Veterinary Medicines Directorate

**United Kingdom**
**Veterinary Medicines Directorate**
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**NATIONAL PROCEDURE**

# PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A PROPOSED VETERINARY MEDICINAL PRODUCT

## Primun Gumboro W2512 Lyophilisate for Use in Drinking Water

**NOTE: This medicine was refused authorisation**

**Date Created: April 2025**

# MODULE 1

## PROPOSED PRODUCT SUMMARY

| | |
|---|---|
| Name, strength and pharmaceutical form | Primun Gumboro W2512 Lyophilisate for Use in Drinking Water, Lyophilisate for use in drinking water |
| Applicant | Laboratorios Calier, S.A., C/Barcelones 26 (Pla del Ramassa), 08520 Les Franqueses del Valles, Spain |
| Active substance(s) | Live Infectious bursal disease virus, strain W2512 |
| ATC Vetcode | QI01AD09 |
| Target species | Chickens |
| Indication for use | For the active immunisation of broiler chickens with maternally derived antibodies (MDA) to reduce mortality, clinical disease and acute lesions in the bursa of Fabricius associated with infection caused by very virulent strains of infectious bursal disease viruses.<br>Onset of immunity: 14 days post vaccination.<br>Duration of immunity: 28 days. |

# 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 | Full application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Part 1) as amended. |
| Date of conclusion of the procedure | 21/01/2025 |

## SCIENTIFIC OVERVIEW

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

In light of the overall data submitted and the scientific discussion within the VMD, a negative opinion for Primun Gumboro W2512 Lyophilisate for Use in Drinking Water was adopted. The overall benefit/risk analysis was not in favour of granting a marketing authorisation.

### PROPOSED INDICATION

For the active immunisation of broiler chickens with maternally derived antibodies (MDA) to reduce mortality, clinical disease and acute lesions in the bursa of Fabricius associated with infection caused by very virulent strains of infectious bursal disease viruses.

### METHOD OF ACTION

When the vaccine is administered, the immune system of the vaccinated animals recognises these antigens as foreign invaders and responds by producing antibodies and/or by priming cell mediated immunity.

### REASONS FOR REFUSAL

The minimum potency proposed for the vaccine has not been addressed adequately and therefore the application is not approvable and it is the intent to refuse the application.

### Chemical, Pharmaceutical & Biological Documentation

A decline in titre of up to 1.0 $\log_{10}$ $EID_{50}$/dose is noted during storage, therefore the release titre should be increased to accommodate this loss. However, it does not seem possible to increase the minimum titre specification at release to that supported by the safety and efficacy data provided. Overall, there is an outstanding issue regarding the proposed specification in the finished product test for virus titre (potency test), as major concerns regarding demonstration of efficacy (duration of immunity and lack of interference of MDA) at the minimum potency proposed for the vaccine have not been addressed therefore the application is not approvable.

### Safety & Residues Documentation

The safety (target and non-target animals, user, consumer and the environment) of Primun Gumboro W2512 can be considered adequately demonstrated.

### Pre-Clinical & Clinical Documentation

The duration of immunity and interference of MDA has not been demonstrated at the proposed minimum titre ($10^{1.5}$ $EID_{50}$/bird) and it does not seem possible to increase the minimum titre specification at release to that supported by the stability, safety and efficacy data provided. In the absence of duration of immunity and MDA studies conducted with the vaccine at the proposed minimum titre, the application is not approvable.

## OVERALL CONCLUSION AND BENEFIT–RISK ASSESSMENT

Whilst the concerns might have been resolvable, it was considered that it was not appropriate for the applicant to address these significant deficiencies within the timeframe of the application process. 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:

- There are outstanding issues/major concerns remaining in Parts 2 and 4 of the dossier. The efficacy of Primun Gumboro W2512 cannot be considered adequately demonstrated at the proposed minimum titre. There is a consequential outstanding issue in Part 2 regarding the proposed specification in the finished product test for virus titre (potency test).

# MODULE 4

## POST- AUTHORISATION ASSESSMENTS

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