EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Regulatory Science to 2025

Overview of the outcome of the Publication Consultation

Veterinary Stakeholders Workshop

Presented by Ivo Claassen on 5 December 2019
Head of Veterinary Medicines Division

Why now?

- To monitor and sign-post emerging and future trends in science and technology
- To identify key priorities where new or enhanced engagement is essential to the continued success of the Agency's mission
- To prioritise use of resources and external collaborations to strategically advance regulatory science
- To shape and influence the vision for the EU Medicines Agencies Network (EMRN) Strategy 2020–25

Vision - EMA Regulatory Science to 2025

"To foster scientific excellence in the regulation of veterinary medicines for the benefit of animal and public health while facilitating and promoting innovation and access to novel medicinal products."

EMA Regulatory Science to 2025

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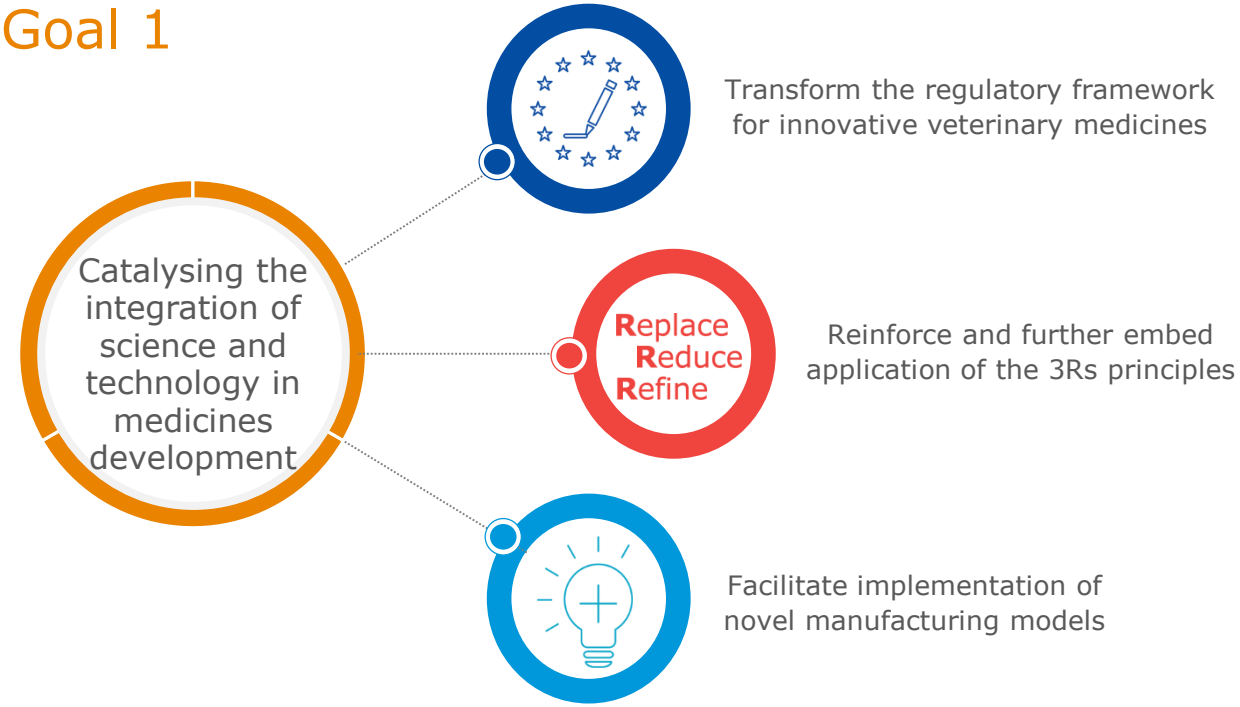
Goal 1



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Goal 2

Update Environmental Risk Assessments in line with the latest scientific knowledge

Apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines

Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

Develop new and improved communication and engagement channels and methods to reach out to stakeholders

Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products

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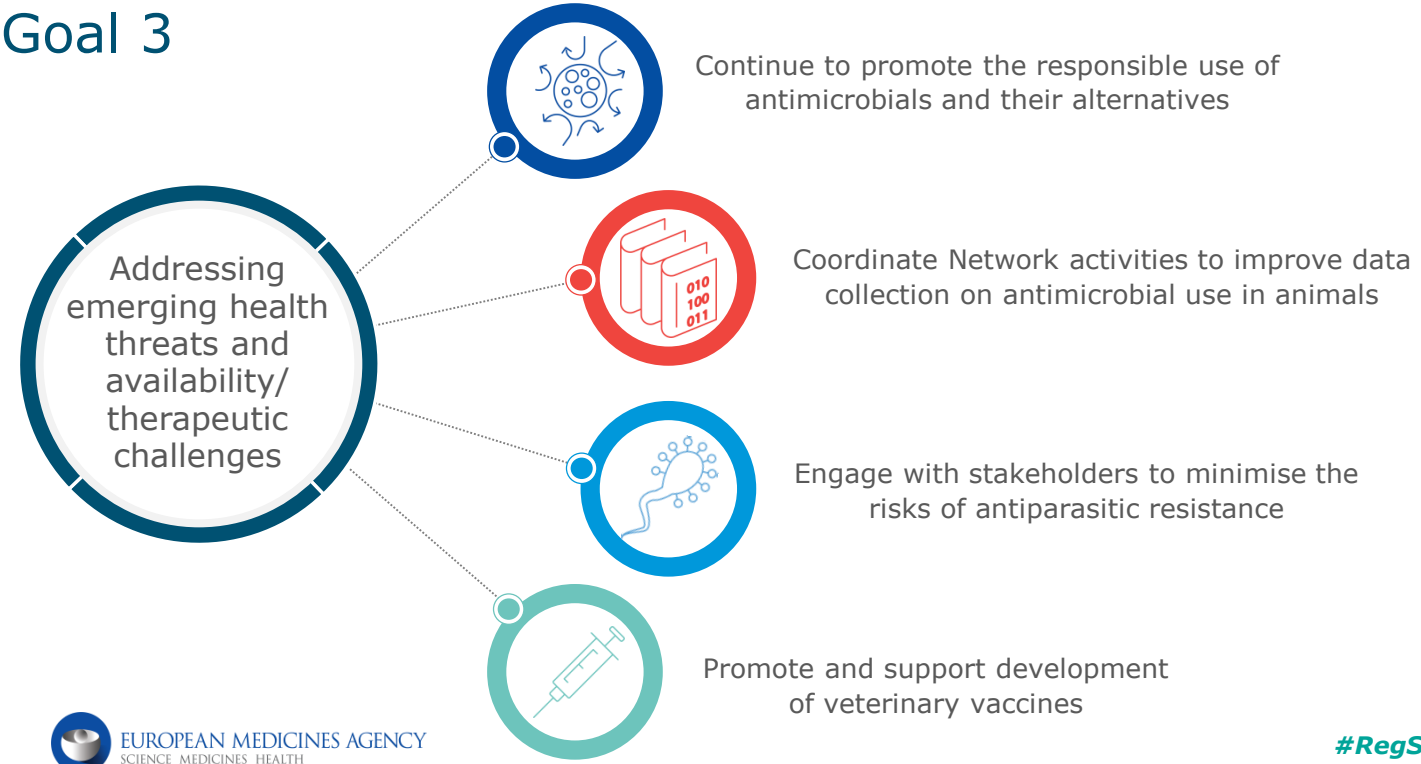
Goal 3



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Goal 4

Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science

Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions

Identify and enable access to the best expertise across Europe and internationally

Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders

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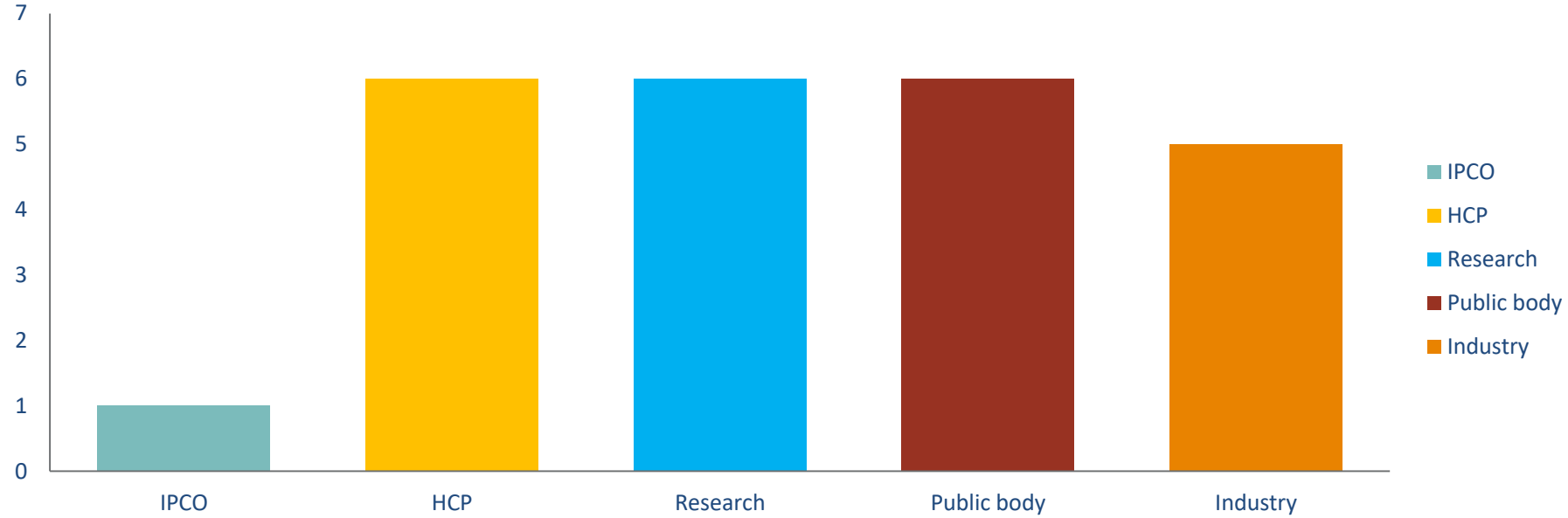
Cluster composition

