EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

Underlying actions

EMA's Regulatory Science Strategy to 2025 – Veterinary Stakeholder Workshop

Presented by David Murphy, CVMP Chair
Supported by Jordi Torren Edo, EMA, on 5th December 2019

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

- Develop regulatory approaches to accommodate advances in technology such as whole genome sequencing and analytical methodology to access ever-lower limits of detection
- Develop methodology for the benefit-risk evaluation of novel medicines intended to promote, or manage, the health of herds, rather than the health of the individual animal
- Promote systematic application of structured benefit-risk methodology and quality assurance systems across the network
- Develop criteria to accept non-conventional sources of data
- Collaborate with regulators of human medicinal products to develop methodology to evaluate the efficacy of a veterinary medicine which is used to produce an improvement in human health
- Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders

High level concerns/recommendations

- Need to adapt B/R to innovation in the development of medicinal products
- Consistent B/R through the different areas of the world
- Use of non-conventional sources of data in B/R
- B/R of veterinary medicinal products where benefit for animals might be secondary
- Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders

Develop regulatory approaches to accommodate advances in technology such as whole genome sequencing and analytical methodology to access ever-lower limits of detection

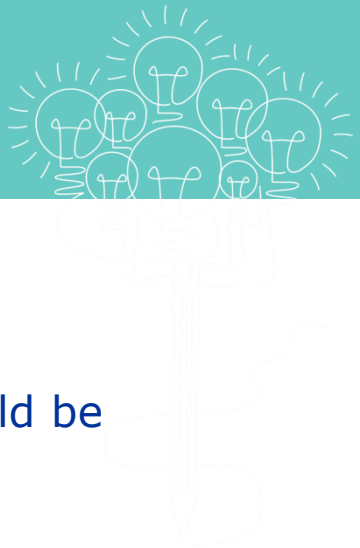
- We can now detect the smallest residue and we need to ensure how to deal with those residues.
  - Precautionary principle vs pragmatic approach.

- How to regulate when the press might amplify any kind of risk

Develop methodology for the benefit-risk evaluation of novel medicines intended to promote, or manage, the health of herds, rather than the health of the individual animal

- Is it really needed?
- Is health of herds what is already commonly evaluated?
- If needed, how could it be implemented?
- The benefit-risk evaluation must include the activities to improve the responsible use of antimicrobials / antiparasitic drugs and their alternatives and to promote the development of veterinary vaccines

Promote systematic application of structured benefit-risk methodology and quality assurance systems across the network



- We need a framework for dealing with uncertainties.
- Risk-mitigation measures should reflect a structured B/R.
- A standardized methodology for the benefit-risk assessment should be developed

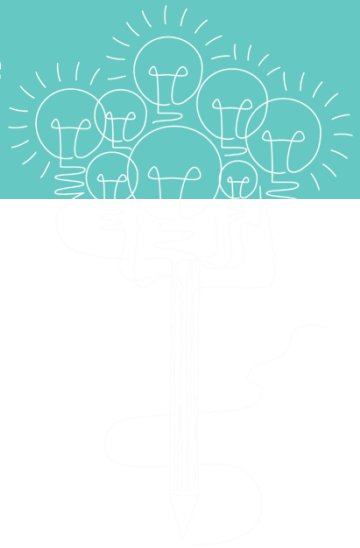
Develop criteria to accept non-conventional sources of data

- In the future, non-conventional sources of data could be an important part of the B/R.
- How to capture and validate those data?

Collaborate with regulators of human medicinal products to develop methodology to evaluate the efficacy of a veterinary medicine which is used to produce an improvement in human health

- Collaborate with regulators of human medicinal products to develop methodology including biomarkers to evaluate the efficacy of a veterinary medicine which is used to produce an improvement in human health.
- Need for collaboration between human and veterinary fields to accelerate access in the event of an emerging health threats (AMR and emergence of new pathogens).
- Need for a more streamlined and clearly communicated regulatory pathway for emerging health threats

Optimise quality and consistency of outputs from EMA and maximise their dissemination to relevant stakeholders



- Increase competence of the network and EMA staff
- Training as a tool to increase quality of B/R

Any questions?

Further information

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