EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 October 2016
EMA/CVMP/618897/2016
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

VarroMed

International non-proprietary name (INN): oxalic acid dihydrate / formic acid

On 6 October 2016, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product VarroMed, a bee-hive dispersion intended for the treatment of Varroa-mite infestation in honey bee colonies with and without brood. The applicant for this veterinary medicinal product is BeeVital GmbH. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

VarroMed is an antiparasitic medicinal product containing as active substance a fixed combination of two organic acids, oxalic acid dihydrate and formic acid (ATCvet code QP53AG). The mode of action of both substances is still not well-known, although direct contact to mites is needed. The withdrawal period for honey is zero days.

The benefit of VarroMed is its effective use in treatment of honey bees in hives infested with Varroa destructor mites. Single treatment with VarroMed is generally well-tolerated at the recommended dose; increased bee mortality was noted following repeated administration.

The CVMP considered the appropriate CVMP guidelines on data requirements for veterinary medicinal products intended for minor use or minor species/limited markets have been applied in the assessment of the application.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for VarroMed and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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