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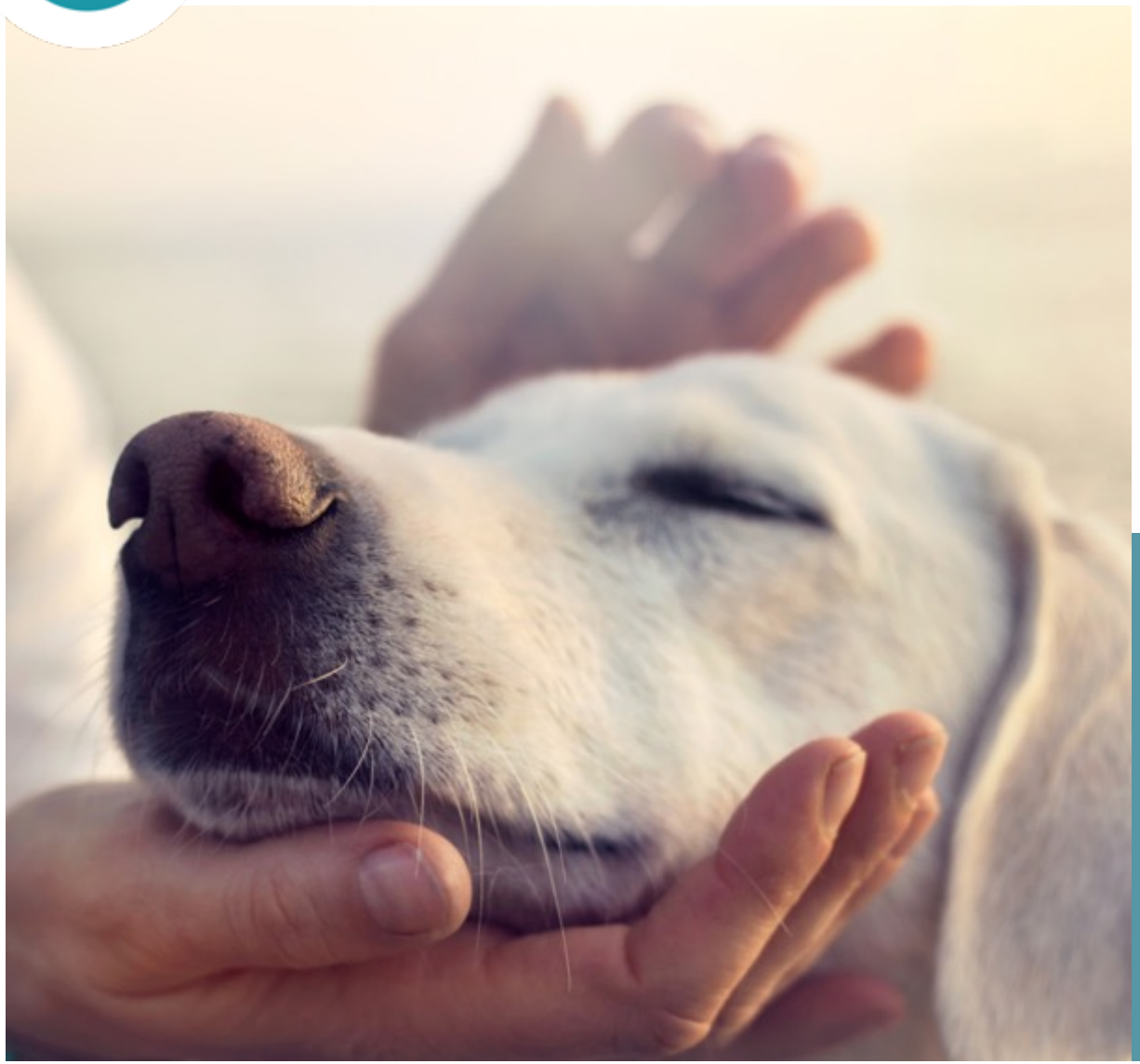

Regulatory Science Strategy and European medicines agencies network strategy to 2025

