PUBLIC ASSESSMENT REPORT

REPORT

Date: 24-01-2025

Procedure type: Assessment upon request of the Dutch Ministery of Agriculture (LVVN) concerning advice for allowance for use of (not yet authorized) Hepizovac (EHDV vaccine) in the Netherlands (Article 110, sub 2, of regulation EU/2019/6)

Product

Product name:	Hepizovac
Pharmaceutical form:	Suspension for injection
Type of product:	vaccine
Target species:	cattle
Marketing authorization number:	not applicable (not authorized)
Applicant and manufacturer:	CZ Vaccines S.A.U., Spain

Composition

Inactivated Epizootic Haemorrhagic Disease Virus (EHDV), serotype 8
Adjuvants: aluminium hydroxide, saponine

Assessment Bureau Diergeneesmiddelen (BD), agentschap College ter beoordeling van Geneesmiddelen (aCBG)

Introduction

EHDV serotype 8 is circulating in Europe since 2022. It is currently found in a number of member states (ES, PT, IT, FR) and is spreading northward. This serotype affects around 10-15% of cattle in an outbreak and mortality is estimated at 1%. There is no specific treatment available and vaccination is expected to be in important tool, mostly to limit or prevent clinical signs in cattle and deer.

Hepizovac is an inactivated monovalent Epizootic Haemorrhagic Disease virus (EHDV) vaccine for the active immunization of cattle against EHDV serotype 8. The active substance is the inactivated EHDV serotype 8. The vaccine contains aluminum hydroxide and saponin as adjuvants, thiomersal as preservative. The vaccine is offered as a suspension for injection to be administered by subcutaneous administration in cattle.

Benefit-risk evaluation:

Although a number of minor risks have been identified with respect to the quality of the vaccine, these are a consequence of the absence of data which can be accepted as these are considered minor. It should be taken into account that the vaccine is a standard adjuvanted and inactivated vaccine, manufactured under GMP and as such poses little to no risk to user, consumer and the target animal.

In target animals adverse events were observed, these were mainly local effects, that occurred very frequently, but no systemic adverse effects were observed. The observed effects are comparable in severity and frequency to those observed for the (similar) Bluevac BTV vaccines.

The efficacy of the vaccine is supported by an effect on viraemia and pyrexia. No effects on clinical signs could be observed, however this was likely due to the very mild effects observed in the non-vaccinated control group. The vaccinated animals showed a strongly reduced viraemia (undetectable) and pyrexia (no increase in mean rectal temperature) compared to controls. This is considered indicative of a reduction in disease symptoms. The prevention of viraemia may have an effect on transmission of virus to the vector, however it should be taken into account that other wild and non-vaccinated ruminants will have effects on the epidemiology of the disease.

In conclusion, the benefit-risk balance of the product is considered positive.