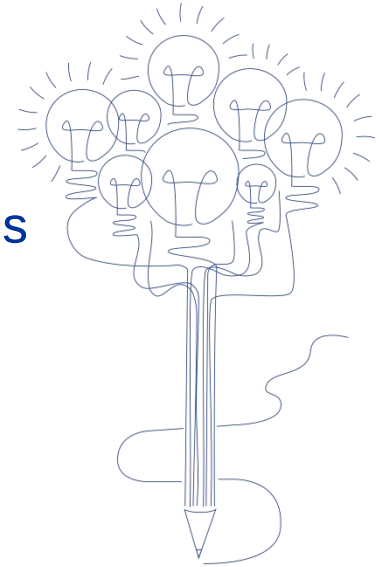
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Driving collaborative evidence generation and improving the scientific quality of evaluations



EMA's core recommendations

Veterinary Stakeholders Workshop

Presented by Nicholas Jarrett on 6 December 2018
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Core recommendations

- Update Environmental Risk Assessments (ERAs) 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

Update Environmental Risk Assessments (ERAs) in line with the latest scientific knowledge

- Contribute to the evaluation of novel approaches to ERA and examine the feasibility of establishing active substance monographs
- Develop further guidance on when the use of persistent, bioaccumulative and toxic substances can be justified
- Develop additional guidance on the ERA of active substances used in aquaculture, including use of antimicrobials under the 'prescribing cascade'.
- Cooperate with DG RTD to fund relevant ERA-related research in veterinary medicines, e.g., AMR in the environment and endocrine disruptors

Update Environmental Risk Assessments (ERAs) in line with the latest scientific knowledge

Provide scientific support to the European Commission and the EU network to ensure a ‘One Health’ approach is applied to ERA, and particularly AMR

Increase cooperation in ERA with European agencies, particularly ECHA and EFSA, and establish cooperation with international institutions, academic organisations, etc.

Strengthen capacity and capability to evaluate the environmental fate and effects of novel veterinary therapies, to consider ERA in the risk/benefit assessment of a product, and to apply ERA to combinations of substances

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

- Develop methodology to evaluate the safety of novel biological substances
- Monitor development of relevant methodologies to further align the approach of the EU network with other European and international bodies
- Increase capability in modelling, simulation and extrapolation
- Work with DG RTD to fund research relevant to safety evaluation e.g., developing robust methods to classify uncertainties

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

- Investigate with EU and international partners the combined effects of residues in the food chain
- Enhance cooperation between European institutions on the safety evaluation of dual-use substances
- Motivate increased data-sharing by industry to reduce animal use in safety evaluations
- Improve communication on the safety evaluation of residues to enhance public understanding of EMA's role

Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

Motivate increased international and stakeholder involvement in pharmacovigilance

Using data on the sales of veterinary products made available, develop methodology to collate, analyse and communicate information about the incidence of adverse reactions related to medicines' use

Develop methodology to analyse the results of signal detection and improve communication of veterinary pharmacovigilance to the general public

Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

- Develop new and improved continuous surveillance and signal detection methodology using the network's pharmacovigilance database
- Establish stakeholder expert groups for different food-producing species to access actual-use data of products in the field, both off and on label
- Facilitate development of methodology using new technology (e.g., mobile phone apps) to increase reporting rates of ADRs

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

- Clearly inform the public of the scientific underpinning of new technologies approved (e.g., biological products including DNA vaccines or gene therapy)
- Promote the presentation of medicinal product information that is readily and easily accessible and able to be updated rapidly
- Ensure authoritative communication on key issues, such as AMR, antiparasitics in companion animals
- Address the problem of under-reporting in pharmacovigilance using new communication approaches

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

Develop regulatory approaches to accommodate advances in technology e.g. whole genome sequencing and analytical methodology with 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

Develop criteria to accept non-conventional sources of data

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

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

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