16 February 2022
EMA/CVMP/104859/2022
Committee for Veterinary Medicinal Products

List of questions to be addressed by the marketing authorisation holders

For veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection

Article 82 of Regulation (EU) 2019/6

Procedure number: EMEA/V/A/145

The marketing authorisation holders for veterinary medicinal products containing procaine benzylpenicillin as a single active antimicrobial substance presented as suspensions for injection are requested to provide the following:

1. The qualitative and quantitative composition of the products concerned by the procedure.
2. Relevant pre-clinical (e.g. recent MIC data of target pathogens, PK data of target animal species, PK/PD relationship, dose finding studies) and clinical data (e.g. dose confirmation studies, field trials), together with an Expert comment on the data, justifying the dosage regimen (dose rate, frequency and treatment duration) in each target animal species (cattle, horses, sheep, goats, pigs, dogs and cats) and for each indication of their concerned products. Concerns regarding antimicrobial resistance development in target pathogens should be taken into account.
3. Relevant residue data substantiating the established withdrawal periods for food-producing target animal species, data for the positive decision for the environmental risk, and data for target animal safety in all target animal species at the proposed dose rate and treatment duration, together with an Expert comment on the data.

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.