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College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Distemink Vet, lyophilisate and solvent for suspension for injection for minks

Created: December 2019

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0238/001/DC
Name, strength and pharmaceutical form	Distemink Vet, lyophilisate and solvent for suspension for injection for minks
Applicant	United Vaccines Holding B.V. Molenweg 7 6612 AE, Nederasselt The Netherlands
Active substance(s)	Live attenuated canine distemper virus.
ATC Vetcode	QI20CD01
Target species	Minks
Indication for use	For the active immunization of minks from an age of 10 weeks to prevent mortality and clinical symptoms caused by canine distemper virus.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Similar biological application in accordance with Article 13 (4) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	28 February 2018
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	DK, EL, ES, FI, IT, LT, LV, NO, PL, RO, SE

I. SCIENTIFIC OVERVIEW

Distemink is a similar biological application according to Article 13(4). The reference product is Distemink, lyofilisaat en suspendeervloeistof voor suspensie voor injectie voor nertsen, first authorised in the Netherlands on 15 December 1994 (REG NL 4902) by Coöperatieve Federatie van Edelpelsdierenhouders (CFE). The product concerned by the present application is identical to the reference biological veterinary product as the raw materials used for the production, the manufacturers and the manufacturing processes are the same.

II. QUALITY ASPECTS

A. Composition

The product contains live, attenuated canine distemper virus, Lederle strain at $10^{3.0}$ to $10^{4.8}$ EID_{50} (50% Egg infective dose). Excipients are casein hydrolysate, gelatin and D-sorbitol. The solvent consists of water for injections.

The container consists of a Type I glass vial closed with a rubber stopper and an aluminium cap. The solvent is packed in high density polyethylene vials closed with a rubber stopper and sealed with an aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain and the choice of the composition is justified.
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is live, attenuated canine distemper virus, an established substance described in the European Veterinary Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

Starting materials of non-biological origin used in production comply with the European Pharmacopoeial (Ph. Eur.) monographs where these exist. For the substances where there is no such requirement the company has identified the source of the substance, explained how its quality is controlled and provided relevant certificates of analysis.

Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines and are appropriately screened for the absence of extraneous agents according to the Ph. Eur. Guidelines; any deviation was adequately justified.

The master and working seeds have been produced according to the Seed Lot System as described in the relevant guideline.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

E. Control on intermediate product

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

F. Control Tests on the Finished Product

The tests performed on the final product conform to the relevant requirements; any deviation from these requirements is justified. The tests include in particular

appearance, virus identity, virus titer, sterility, absence of mycoplasma and absence of extraneous agents.

The demonstration of the batch to batch consistency is based on the results of 3 batches produced according to the method described in the dossier.

G. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

None.

III. SAFETY ASSESSMENT

As this is an auto-generic application submitted according to Article 13(4) – similar biological application. The biological veterinary medicinal product is identical to the reference product. Results of safety tests are not required, except an Environmental Risk Assessment.

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment was required.
Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is an auto-generic application submitted according to Article 13(4) – similar biological application. The biological veterinary medicinal product is identical to the reference product and efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Veterinary Medicines Agencies website (www.HMA.eu).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Summary of change (Application number)	**Section updated in Module 3**	**Approval date**
Change in manufacturer (starting material/active substance) and replacement of secondary packaging site and site where any manufacturing operations take place (except batch release, batch control and secondary packaging) (NL/V/0238/II/001/G)	N/A	5 July 2018
Change of the invented name of the product in DK and FI (NL/V/0238/001/IB/002)	N/A	28 August 2018