EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 April 2018
EMA/CVMP/178553/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Dany's BienenWohl

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

On 19 April 2018, 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 Dany's BienenWohl, powder and solution for bee-hive dispersion, intended for the treatment of varroosis. The applicant for this veterinary medicinal product is Dany's BienenWohl GmbH. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Dany's BienenWohl 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 Dany's BienenWohl is its effective use in the treatment of honey bees in hives infested with *Varroa destructor* mites. The most common side effect is a dose-dependent increase in bee mortality.

The application for Dany's BienenWohl was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Dany's BienenWohl is Oxybee (EU/2/17/216/001-002).

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.

[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