Industry Perspective

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25 March 2021

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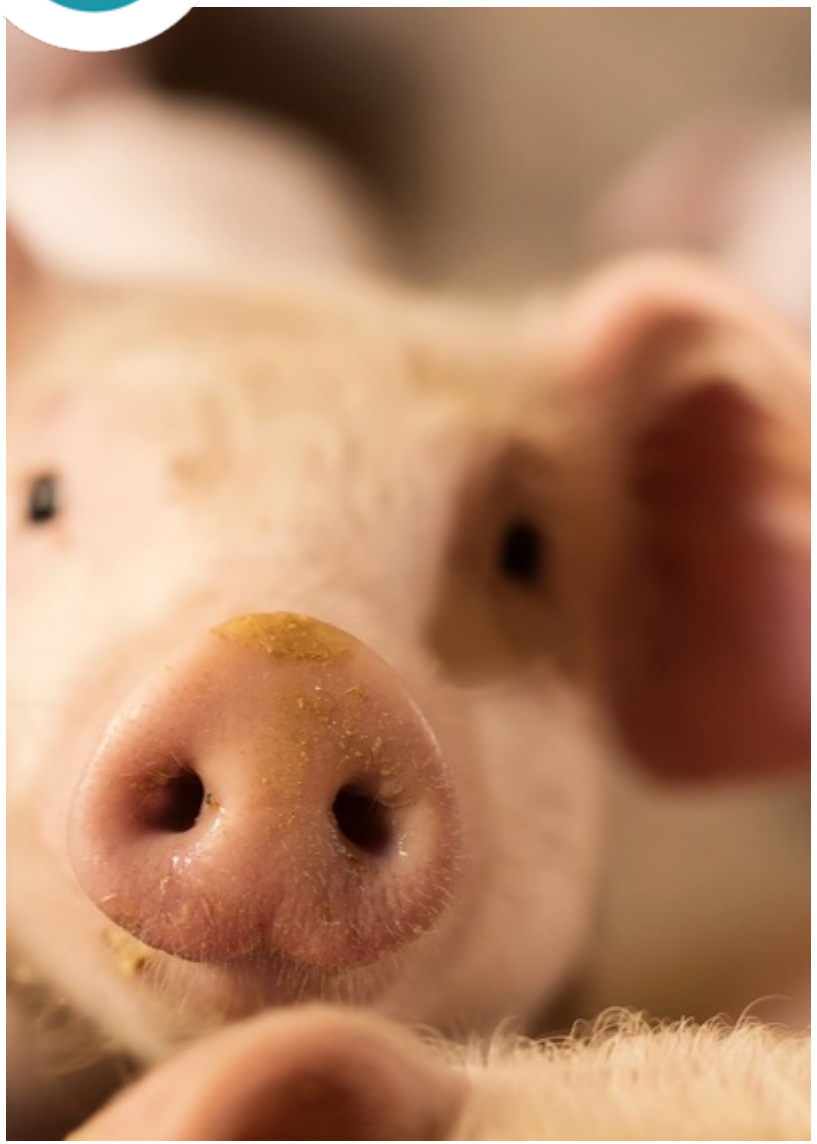


Key points for success

Industry fully supports both the
- Regulatory Science Strategy (RSS) and
- European Medicines Network strategy to 2025

Both represent significant opportunities
- for innovation and
- to improve and accelerate medicines availability with the right collaboration

However
- We must avoid approaches that can limit innovation
- We must not loose sight of important benefits when considering risks e.g. to the environment

Benefit/Risk (B/R) is critical

A key factor in success of the regulatory science strategy

Industry will fully engage with new B/R guidance

- Developmental guidance and dialogue will be critical (ITF/SA/Vet PRIME/other)
- Balance risks from unknowns at licensure with potential product benefits
- Avoid hazard-based approach
- Avoid academic based “nice to have” requirements and establish minimum requirements to determine if positive benefit/risk

Benefit/Risk (B/R) is critical

- Environmental aspects, as well as AMR, are critical
- We need expansion on indirect (additional) benefits

  (3Rs, Animal welfare, food sustainability, ATAs)

Understand key aspects of B/R in the current climate

(AMR (esp for new approaches), Environmental risk)

- No undue restriction on interpretations of when data protection for new studies can apply
- We need incentives and support not hurdles
  - new projects for EU are already abandoned, or EU is left out due to perceived B/R assessment

Embedding 3Rs principles

- Industry see the 3Rs and animal welfare as important
- The EU is already leading the way
- It is positive that this is a major part of the RSS

However

- Innovation is needed in regulatory approach as well as science to realise benefits
- We need to ensure that 3Rs and animal welfare legislation don't negatively impact product development & registration
- This is closely linked to revision of SPC claim guidance
  - Positive examples with welfare statements (Improvac, Exzolt)
  - Welfare claims/approaches can improve product benefits/value