Cluster 1 (IPCO+)	Cluster 2 (HCP)	Cluster 3 (Research)	Cluster 4 (Public body)	Cluster 5 (Industry)
• Individual member of the public	• Healthcare professional organisation • Veterinarian	• Learned society • Academic researcher • Other scientific organisation	• EU Regulatory partner / EU Institution	• Pharmaceutical industry(trade association, individual company, SME)

Overall public consultation responses per stakeholder cluster



Qualitative analysis of stakeholders‘ views on the Regulatory Science Strategy

DATA SOURCE:

- Responses to the open-ended questions (Q3,5,6,7) on:
  - Overall views
  - Core recommendations and their underlying actions
  - Missing elements

OBJECTIVES:

- Summarising these responses
- Identifying missing elements
- **Extracting *concrete actions* for further internal and external discussion**

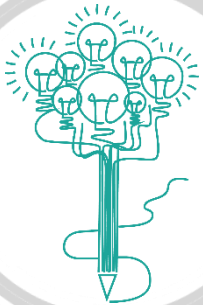
METHOD FOR ONGOING ANALYSIS:

- Framework analysis consisting of 5 iterative steps
- Investigator triangulation via independent analysis and comparison by a team of researchers

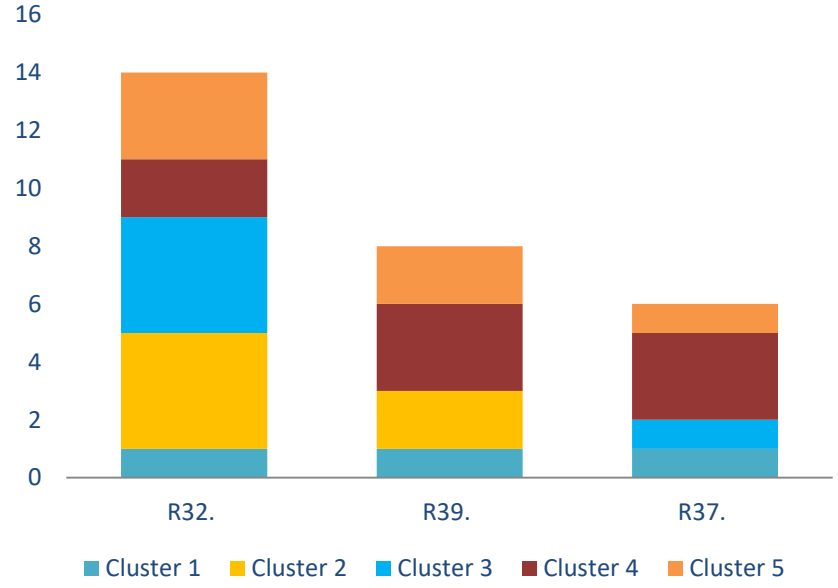
Lacey A. and Luff D., Qualitative Research Analysis. The NIHR RDS for the East Midlands/Yorkshire & the Humber, 2007.

Question 5

"Please identify the top three core recommendations (in order of importance) that you believe will deliver the most significant change in the regulatory system over the next five years and why."



