



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## CVMP workplan for 2024 and beyond

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EMA Veterinary Medicines Info Day 2024

Presented by Johan Schefferlie on 14 March 2024  
Chair of the Committee for Veterinary Medicinal Products (CVMP)

An agency of the European Union



# Content

## CVMP Workplan 2024

- Published on EMA website



## 3-Year Strategic Workplan Veterinary Domain

- From January 2025 to December 2027
- Under construction
- Stakeholder consultation





# CVMP Workplan 2024

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# CVMP Workplan 2024 - overview

## Evaluation activities for VMPs

- Support for product development
- Authorisation activities
- Specialised areas

## Horizontal activities

- Antimicrobial resistance
- Antiparasitic resistance
- Alternatives to antimicrobials
- Vaccine and other immunologicals availability
- Availability of VMPs for food producing species
- Application of 3Rs in regulatory testing
- Reinforce scientific capacity/capability
- International cooperation and harmonisation
- Stakeholder engagement

# CVMP Workplan 2024 – some highlights

Support for product development

## Emerging therapies and technologies:

- Develop guidance for for nanotechnologies

## Limited markets

- Finalise guidance for limited markets not eligible for article 23

## Scientific Advice

# CVMP Workplan 2024 – some highlights

## Authorisation procedures

- Guideline on the benefit-risk evaluation – *in consultation*
- Guideline on criteria for article 40(5)
- Concept paper for guidance on demonstration biosimilarity
- Finalise guidance for limited markets not eligible for article 23
- Scientific Advice

## Post authorisation procedures

- Ongoing review of signal management worksharing

# CVMP Workplan 2024 – some highlights

## Specialised areas

### Environmental Risk Assessment

- Guideline on ERA aquaculture
- Concept paper on risk for AMR in humans exposed (from VMPs) via the environment
- Methodology for ERA for ectoparasiticides used in dogs and cats

### Maximum Residue Limits

- Concept paper for guidance on consumer safety assessment for IVMPs acting against endogenous targets

### Efficacy

- Revision of various guidelines (varroa, anticancer, BE, anticoccidials)

# CVMP Workplan 2024 – some highlights

## Horizontal activities



### **Antimicrobial resistance**

Guideline on risk assessment  
Guideline on post-authorisation studies  
Reflection paper diagnostic tests  
Dose adjustment for established veterinary antibiotics



### **Immunologicals**

Concept paper for guidance on quality aspects mRNA vaccines  
Revision of various GLs (plasmid DNA, live recombinant vector vaccines, combined vaccines)





# CVMP Workplan 2024 – some highlights

## Other ongoing activities

- Contribute to VICH
- Engage with EDQM
- Cooperate with EC and EU Agencies
- Foster scientific capacity and capability
- Promote stakeholder engagement



## 3-Year Strategic Workplan Veterinary Domain

## 3-Year Strategic Workplan Veterinary Domain - overview



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Covering January 2025 – December 2027

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Specifies strategic goals, key objectives, and underlying activities

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Not every detail – details in the annual workplans of CVMP and Working Parties

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Stakeholder consultation during weeks 22-25 (provisional) with a stakeholder meeting in week 26 (provisional)

## 3-Year Strategic Workplan – Strategic goals

- 7 strategic goals
- Innovation
- Availability
- Post-authorisation
- AMR
- ERA
- 3Rs
- Scientific process and stakeholders





## 3-Year Strategic Workplan – Key Objectives and Activities

- A number of activities from 2024 will continue in 2025
- Examples of new activities that may be included
  - CVMP strategy on AMR 2026-2030
  - Guidance on gene therapy
  - Guidance on risk assessment AMR in companion animals



# Any questions?

## Further information

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