



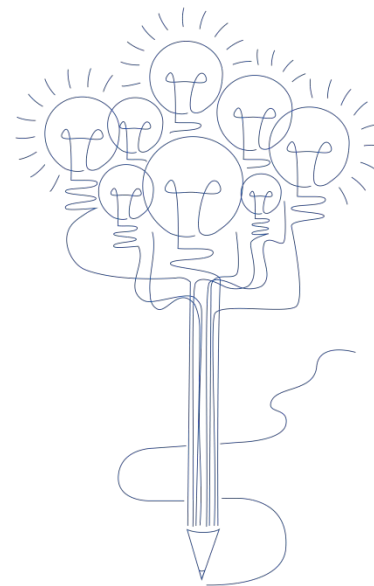
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Addressing emerging health threats and availability/therapeutic challenges

EMA's core recommendations

Veterinary Stakeholders Workshop

Presented by Helen Jukes on 6 December 2018
Vice Chair of CVMP



An agency of the European Union





Core recommendations



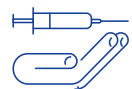
Continue to promote the responsible use of antimicrobials and their alternatives



Coordinate Network activities to improve data collection on antimicrobial use in animals



Engage with stakeholders to minimise the risks of antiparasitic resistance



Promote and support development of veterinary vaccines



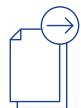
Continue to promote the responsible use of antimicrobials and their alternatives



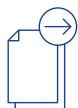
Support prudent and responsible use of antimicrobials, via updated and/or new regulatory guidance and scientific opinion



Promote authorisation of alternatives to the use of conventional antimicrobials



Develop novel regulatory paradigms for efficacy, such as measuring a medicinal product's effect at the level of herd rather than in the individual animal



Develop a regulatory approach for bactericidal compounds that are not themselves traditional antibiotics



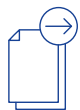
Continue to promote the responsible use of antimicrobials and their alternatives



Facilitate cooperation between stakeholders in AMR and veterinary vaccine availability



Identify funding to generate data, e.g., via modelling and extrapolation, to support existing, including off-patent, antimicrobials



Foster development of pen-side and accompanying diagnostics for antimicrobial sensitivity testing



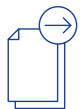
Explore linkage of authorisation and use of high-risk antimicrobials with the approval and use of a companion diagnostic



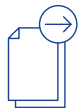
Coordinate Network activities to improve data collection on antimicrobial use in animals



Define requirements for harmonised data collection on antimicrobial use in animals by species



Align standards and methods of data collection to complement those developed internationally



Refine the methodology for 'stratification' of sales data to derive and validate estimates of antimicrobial sales by species



Develop methodology to collate, analyse and communicate data on antimicrobial use





Coordinate Network activities to improve data collection on antimicrobial use in animals



Formulate policy decisions via enhanced cooperation with European institutions (EFSA, ECDC) to collate data on antimicrobial use with information on AMR in animals, humans and food



Participate in international initiatives and action plans to reduce the risk of AMR



Engage with stakeholders to minimise the risks of antiparasitic resistance



Cooperate with DG RTD to fund research into antiparasitic resistance and its control/prevention



Align with EU institutions to survey and monitor antiparasitic use in food-producing species



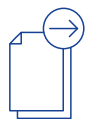
Promote responsible use of antiparasitics in the EU and monitor for development of antiparasitic resistance



Catalyse international cooperation to combat antiparasitic resistance and establish best practice



Promote and support development of veterinary vaccines



Clarify the criteria required for field efficacy trials to support a marketing authorisation application for new vaccines



Acknowledge that different benefit/risk approaches are required for assessment of specific vaccine types, especially zoonotic vaccines



Interact collaboratively with industry to focus development on areas where vaccines are most needed



Develop criteria for epidemiological modelling to demonstrate vaccine efficacy against epizootic disease





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