EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 December 2022
EMA/CVMP/889858/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Brucellin Aquilon

Common name: Brucella abortus, strain AQ1302, protein extract

On 8 December 2022, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Brucellin Aquilon, Solution for injection, intended for pig. The applicant for this veterinary medicinal product is Aquilon Cyl S.L. The applicant is registered as an SME pursuant to the definition set out in Commission Recommendation 2003/361/EC.

Brucellin Aquilon is an immunological veterinary medicinal product containing *Brucella abortus*, strain AQ1302, protein extract (ATCvet code QI09AR) as active substance.

The benefit of Brucellin Aquilon is its use for *in vivo* diagnosis of *Brucella*-infected pigs through a positive skin reaction after a positive serological *Brucella* test. Brucellin Aquilon has been specifically designed as a second line diagnostic test to differentiate Brucella-infected pigs, from the age of 5 months, from the *Brucella*-free pigs having given false positive serological reactions (FPSR) in brucellosis serological tests based on anti-O-PS antibodies (e.g. Rose Bengal).

Brucellin Aquilon is generally well tolerated at the recommended dose, no adverse reactions are seen at overdoses.

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

Detailed conditions for the use of this product are 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 Brucellin Aquilon 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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