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Start of review concerning veterinary medicines containing albendazole

EMA has started a review of veterinary medicines containing albendazole as a single active substance presented as oral suspension indicated against gastrointestinal nematodes in sheep.

These veterinary medicines have been used widely throughout the EU for decades. It has been noticed that the authorised doses of 3.75-5 mg of albendazole/kg bodyweight of the concerned veterinary medicines might no longer be appropriate to ensure the effective use against gastrointestinal nematodes. This could also contribute to a risk of development of antiparasitic 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 albendazole as a single active substance presented as oral suspension indicated against gastrointestinal nematodes in sheep.

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 albendazole as a single active substance presented as oral suspension indicated against gastrointestinal nematodes in sheep.

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.

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