16 February 2022
EMA/CVMP/104860/2022
Committee for Veterinary Medicinal Products

CVMP list of questions to be addressed by the stakeholders

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

On 9 February 2022, the German National Competent Authority notified the European Medicines Agency, in accordance with Article 82 of Regulation (EU) 2019/6, informing on concerns regarding the discrepancies among the authorised dosage regimens (dose rate and treatment duration) of veterinary medicinal products containing procaine benzylpenicillin as a single active substance presented as suspensions for injection. The German National Competent Authority considered that a review of the treatment duration of the concerned products is necessary to ensure a safe and effective use of those veterinary medicines and to avoid an unnecessary risk of resistance development, for the environment and the consumer.

The notification of the German National Competent Authority triggering the procedure is available on the webpage of the procedure.

In accordance with Article 83(1) of Regulation (EU) 2019/6, interested parties (e.g. veterinary healthcare professionals, farmers, academia) are invited to submit information relevant to the procedure, addressing the below Committee for Veterinary Medicinal Products (CVMP) list of questions by 9 September 2022:

Question 1

Please provide information or data (i.e. non-clinical data e.g. PK/PD relationship, clinical data, published literature) you may have and which could be relevant to evaluate the established dosage regimen (dose rate, frequency and treatment duration) of veterinary medicinal products containing procaine benzylpenicillin presented as suspensions for injection.