



Date: 23-04-2025

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Cunitraxx 25 mg/ml oral suspension for rabbits -
EMA/V/C/006595/0000

Dear CVMP,

For the withdrawal of initial marketing authorisation applications

I would like to inform you that, at this point of time, *Avimedical B.V.* has taken the decision to withdraw the application for Marketing Authorisation of *Cunitraxx 25 mg/ml oral suspension*, which was intended to be used for *Treatment and control of protozoan parasites in rabbits infected with: - Encephalitozoon cuniculi.*

This withdrawal is based on the following reasons :

Given the magnitude of the request for supplementary information sent for Cunitraxx application following February CVMP, the applicant has to decide not to continue with this procedure.

Although the request for additional clinical data can be appreciated, the applicant considered some pharmaceutical questions as discouraging for an LMA, since the application was based on an "authorized" composition.

The fact that pet rabbits could not be considered a separate target species was considered disappointing, as this apparently rules out any LMA for these pets. This was also not communicated during the application for a LMA and in the draft assessment report LoQ-D85.

We reserve the right to make further Marketing Authorisation Application submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Yours sincerely,

