EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 June 2025
EMA/CVMP/180970/2025
Committee for Veterinary Medicinal Products (CVMP)

CVMP List of questions

To be addressed by the marketing authorisation holders for veterinary medicinal products containing albendazole as a single active substance presented as oral suspension for sheep

Referral procedure under Article 82 of Regulation (EU) 2019/6

Procedure number: EMA/REF/0000271819

INN/active substance: albendazole

The marketing authorisation holders (MAHs) for veterinary medicinal products containing albendazole as a single active substance presented as oral suspension for sheep are requested to provide the following:

1. The qualitative and quantitative composition as well as specifications of the products concerned by the procedure.
2. Any relevant, already available pre-clinical (e.g. pharmacokinetic data in sheep, PK/PD relationship, dose determination studies, dose confirmation studies) and clinical data (e.g. clinical trials), together with an Expert comment on the data, justifying the dosage regimen (dose rate, dosing interval and treatment duration) in the target species sheep and for treatment of gastrointestinal nematodes. Considerations regarding antiparasitic resistance development should also be taken into account.
3. Any relevant, already available residue data substantiating the withdrawal periods for sheep, data for the positive decision for the environmental risk, and data for target animal safety in sheep at the proposed dose rate, dosing interval and treatment duration, together with an Expert comment on the data.

It should be noted that, in addition to the data provided by the MAHs in response 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.