Responsible use and alternatives

- Industry fully supports responsible use
- Much innovation could come in the form or novel antimicrobial approaches or alternative approaches
  - Products that enhance health/immune system
  - Indirect benefit claims (SPC claim GL revision)
  - Biological products with antimicrobial effect

- Work with industry in development and licensure to provide incentives and guidance

- Encourage and support alternatives
  - Continuous benefit/risk assessment
  - Risk managements plans to allow early registration
  - Alternate approaches to proving benefits

Training and Academic collaboration

What industry see as positive

- Development of new technologies and approaches
- Independent expert support
- Knowledge sharing
- Engagement with academia e.g., to develop training modules

Where industry see challenges

- Risk of a “nice to know” vs “need to know” approach
- Lack of understanding from academics of regulatory framework
- Much of the expert knowledge lies within industry

We are ready to work together with EMA to support training and collaboration

Promote and support Vaccine

- Important area for industry

- Potential for major benefits

- New limited market classification and data reduction guidance will be a key area for success

- **Benefit/Risk becomes critical for success**

- Industry supports adaption of GMP (and quality) requirements, so they are appropriate for veterinary products, including vaccines

- Important GLs to deliver
  - Exceptional marketing authorisation guidance
  - Vaccine antigen master file guidance
  - Platform antigen master files

New/Novel types of claims and endpoints

From the Medicines Network strategy

"The opportunities provided by Regulation 2019/6 for new types of claims and endpoints should be maximized to foster new technology and innovation in the animal health sector."

This is critically important, but not just for new technologies

A big part of the innovative claims could come from existing technology, where the full potential of the definition of a VMP is until now, restricted to clinical endpoints

Industry hope to work with EMA/CVMP to realise the benefits

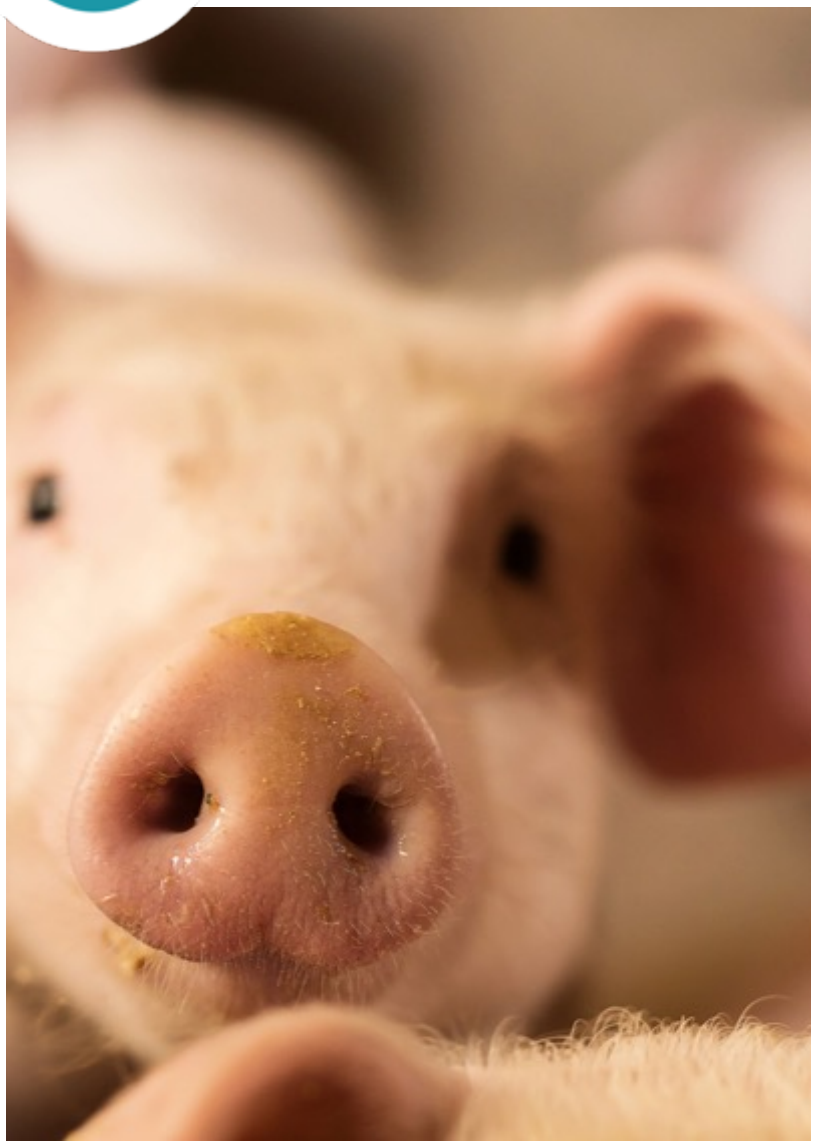
Horizon Scanning

Industry support horizon scanning capability such that

- regulators can become aware of innovation earlier and
- address questions from innovators at a much earlier stage

