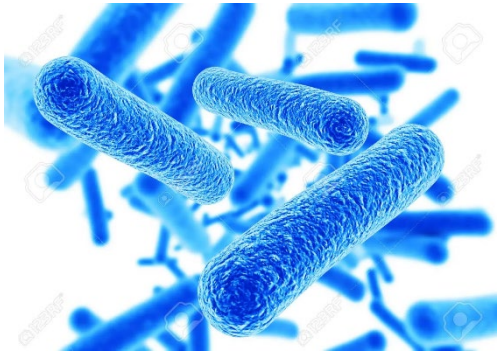
- EMA scientific recommendation: 'reserved' AMs (Feb 2022) - **Finalised**
- EMA scientific recommendation: AMs 'restricted' when used under 'cascade' Q2 2023
- Guideline on risk assessment of AM VMPs (~~Q3 2022~~) Q4 2023
- Art. 107(3) - Elaborate criteria for determining 'exceptional cases' when AM prophylaxis would be accepted (~~Q3 2022~~) Will not be progressed further
  - Review the intramammary and AM efficacy GLs and revise as appropriate (~~Dec 2022~~) To be determined
- ~~Guideline on~~ Potential claims for products that can contribute to the reduction of the need for antimicrobials (~~Q2 2024~~) To be addressed in the B/R Guideline and product-type specific guidelines

Activities relating to antimicrobial resistance

Article 36(2): GL on post-authorisation studies for antimicrobial VMPs to ensure the benefit-risk remains positive in case of development of antimicrobial resistance

Reflection paper on the availability and characteristics of diagnostic tests to improve the responsible use of antibiotics in animals

Dose review and adjustment (research - follow up of PPHOVA) – establish a prioritised list of products (your suggestions are welcome)



Activities relating to environmental risk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16 December 2022
EMA/CVMP/ERA/31905/2021
Committee for Veterinary Medicinal Products (CVMP)

Reflection paper on the environmental risk assessment of ectoparasiticidal veterinary medicinal products used in cats and dogs

Consultation open until 31 March

Other activities:

- Guideline on ERA for VMPs used in aquaculture
- Reflection Paper on Risk Mitigation Measures (revision)
- Concept Paper on AMR in the environment

Activities relating to consumer safety

2023:

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

Reinforce the scientific and regulatory capacity and capability of the network

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 2023
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 2023

Stakeholder engagement

Introduce systematic and structured stakeholder engagement at domain level to underpin strategic priority planning and individual GL generation/revision

- Interested Parties Meeting (24 May)
- Veterinary Medicines Info Day (today)
- Development of the Strategic 3-years Work Plan of the Veterinary Domain (2025-2027)

Conclusion

- Many ambitions for 2023 CVMP and beyond
- Still some challenges relating to implementation on Regulation 2019/6,
- But, focus must be on the opportunities and realising meaningful benefits:
  - To support innovation, product development and availability
  - To increase efficiency of regulatory processes
  - To adopt a more effective risk-based approach to activities/decision-making
  - To foster proportionate decision making

  While promoting and protecting animal and public health
- There is a need for continued active stakeholder engagement

Any questions?

Further information

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