19 April 2018
EMA/247684/2018
Veterinary Medicines Division

Committee for Medicinal Products for Veterinary Use

CVMP assessment report for Dany's BienenWohl (EMEA/V/C/004667/0000)

International non-proprietary name: oxalic acid dihydrate

Assessment report as adopted by the CVMP with all information of a commercially confidential nature deleted.

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Introduction

The applicant Dany Bienenwohl GmbH submitted on 5 February 2018 an application for a marketing authorisation to the European Medicines Agency (The Agency) for Dany's BienenWohl, through the centralised procedure under Article 3(2) of Regulation (EC) No 726/2004 (optional scope).

The legal basis for this application refers to Article 13(c) of Directive 2001/82/EC, relating to informed consent from a marketing authorisation holder for an authorised veterinary medicinal product: Oxybee, authorised in the Community on 1 February 2018 (EU/2/17/216/001-002).

This application is submitted as a multiple application of the centrally authorised product Oxybee (EU/2/17/216/001-002), authorised to Dany Bienenwohl, in accordance with Article 82(1) of Regulation (EC) No 726/2004.

The eligibility to the centralised procedure was agreed upon by the CVMP on 6 October 2016.

The applicant applied for the following indication: For the treatment of varroosis (*Varroa destructor*) of honey bees (*Apis mellifera*) in brood-free colonies.

The active substance of Dany's BienenWohl is oxalic acid dihydrate, an antiparasitic product used in honey bees for treatment of varroosis. The target species is honey bees.

Dany's BienenWohl is a powder and solution for bee-hive dispersion, which when mixed contains 39.4 mg oxalic acid dihydrate (OAD)/ml. The product is available in two pack sizes. The smaller is a 500 ml bottle containing 17.5 g OAD (in 375 g of solution) which is packaged with one 125 g sachet of (flavoured) sucrose. The larger pack size consists of a 1000 ml bottle containing 35 g OAD (in 750 g of solution) packaged with two 125 g sachets of (flavoured) sucrose. Prior to use, the sucrose powder is added to the solution (containing the active substance) in the bottle, and then mixed, in order to achieve the final bee-hive dispersion (which contains 35 g OAD per kg of dispersion, equivalent to 25 mg/ml oxalic acid anhydrous).

The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

The rapporteur appointed is Gerrit Johan Schefferlie and the co-rapporteur is Katarina Straus.

The dossier has been submitted in line with the requirements for submissions under Article 13c of Directive 2001/82/EC – an informed consent application. The application submitted is composed of administrative information with consent from Dany Bienenwohl GmbH allowing the cross-reference to relevant quality, safety and efficacy data of the reference product.

On 19 April 2018, the CVMP adopted an opinion and CVMP assessment report.

On 14 June 2018, the European Commission adopted a Commission Decision granting the marketing authorisation for Dany's BienenWohl.

Scientific advice

Not applicable.

MUMS/limited market status

The applicant requested classification of this application as MUMS/limited market by the CVMP, and the Committee confirmed that, where appropriate, the data requirements in the relevant CVMP guideline(s) on minor use minor species (MUMS) data requirements would be applied when assessing the application. MUMS/limited market status was granted as honey bees are considered a minor species.

Prescription status

The applicant applied for exemption from the requirement for the veterinary medicinal product to be dispensed only against veterinary prescription by reference to Article 2 of Commission Directive 2006/130/EC.

Part 1 - Administrative particulars

Detailed description of the pharmacovigilance system

The applicant has provided a detailed description of the pharmacovigilance system (completion date: 24 January 2018) which fulfils the requirements of Directive 2001/82/EC. Based on the information provided the applicant has the services of a qualified person responsible for pharmacovigilance and the necessary means for the notification of any adverse reaction occurring either in the Community or in a third country.

Manufacturing authorisations and inspection status

Manufacture, quality control and release of the active substance, oxalic acid dihydrate, takes place in the EU. The sites have GMP certificates issued by the relevant authorities confirming GMP compliance. A GMP declaration for the active substance manufacturing site was provided from the Qualified Person (QP) at the batch release site. The declaration was based on a GMP certificate available for the active substance manufacturing site.

