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Reflection paper providing the current regulatory testing requirements for veterinary medicinal products and opportunities for implementation of the 3Rs (Draft 2025)

An Industry Perspective

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Reflection Paper on Current Regulatory Testing Requirements for Veterinary Medicinal Products and Opportunities for Applying the 3Rs

Consultation closed on 30 June 2025

What does this Reflection Paper offer to the industry?

- ✓ Integrates recent advancements and methods related to the 3Rs.
- ✓ Suitable for regulatory decision-making during veterinary medicinal product assessments.
- ✓ Provides comprehensive and precise guidance on regulatory requirements for animal testing and viable alternatives.
- ✓ Covers a broad range of areas including quality, safety, efficacy, innovative therapies, immunologicals, and environmental considerations.
- ✓ A balanced industry perspective on feasibility, barriers and future direction.
- ✓ HIGHLY APPRECIATED, EXTREMELY INFORMATIVE, VALUABLE RESOURCE

Given the rapid advancements in scientific, technological, and regulatory framework, it is essential to update guidance document regularly, such as annually, to ensure the 3Rs approach remains appropriate for the assessment of quality, safety, and efficacy parameters.

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What can be actioned now?

- Acceptance and Adoption of Existing 3Rs approaches
  - ➢ Innovation Task Force and Scientific Advice – very helpful
  - ➢ Need for joint industry - regulatory training / learning
  - ➢ Training and best practices on 3Rs
    - ✓ Workshops based on information exchange & case studies (safe harbour approach)
    - ✓ Highly effective in other sectors e.g., ECHA - Industry

Longer timescale to achieve:

- NAMs (New approach methodology)
- Development and Validation specific and relevant to veterinary target species
- International harmonisation (VICH)

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Implementation of 3Rs for veterinary specific use

Replacement	Reduction	Refinement
Potential areas	***Approaches which can reduce duplication of studies***	***Approaches relevant mainly for efficacy & target animal safety studies***
• *In vitro* toxicity models	• Optimised and adaptive study designs	• Less invasive sampling techniques
• Organ-on-chip and advanced cell system	• Statistical modelling	• Remote monitoring and digital biomarkers
• Physiologically based pharmacokinetic (PBPK) modelling	• Shared control groups	• Earlier endpoints
• Computational exposure modelling	• Use of historical control data	• Improved housing and handling
• Use of existing data, literature and class effects	• Regulatory reliance on existing datasets	• Precision dosing and targeted study designs
	• Work-sharing between Member States	
	• Integration of pharmacovigilance data and farm-monitoring systems	
Promising for		
• User safety and Environmental fate prediction		
• Dose selection		
• Mechanistic toxicology		

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What are different challenges and barriers?

Scientific challenges	Regulatory challenges	Operational challenges
• Diversity of target species	• Uncertainty around acceptance of novel methodologies	• Legal regulatory expectations
• Biological variability	• Variability between Member States	• Global development programmes requiring alignment across jurisdictions
• Limited validation of alternative models	• Need for robust validation frameworks	• Investment requirements for alternative technologies
• Complex disease endpoints		

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Implementation of 3Rs and different company types

Company type	
Large pharmaceutical	**SMEs**
Greater access to modelling tools and data	Limited resources
Dedicated regulatory science functions	Reliance on traditional study paradigms
Stronger capacity for innovation	Higher perceived regulatory risk in adopting novel approaches

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Future outlook

- Regulatory evolution to reduce ambiguity for industry developers and broader acceptance of advanced alternatives.

➢ Regular updating and revision of guidelines
➢ Specific acceptance criteria for complex methods .

- New Approach Methodologies (NAMs)

- Cross-Sector Collaboration.

➢ Partnerships between regulators, industry and research organisations to promote shared development of standards, reference data, NAMs and validation frameworks.

- Integration of artificial intelligence in study design

- Progressive reduction of pre-authorisation animal testing

- Encourage industry and regulators to use this document

- Conduct of regular trainings by regulatory agencies for the effective implementation of 3Rs

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Thank you for your attention!