



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Start of review concerning veterinary medicines containing amoxicillin

The European Medicines Agency (EMA) has started a review of veterinary medicines containing amoxicillin as a single active substance for use in drinking water or in feed in pigs, specifically for respiratory indications.

In the context of the Dosage Review and Adjustment of established veterinary Antibiotics (ADRA) project, the EMA's veterinary medicines committee (CVMP) will review and refine the dosage regimen (i.e., dose, frequency and treatment duration) in the product information of the above-mentioned veterinary antibiotics, using non-experimental approaches (i.e. not necessitating the generation of new data), including pharmacokinetics/pharmacodynamics (PK/PD) integration for dose review and adjustment, PK modelling for withdrawal period adjustment, and scientific review approaches to address the safety of both target animals and the environment.

The aim of this scientific advice provided by the CVMP is to minimise the occurrence of antimicrobial resistance in the Union, and the outcome of this procedure will be considered to constitute current scientific knowledge, thus allowing the product information of the concerned products to be aligned accordingly.

In the interest of transparency, the Agency invites stakeholders (e.g., marketing authorisation holders (MAHs), veterinary healthcare professionals, farmers, academia) to submit any relevant information or data that may assist the CVMP in preparing its scientific advice. Relevant data should be submitted to vet.referrals@ema.europa.eu by 19 February 2026. For MAHs, the Agency would greatly appreciate if data were submitted using the eSubmission Gateway and Web Client.

More about the procedure

The review has been self-mandated by the Committee for Veterinary Medicinal Products (CVMP) under Article 141(1)(i) of Regulation (EU) 2019/6. The review is being carried out by the CVMP, responsible for questions concerning medicines for veterinary use, and will result in a scientific advice.