Overall aggregate ranking of core recommendations – Top 3

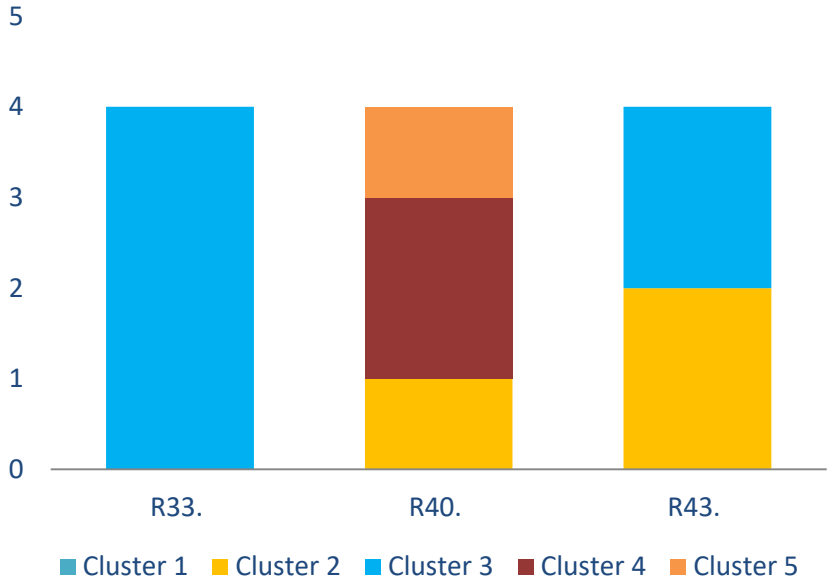


R32. Transform the regulatory framework for innovative veterinary medicines

R39. Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products

R37. Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

Overall aggregate ranking of core recommendations – next 3



R33. Reinforce and further embed application of the 3Rs principles

R40. Continue to promote the responsible use of antimicrobials and their alternatives

R43. Promote and support development of veterinary vaccines

Cluster 1: Individual member of the public/patient or consumer organisation and advocacy groups

- Need for a more streamlined and clearly communicated regulatory pathway for emerging health threats.
- Need for collaboration between human and veterinary fields to accelerate access in the event of an emerging health threats, particularly given the potential zoonotic origin of the threat and similar vaccine mechanism of action.
- Actions on 3Rs should include developing clear guidance on when these methods should be used to replace traditional animal tests.

Cluster 2: Healthcare professionals + organisations

- Splitting up the vision for human medicines and veterinary medicine, we miss a true 'One Health' approach.
  - The same goals might be implemented via different actions but the core principles are the same.
  - The same type of medicines, same technology, similar distribution networks, similar safety concerns, ePI, shortages, etc. are mostly relevant in both fields.

- The strategy should be more focused on prevention vs innovative therapies.

Cluster 3: Researchers

- AMR is the single, largest threat to public health and needs diligent and immediate attention from both the human and veterinary perspectives. It is of utmost importance to strengthen the work in this area, including in the regulatory context.
- To implement many of the proposed recommendations would require a Network effort.
- The administrative burden from scientific advice and the long pre- and post- meeting administrative procedures should be better addressed. Fast track licensing should also shorten the administrative time as well as the scientific assessment.

Cluster 5: Industry

- Welcomed the drive to modernise and improve regulatory science.
- The strategy should include a focus on preventing disease, including in emerging health threats.
- “Novel therapies” should be expanded to “novel therapies and approaches.”
- Support was expressed for 3R standards. More should be done in terms of creating, validating and harmonising novel methods and standards.
- Importance of sharing resources with the human medicines sector.

Cluster 5: Industry

- In many new scientific areas the experts lie within companies, particularly the practical application of a new technology.
- The strategy should include more reference to finding ways to engage also with industry experts.
- Industry has to work with applied science and that is generally a different approach compared to academia, who are generally more focussed on basic research.
- A conflict between "like to know" and "need to know" may result, which could have a negative impact on affordability of innovation.

To foster scientific excellence in the regulation of veterinary medicines for the benefit of animal and public health while facilitating and promoting innovation and access to novel medicinal products.

Catalysing the integration of Sci &Tech in medicines development

Session 3b/6:
Reinforce and further embed application of the 3Rs principles

Session 7:
Transform the regulatory framework for innovative veterinary medicines

Driving collaborative evidence generation

Session 2:
Develop new approaches to improve the benefit-risk assessment of veterinary medicinal products

Session 4:
Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

Addressing emerging health threats

Session 3a/6:
Continue to promote the responsible use of antimicrobials and their alternatives

Session 5:
Promote and support development of veterinary vaccines

Enabling and leveraging R & I in regulatory science

"enabler"

Any questions?

Further information

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