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College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

**Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands**

DECENTRALISED PROCEDURE

**PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY
MEDICINAL PRODUCT**

BIOCOM P Vet, suspension for injection for mink

Created: December 2019

BIOCOM P Vet	NL/V/0227/001/DC
United Vaccines Holding B.V.	DCP
	Publicly available assessment report

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0227/001/DC
Name, strength and pharmaceutical form	BIOCOM P Vet, suspension for injection for mink
Applicant	United Vaccines Holding B.V. Molenweg 7 6612 AE Nederasselt The Netherlands
Active substance(s)	Inactivated Mink Enteritis Virus types 1 and 2 <i>Clostridium botulinum</i> type C toxoid Inactivated <i>Pseudomonas aeruginosa</i> serotypes 5, 6, and 7-8
ATC Vetcode	QI20CL01
Target species	Mink
Indication for use	For the active immunization of mink from an age of 6 weeks to reduce mortality and clinical symptoms caused by Mink Enteritis Virus Types 1 and 2, <i>Clostridium botulinum</i> Type C toxin, and <i>Pseudomonas aeruginosa</i> Serotypes 5, 6, and 7-8 (in accordance with the International Antigenic Typing Scheme (IATS)).

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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>).

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MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	20 September 2017
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	DK, EL, ES, IT, LT, LV, NO, PL, RO, SE

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.

The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the product was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

Biocom P Vet is a generic product. The reference product is BIOCOM-P, suspensie voor injectie voor nertsen, first authorized in the Netherlands on 27 June 2000 (REG NL 6385) by Coöperatieve Federatie van Edelpelsdierenhouders (CFE). The initial application for BIOCOM-P, suspensie voor injectie voor nertsen was assessed before there was a requirement to have a public assessment report; therefore no details in this section are available.

II. QUALITY ASPECTS

A. *Qualitative and quantitative particulars*

The product contains: *C. botulinum* Type C Bacterin-Toxoid, Mink Enteritis Virus Type 1, Mink Enteritis Virus Type 2, *P. aeruginosa* Serotype 5 Strain PA7G-485 and Strain PA7M-485-347, *P. aeruginosa* Serotype 7-8 Strain PA6M-485-JB and Strain PA6M-485-JA and Strain PA6G-485, *P. aeruginosa* Serotype 6 Strain PA5M-485-P and Strain PA5G-485. The adjuvant is Aluminum hydroxide hydrated for adsorption and the excipients are antifoam 1%, 1M citrate buffer, thimerosal (thiomersal) and water for injections.

The container/closure system consists of 625, 250 and 120 ml HDPE vials. The vials are composed of Olefin polymer as defined in 21 CFR 177.1520 and Ph.Eur. 3.1.5. Vials are closed with Ph.Eur. 3.2.9 type I bromobutyl rubber stoppers. Vials are sterilized by gamma irradiation, stoppers are sterilized with steam sterilization using validated equipment. The vials are sealed with an aluminum cap, which is sterilized by steam sterilization.

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The choice of the pathogens, adjuvant and thiomersal as a preservative are justified.

The inactivation process and the detection limit of the control of inactivation are correctly validated.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at 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

Starting materials of non-biological origin used in production comply with Ph. Eur. 1664, Ph. Eur. 0456, Ph. Eur. 0826, Ph. Eur. 0177, Ph. Eur. 0496, Ph. Eur. 0193, Ph. Eur. 0412, Ph. Eur. 1625, Ph. Eur. 0169.

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. 2262 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. Control tests during production

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

E. 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.

Batch to batch consistency is demonstrated. Other supportive data provided confirm the consistency of the production process.

F. Stability

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.

No in-use stability data are submitted, as the product is to be used immediately after broaching the container.

G. Other Information

None.

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III. SAFETY ASSESSMENT

The application is made in accordance with Article 13.1 of the Directive 2001/82/EC, as amended. The generic product is identical to the reference product (auto-generic application). The raw materials used, the manufacturers and the manufacturing processes are the same.

The safety aspects of this product are identical to the reference product.

Warning statements and precautions as listed in the product literature are based on those of the reference product and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users, consumers and the environment.

Environmental Risk Assessment

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required. The assessment concluded that the overall risk to the environment is estimated to be effectively zero, there is no necessity to conduct a phase II assessment. No warnings regarding risks to the environment are therefore required.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, 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.

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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 name of veterinary medicinal product in DK (NL/V/0227/001/IB/001)	N/A	1 March 2018
Addition of a manufacturing site for antigen production, formulation, primary packaging and secondary packaging (NL/V/0227/II/002/G)		14 November 2018