13 June 2025
EMA/CVMP/184015/2025
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Biobhyo

Common name: Swine dysentery vaccine (inactivated)

On 12 June 2025, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Biobhyo, emulsion for injection, intended for Pigs. 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.

Biobhyo is a vaccine containing *Brachyspira hyodysenteriae*, strain AqDys057, inactivated (ATCvet code is QI09AB) as active substance. It is intended for the active immunisation of pigs for fattening against swine dysentery.

The benefit of Biobhyo for fattening pigs is that reduces the occurrence of dysenteric diarrhoea caused by *Brachyspira hyodysenteriae.*

The most common side effects are elevated temperature, injection site erythema, injection site swelling, and injection site nodule.

The full indication is:

For the active immunisation of pigs for fattening to reduce the occurrence of dysenteric diarrhoea caused by *Brachyspira hyodysenteriae.*

Onset of immunity: 2 weeks after vaccination.
Duration of immunity: 18 weeks after vaccination.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) 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.
[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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The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Biobhyo and therefore recommends the granting of the marketing authorisation.