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Start of review concerning veterinary medicines containing procaine benzylpenicillin

EMA has started a review of veterinary medicines containing procaine benzylpenicillin as a single active substance presented as suspensions for injection.

These medicines have been used widely throughout the EU for decades. It has been noticed that the authorised durations of treatment vary between the different products and based on available data not all of them might be appropriate to treat all claimed indications effectively. This could also lead to a risk of development of antimicrobial resistance.

Having considered this issue, the national veterinary medicines regulatory authority of Germany requested EMA's veterinary medicines committee (CVMP) to assess its impact on the benefits and risks of veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection.

EMA will now review the available data to determine if any action is necessary to protect animal or public health or the environment.

More about the medicines

The review covers veterinary medicines containing procaine benzylpenicillin as a single active substance presented as suspensions for injection authorised for use in cattle, horses, sheep, goats, pigs, dogs and cats.

More about the procedure

The review has been initiated at the request of the veterinary medicines regulatory agency of Germany under Article 82 of Regulation (EU) 2019/6. The review is being carried out by the Committee for Veterinary Medicinal Products (CVMP), responsible for questions concerning medicines for veterinary use, which will adopt the Agency's opinion. The CVMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

