Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A PROPOSED VETERINARY MEDICINAL PRODUCT

Asimel Vet 1.5 mg/ml Oral Suspension for Dogs

NOTE: This medicine was refused authorisation

Date Created: May 2026

MODULE 1

PROPOSED PRODUCT SUMMARY

Name, strength and pharmaceutical form	Asimel Vet 1.5 mg/ml Oral Suspension for Dogs
Applicant	Ashish Life Science Holding B.V., Herengracht 454, 1017 CA Amsterdam, NETHERLANDS
Active substances	Meloxicam
ATC Vetcode	QM01AC06
Target species	Dogs
Proposed indication for use	Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

MODULE 2

As the product was refused a marketing authorisation, a Summary of Product Characteristics was not approved for this product.

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.
Date of conclusion of the procedure	12/05/2026

I. SCIENTIFIC OVERVIEW

The application was for a Marketing Authorisation in Great Britain (GB) and was assessed as a generic application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Para 10) as amended.

In light of the overall data submitted and the scientific discussion within the VMD, a negative opinion for Asimel Vet 1.5 mg/ml Oral Suspension for Dogs was adopted. The overall benefit/risk analysis was not in favour of granting a marketing authorisation.

I.A. Proposed Indication

Asimel Vet 1.5 mg/ml Oral Suspension for Dogs was expected to be used for alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs. The product was intended to be administered orally.

I.B. Method of Action

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibiting prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

I.C. Reasons for Refusal

The application was refused as the manufacturing process validation did not demonstrate that the product can be manufactured with consistent particle size distribution (PSD) levels. The levels observed for validation batches were significantly different to those observed for the batch used for bioequivalence studies.

A valid ISO certification for the child resistant packaging was also not provided.

II. CHEMICAL, PHARMACEUTICAL & BIOLOGICAL DOCUMENTATION

As in section 1.C., it was not demonstrated that the product can be manufactured with consistent particle size distribution (PSD) levels. This is an important factor as it influences the *in vivo* dissolution and availability of the active substance in the target animal species, with potential consequences for product efficacy.

III. SAFETY & RESIDUES DOCUMENTATION

Due to the legal basis of the application, no new pharmacological or toxicological studies were submitted. The applicant provided a user risk assessment that stated the tasks and situations that lead to exposure, and the exposure scenarios would be the same for both the reference and proposed product.

The applicant provided a Phase I environmental risk assessment containing sufficient information to conclude that the assessment ends at Phase I.

IV. PRE-CLINICAL & CLINICAL DOCUMENTATION

As this application was for a generic product and the applicant claimed to have demonstrated bioequivalence between the test and reference products, no new pharmacodynamic, tolerance and/or clinical data were provided.

V. OVERALL CONCLUSION AND BENEFIT–RISK ASSESSMENT

In conclusion, the data submitted in the dossier do not support a favourable benefit/risk profile for the product, and the application has been refused.

The grounds for refusal were as follows:

- With respect to Great Britain, as per the UK Veterinary Medicines Regulations 2013 (as amended), the Secretary of State must refuse to grant a marketing authorisation if the data submitted with the application are inadequate (Schedule 1, Part 3, paragraph 24.2a).

MODULE 4

POST- AUTHORISATION ASSESSMENTS

As the application was refused, there are no post-authorisation assessments.