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Press release

New medicine to protect honey bees against Varroa mites

VarroMed recommended for marketing authorisation

At its October meeting, the Committee for Medicinal Products for Veterinary Use (CVMP) of the European Medicines Agency (EMA) recommended the granting of a marketing authorisation in the European Union (EU) for VarroMed (oxalic acid dihydrate / formic acid). This antiparasitic medicine treats the Varroa mite infestation in honey-bee colonies, which is considered to be the most significant parasitic health concern affecting honey bees worldwide.

Honey bees are essential for pollination of crops and wild plants in Europe. The European Commission estimates that pollinators, including honey bees, bumble bees and wild bees, contribute at least 22 billion euros each year to European agriculture and pollinate over 80% of crops and wild plants on the continent.

However, beekeepers around the world have reported losses of honey-bee colonies, which are considered to be caused by a combination of different factors such as habitat loss, climate change, pesticide use, and also diseases affecting bee health. A continued decline of these pollinators could lead to serious biological, agricultural, environmental and economic difficulties.

The main parasite affecting honey bees is the Varroa mite (*Varroa destructor*), an invasive species from Asia that has affected bee colonies worldwide. The Varroa mite feeds on the circulatory fluid of bees and brood (bee larvae) and can also contribute to the spread of viruses and bacteria.

VarroMed is intended to kill Varroa mites and is a liquid which is trickled onto bees in the hive. It contains as active substance a fixed combination of two organic acids, oxalic acid dihydrate and formic acid. Both substances have been known in veterinary medicine for a long time and are either naturally present in foods or accepted for use in foods. The medicine is not expected to pose a risk to human or animal health or the environment, if used according to the product information.

VarroMed is intended to be used as part of an integrated Varroa control programme, which includes not only treatment with medicines but also non-chemical techniques like queen trapping or drone brood removal. It can be used either as a single-dose treatment during the broodless period (winter treatment) or in the presence of brood (spring or autumn), which will usually require repeated treatments.

Treatment should only be given at times when honey is not produced by bees.

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The effectiveness and safety of the product in the protection of honey bees against Varroa mites was tested in laboratory and field studies in different European climate conditions. VarroMed was effective in killing more than 80% of mites, which is below the effectiveness level of 90% recommended by the CVMP Varroa guideline. However, CVMP agreed that a lower level of 80% could be accepted when integrated Varroa control techniques are put in place. Repeated treatment of VarroMed might also result in increased bee mortality, and careful dosing is recommended to avoid overdosing.

The medicine has been classified as MUMS (minor use minor species/limited market), and, therefore, reduced data requirements apply, and these have been considered in the assessment. EMA's MUMS policy aims to stimulate the development of new veterinary medicines for minor species and for diseases in major species for which the market is limited and that would otherwise not be developed under current market conditions.

The CVMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation.

Notes

1. The applicant for this veterinary medicinal product is BeeVital GmbH.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu.
3. More details on honey bees are available on the European Commission website.

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