EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 November 2025
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Committee for Veterinary Medicinal Products (CVMP)

CVMP List of questions to be addressed by the marketing authorisation holders

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

Marketing authorisation holders for veterinary medicinal products containing amoxicillin (as a single active substance) in pigs for use in drinking water or in feed, for respiratory indications are requested to provide 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.

It should be noted that in addition to the questions raised in this document, the CVMP may consider other available data related to the quality, safety and efficacy of the veterinary medicinal products concerned.

All documents should be presented in English.

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.