5 October 2023
EMA/460807/2023
Veterinary Medicines Division

Committee for Veterinary Medicinal Products (CVMP)

CVMP assessment report for a variation requiring assessment for Porcilis PCV ID (EMEA/V/C/003942/VRA/0008)

Vaccine common name: Porcine circovirus vaccine (inactivated)

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

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1. Introduction

1.1. Submission of the variation application

In accordance with Article 62 of Regulation (EU) 2019/6, the marketing authorisation holder, Intervet International B.V. (the applicant), submitted to the European Medicines Agency (the Agency) on 21 July 2023 an application for a variation requiring assessment for Porcilis PCV ID.

1.2. Scope of the variation

Variation(s) requested	
G.I.7.a	G.I.7.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one

To extend the duration of immunity from 23 weeks to 26 weeks.

1.3. Changes to the dossier held by the European Medicines Agency

This application relates to the following sections of the current dossier held by the Agency:

Part 1 and Part 4

1.4. Scientific advice

Not applicable.

1.5. Limited market status

Not applicable.

2. Scientific Overview

Porcilis PCV ID is intended for active immunisation of pigs from 3 weeks of age, to reduce viraemia, virus load in lungs and lymphoid tissues and virus shedding caused by PCV2 infection, and to reduce loss of daily weight gain and mortality associated with PCV2 infection. The current onset of immunity is 2 weeks and the duration of immunity 23 weeks. With this variation, the applicant aims to extend the approved duration of immunity to 26 weeks.

A laboratory study was performed to assess the efficacy of Porcilis PCV ID against challenge with PCV2 at 26 weeks. In this study, groups of 3 weeks old pigs were vaccinated with a 4-way combination of Porcilis PCV ID, Porcilis Lawsonia ID, Porcilis M Hyo ID ONCE and Porcilis PRRS. The study was previously included in a dossier for a variation to include this associated use for Porcilis PCV ID (EMEA/V/C/WS2294/0007), which was approved. Challenge with a wild-type PCV2b challenge virus, strain I-12/11, applied intranasally was performed at 26 weeks post vaccination. Serum samples and faecal swabs were collected and tested for

presence of PCV2 nucleic acid and antibody against PCV2. Three weeks post challenge, all animals were necropsied and samples of lymph nodes, tonsil and lung were tested for presence of PCV2 nucleic acid.

These results support reduction of viraemia, virus load in lungs and lymphoid tissues and virus shedding caused by PCV2 infection. The study was appropriately designed and conducted to an acceptable standard. The vaccine used was of standard potency, which is acceptable for this vaccine since it is blended at a standard dose. Use of the four-way combination of vaccines in this study is considered to represent a worst-case scenario and the data can be used to support the duration of immunity for Porcilis PCV ID.

In the original dossier, data on performance parameters were generated in three field studies, fully supporting the claim for reduction of loss of daily weight gain and mortality due to PCV2 infection. In these studies, pigs were slaughtered between 23 and 24 weeks post vaccination. Since the laboratory study provided for this variation gives no indication of a reduction in efficacy at 26 weeks post vaccination, it can be accepted that the data previously generated on performance parameters in the field are acceptable for the proposed 26 weeks duration of immunity.

In conclusion, the efficacy claims are considered to be supported for a 26 weeks duration of immunity.

3. Benefit-risk assessment of the proposed change

Porcilis PCV ID is an emulsion for intradermal injection for the active immunisation of pigs from 3 weeks of age and, before this procedure, re-vaccination at 23 weeks interval was recommended. It reduces viraemia, virus load in lungs and lymphoid tissues and virus shedding caused by PCV2 infection. It also reduces loss of daily weight gain and mortality associated with PCV2 infection. Safety and efficacy of Porcilis PCV ID have been demonstrated using the device IDAL. The withdrawal period is zero days.

The proposed variation is to extend the duration of immunity and interval for re-vaccination from 23 weeks to 26 weeks.

3.1. Benefit assessment

Direct therapeutic benefit

A well-designed laboratory study demonstrated that the product is efficacious up to 26 weeks post vaccination.

Additional benefits

The variation increases the established duration of immunity.

3.2. Risk assessment

Quality:

Quality remains unaffected by this variation.

Safety:

Safety for the user, consumer, environment and target animal remains unaffected by this variation.

3.3. Risk management or mitigation measures

Risk management or mitigation measures remain unaffected by this variation.

3.4. Evaluation of the benefit-risk balance

No change to the impact of the product is envisaged on the following aspects: quality, safety, user safety, environmental safety, consumer safety and target animal safety.

The product has been shown to be efficacious for up to 26 weeks post vaccination.

Based on the data presented, the overall benefit-risk is deemed positive.

4. Conclusion

Based on the original data presented on efficacy the Committee for Veterinary Medicinal Products (CVMP) concluded that the application for variation to the terms of the marketing authorisation for Porcilis PCV ID can be approved, since the data satisfy the requirements as set out in the legislation (Regulation (EU) 2019/6), as follows:

The product has been shown to be efficacious for up to 26 weeks post vaccination.

The CVMP considers that the benefit-risk balance remains positive and, therefore, recommends the approval of the variation to the terms of the marketing authorisation for the above-mentioned medicinal product.

Changes are required in the following Annexes to the Union marketing authorisation:

I and IIIB

Please refer to the separate product information showing the tracked changes.

As a consequence of this variation, sections 3.2, 3.8 and 3.9 of the SPC are updated. The corresponding sections of the Package Leaflet are updated accordingly.