Batch release of the dosage form takes place at Wirtschaftsgenossenschaft Deutscher Tierärzte e.G., Garbsen, Germany. The site has a GMP certificate for the manufacture of the veterinary medicinal products issued by the German authorities (Staatliches Gewerbeaufsichtsamt, Hannover, Germany), which confirms GMP compliance.

Overall conclusions on administrative particulars

The detailed description of the pharmacovigilance system was considered in line with legal requirements.

The GMP status of both the active substance and finished product manufacturing sites has been satisfactorily established and are in line with legal requirements.

Part 2 - Quality

This application is an informed consent of Oxybee powder and solution for bee-hive dispersion for honey bees.

The quality data in support of this application are identical to the up-to-date quality data of the dossier for Oxybee powder and solution for bee-hive dispersion for honey bees, which has already been assessed and approved by the CVMP.

Therefore, no quality data have been submitted in support of this application. This is considered acceptable.

Part 3 – Safety

This application is an informed consent of Oxybee powder and solution for bee-hive dispersion for honey bees.

The safety data in support of this application are identical to the up-to-date safety data of Oxybee powder and solution for bee-hive dispersion for honey bees, which has already been assessed and approved by the CVMP (including any post-marketing procedures).

Therefore, no safety data have been submitted in support of this application. This is considered acceptable.

To ensure comprehensive adverse event surveillance and to benefit from the possibility of aligning periodic safety update report (PSUR) submissions for informed consent products as foreseen in the legislation, PSUR submissions should be synchronised and common PSURs should be submitted for the informed consent product, Dany's Bienenwohl, and the reference product, Oxybee, which is currently on a six monthly reporting cycle.

In addition, surveillance of the data in EudraVigilance Veterinary (EVVet) will also be synchronised for signal detection of the two products.

Part 4 – Efficacy

This application is an informed consent of Oxybee powder and solution for bee-hive dispersion for honey bees.

The efficacy data in support of this application are identical to the up-to-date efficacy data of Oxybee powder and solution for bee-hive dispersion for honey bees, which has already been assessed and approved by the CVMP (including any post-marketing procedures).

Therefore, no efficacy data have been submitted in support of this application. This is considered acceptable.

Part 5 – Benefit-risk assessment

This marketing authorisation application for Dany's BienenWohl powder and solution for bee-hive dispersion has been submitted by Dany Bienenwohl GmbH as an informed consent application in accordance with Article 13c of Directive 2001/82/EC.

The quality, safety and efficacy of Dany's BienenWohl are identical to the up-to-date quality, safety and efficacy profile of Oxybee powder and solution for bee-hive dispersion. The application for Dany's BienenWohl consists of only Part 1 (administrative particulars) of a full marketing authorisation dossier. Information on the scientific discussion can be found in the European Public Assessment Report (EPAR) for Oxybee powder and solution for bee-hive dispersion published on the EMA website.

Consequentially, and in line with the assessment of data provided in the framework of the initial marketing authorisation application, as well as within all post-authorisation procedures for Oxybee powder and solution for bee-hive dispersion, the CVMP considers that the benefit-risk balance for Dany's BienenWohl is positive.

The CVMP also considered that the product complies with all the criteria prescribed in Article 2 of Commission Directive 2006/130/EC, and that therefore the applicant's request for exemption from the requirement for the veterinary medicinal product to be dispensed only against veterinary prescription is acceptable.

To ensure comprehensive adverse event surveillance, signal detection and PSUR submissions will be synchronised with those for the reference product, Oxybee.

Conclusion

Based on the original and complementary data presented on quality, safety and efficacy the Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the application for Dany's BienenWohl is approvable since these data satisfy the requirements for an authorisation set out in the legislation (Regulation (EC) No 726/2004 in conjunction with Directive 2001/82/EC).

The CVMP considers that the benefit-risk balance is positive and, therefore, recommends the granting of the marketing authorisation for the above mentioned medicinal product.