EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Continue to promote the responsible use of antimicrobials and their alternatives

Feedback from breakout session 3A

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

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Disclaimer

Comments to the underlying actions represent the views of stakeholders and not the European Medicines Agency.

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High level actions & feedback

Continued access to established products

- All agreed that old antimicrobials must be kept on the market
- New (clinical) data will be difficult to generate
- Use of modelling methods is supported: Expertise available at VetCAST
- Paucity of data in old dossiers
- Risk of loss of products from the market
- Bottom line for supporting old AMs is return on investment: competing against novel products and ATAs for pharma investment

High level actions & feedback

Reserved List

- Cascade is essential for vets in practice
- List is a disincentive for development of new AMs in case they are put on the list – 'regulatory uncertainty'
- If MSs place further restrictions at national level this will invalidate the EU list
- Need to consider risk of zoonotic infections (pets) if they cannot be treated
- Truly novel human AMs to be reserved for humans only?
- EMA Open Call for information on Cascade use to open shortly

High level actions & feedback

Diagnostic test

- No harmonised EU regulation
- Diagnostic tests available now may be too costly, too slow and inaccurate
- Divergent views over who is responsible for developing diagnostic tests

High level actions & feedback

Alternatives to Antibiotics

- Lack of consistent terminology and uncertainty on classification, need for MRLs
- Limitation of CVMP reflection paper: scope for veterinary medicinal products only
- Issue/risk of presence of unregulated products on the market
- Claims: value of giving information in the SPC on the effect in reducing antimicrobial use, even if not a claim; but need to define main claims; descriptive claims?
- Importance of patent protection (patents only for novel substances)
- Difficulty in identifying the most promising alternative products during development
- Industry ready to start discussions with EMA

Roadmap of actions/deliverables

- New funding models needed for data to maintain old products (PKPD, new clinical data) and establishing break-points e.g. EU project, public funding
- Incentivise MAHs to maintain old AMs e.g. offer fast track authorisation of an ATAb
- Message needed from Regulators: novel vet AMs will not automatically be reserved
- Route to bring back old AMs
- Effectiveness of substances on the reserved list in humans needs to be monitored
- Regulation of diagnostic kits is essential and should be harmonised across EU
- Global leadership needed on AMR - AM in the Environment needs to be addressed
- ATAbs – develop EU position first; then global alignment for GLs

Any questions?

Further information

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