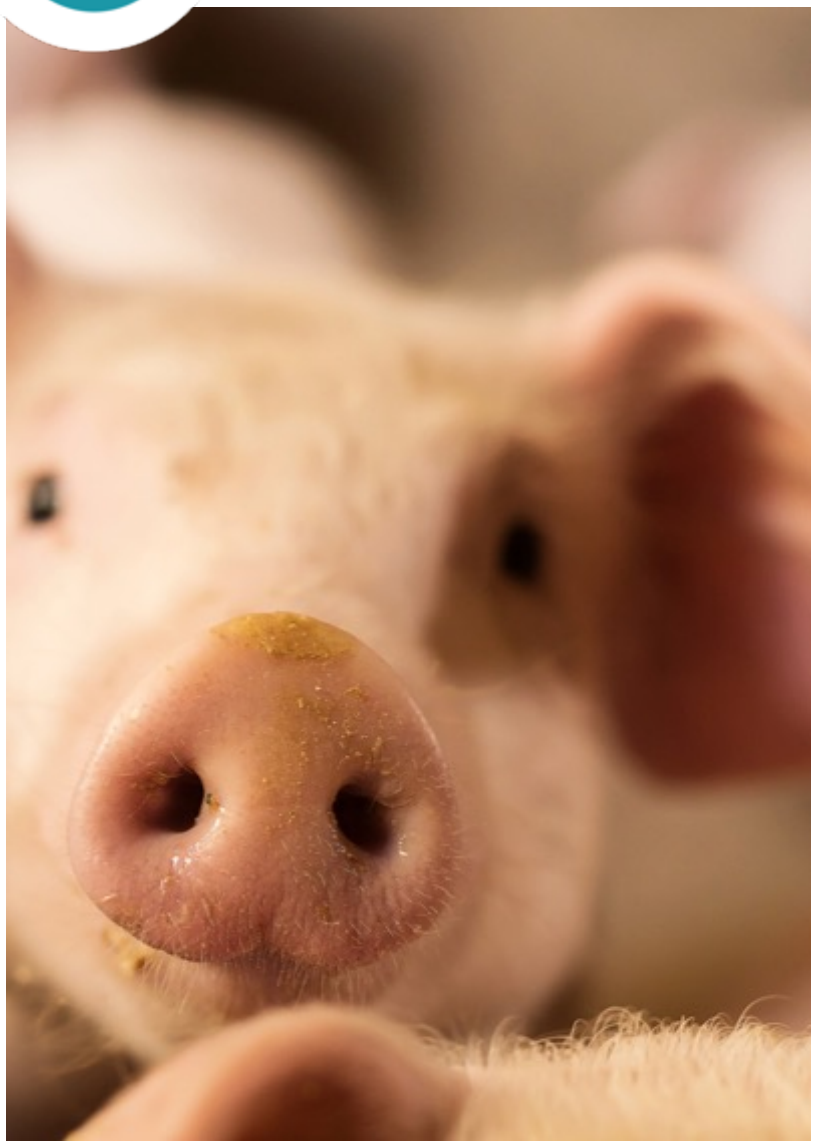
However,

- benefits would be maximized if this happens at global level or at least VICH scale - to allow for appropriate and consistent rules in major geographies



Pharmacovigilance and pharmacoepidemiology

- There is much to be developed but moving from PSURs to signal detection makes this important
- Collaboration with industry on systems and guidance development is important (see PV presentation)
- Major link to B/R assessment and how these data are used to support product registration and continuous B/R balance



Conclusion

- Animal Health Europe supports the work towards implementing and realising the goals of the network regulatory strategy
- Animal Health Europe appreciate the synergies between Regulating 2019/6 and the RSS
- There is a lot of work and discussion needed to meet the goals of the RSS for all stakeholders
- Animal Health Europe are ready to engage with EMA and CVMP, as guidance is developed, that supports this

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Thank you!