8 September 2017
EMA/CVMP/499119/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Oxybee

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

On 7 September 2017, 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 Oxybee, a powder and solution for bee-hive dispersion intended for the treatment of varroosis in honey bees. The applicant for this veterinary medicinal product is Dany Bienenwohl GmbH. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Oxybee is an antiparasitic medicinal product containing oxalic acid dihydrate (ATCvet code QP53AG03) as the active substance. The mode of action of oxalic acid dihydrate against the Varroa mite is not well understood, although direct contact with mites is needed. The withdrawal period for honey is zero days.

The benefit of Oxybee is its effective use in treatment of honey bees in hives infested with *Varroa destructor* mites. Oxybee is generally well-tolerated at the recommended dose; however adverse reactions (dose-dependent increase in bee mortality) was commonly noted.

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 Oxybee 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.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact