6 November 2025
EMA/CVMP/324544/2025
Committee for Veterinary Medicinal Products (CVMP)

CVMP List of questions to be addressed by stakeholders

For veterinary medicinal products containing amoxicillin (as a single active substance) in pigs for use in drinking water or in feed, for respiratory indications

Article 141(1)(i) of Regulation (EU) 2019/6

Procedure number: EMA/REF/0000290626

During its plenary meeting of November 2025, the Committee for Veterinary Medicinal Products (CVMP) initiated a procedure under Article 141(1)(i) of Regulation (EU) 2019/6 on veterinary medicinal products containing amoxicillin (as a single active substance) in pigs for use in drinking water or in feed, for respiratory indications. This procedure is part of the Dosage Review and Adjustment of established veterinary Antibiotics (ADRA) project, to provide scientific advice on the use of antimicrobials in animals in order to minimise the occurrence of resistance in the Union.

The aim of this scientific advice would be to 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 CVMP will review the following:

1. Any relevant, already available pre-clinical and clinical data for the dosage regimen (dose rate, dosing interval and treatment duration) in the target species pig and for respiratory indications.

- Pharmacodynamics data:
  - Ideally, time kill curves of relevant respiratory pathogens for pigs, stability of the antibiotic concentration in the testing media, limits of the quantification/detection of the method(s) used, type of medium used (e.g., broth vs serum).
  - Alternatively, recent MIC distributions of relevant respiratory pathogens for pigs, Minimal Bactericidal Concentration (MBC) data, Mutation Prevention Concentration (MPC) data (emphasising time-dependent PK) and any PK/PD relationship data.
- Pharmacokinetics data:
  - Ideally, individual plasma PK profiles (where available also PK data for compartments of the respiratory tract) following intravenous and oral administration (with detailed individual information: composition of VMP (qualitative/quantitative, considering influence on PK parameters, e.g. micronised forms), individual dose, exact sampling time, breed, age, weight, health status (infectious diseases), analytical method type, LOQ and validation).
  - Alternatively, Mean and SD values for AUC related to different dose regimens or Mean and SD values for each PK parameter (CL, F, f …)
- Dose determination studies, dose confirmation studies:
  - Ideally, for the administration via drinking water or medicated feed (i.e. data on qualitative/quantitative composition of VMP, on dose, dosing interval and treatment duration) for relevant indications in pigs.
- Clinical trials.

  Regarding *in vivo* studies, documented MICs of the target pathogens before and after treatment, as well as data on clinical and bacteriological cure rates will be of particular interest.

2. Any relevant, already available, residue depletion data in pigs (including description and validation of the analytical methods).

3. Any relevant, already available data on the environmental risk, with particular emphasis on data which is in line with current EMA and VICH guidelines.

4. Any relevant, already available data for target animal safety in pigs.

In all cases, raw data would be preferred.

Interested parties (e.g. marketing authorisation holders, academia, veterinary healthcare professionals, farmers) are invited to submit **any information which may be relevant for this scientific advice** by 19 February 2026.

More information on this procedure is available on the webpage of the procedure.

Disclaimer on data submission and required permissions

All parties submitting data as part of the Dosage Review and Adjustment of established veterinary Antibiotics (ADRA) procedures to EMA are reminded that it is their sole responsibility to ensure that appropriate agreement has been obtained from the data owner prior to any submission. Specifically, by providing data to EMA, the sender confirms that the required authorisation for sharing such information with EMA has been obtained and that all necessary permissions have been secured as required in the context of the ADRA procedure, including for the possible disclosure in the public domain subject to the applicable rules, including specifically Regulation (EC) No 1049/2001.

EMA is neither responsible for verifying the ownership of data received, nor for verifying that the required permissions have been obtained in line with the applicable laws. Any issues arising from unauthorised data sharing are the sole responsibility of the respective party that submitted the data, including in particular any possible liability resulting thereof (such as, but not limited to, any direct or consequential damage or loss that might occur). Please also note that no personal data should be shared with EMA.

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Please note that all information submitted in the context of this procedure may be shared and disclosed in the public domain in accordance with the applicable rules, including specifically Regulation (EC) No 1049/2001. In particular, commercially confidential information is subject to appropriate redaction in accordance with highlighted rules prior to disclosure in the public domain.