EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 June 2025
EMA/CVMP/180973/2025
Committee for Veterinary Medicinal Products (CVMP)

CVMP List of questions to be addressed by the stakeholders

For veterinary medicinal products (VMPs) containing albendazole as a single active substance presented as oral suspension for sheep

Article 82 of Regulation (EU) 2019/6

Procedure number: EMA/REF/0000271819

INN/active substance: albendazole

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On 11 June 2025, 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 dose of albendazole administered in sheep, more specifically the dose or lower dose limit of 3.75 – 5.0 mg albendazole/kg bodyweight (bw). A number of scientific publications suggest that this dose may pose a serious risk of insufficient efficacy against gastrointestinal (GIT) nematodes in sheep and, in addition, of selecting for albendazole resistance in the context of the benzimidazole resistance already present in sheep GIT nematodes in Europe. Moreover, the doses of albendazole-containing VMPs against GIT nematodes in sheep are disharmonised across the EU, ranging between 3.75 – 15 mg albendazole/kg bw. Therefore, the German National Competent Authority considered that a review of the doses or lower dose limits of 3.75 – 5.0 mg albendazole/kg bw of the concerned VMPs is required to ensure a safe and effective use of those veterinary medicines and to avoid an unnecessary risk of antiparasitic resistance development.

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 8 September 2025:

Question 1

Please provide information or data (i.e. pre-clinical or clinical data e.g. pharmacokinetic data, PK/PD relationship, dose determination studies, dose confirmation studies, clinical trials; published literature) you may have and which could be relevant to establish an appropriate dosage regimen (dose rate, dosing interval and treatment duration) of veterinary medicinal products containing albendazole as a single active substance presented as oral suspension for the treatment of gastrointestinal nematodes in sheep. Considerations regarding antiparasitic resistance development should also be taken into account.