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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Prid delta 1.55 g vaginal delivery system for cattle

DATE: 2019.03.22.

MODULE1

PRODUCTSUMMARY

EU Procedure number	FR/V/0215/001/DC
Name, strength and pharmaceutical form	Prid delta 1.55 g vaginal delivery system for cattle
Applicant	CEVA SANTE ANIMALE 10 AVENUE DE LA BALLASTIERE 33500 LIBOURNE FRANCE
Active substance(s)	Progesterone
ATC Vetcode	QG03DA04
Target species	Cattle: cows and heifers.
Indication for use	For the control of the œstrus cycle in cows and heifers including: - Synchronisation of œstrus in cycling cattle. To be used in combination with a prostaglandin (PGF2α). - Induction and synchronisation of œstrus in non cycling cattle. To be used in combination with a prostaglandin and equine chorionic gonadotrophin (eCG, in the past called PMSG).

MODULE2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13.2 of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	2010.06.02.
Concerned Member States for original procedure	AT, BE, BG, CY, CZ, DE, EL, ES, FI, HU, IE, IS, IT, LU, NL, PL, PT, RO, SK, UK

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, the consumer of foodstuffs from treated animals 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.

II. QUALITY ASPECTS

A. Composition

The product contains 1.55 g progesterone per device and ethylvinylacetate and polyamide.
The packaging of the finished product is as described on the SPC. The particulars of the containers and controls performed are provided and conform to the regulation.
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 licensed manufacturing sites.
Process validation data on the product have been presented in accordance with the relevant European guidelines.

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C. Control of Starting Materials

The active substance is progesterone, an established active substance described in the European Veterinary Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice. The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

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

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control on intermediate products

Not applicable.

F. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.
Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production sites have been provided demonstrating compliance with the specification.

G. Stability

A re-test period for the active substance is set in the certificate of suitability issued by EDQM.

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. An in-use shelf-life as detailed on the SPC has been supported by appropriate data.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

III.A Safety Testing

Pharmacological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of pharmacological tests are not required.

Toxicological Studies

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of toxicological tests are not required.

User Safety

The applicant has proposed the same risk management measures as those given for the reference product.
Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.
The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the active substance is a naturally occuring substance, and the use of the product will not alter the concentration or distribution of the substance in the environment.
In addition, PECsoils for intensively reared and pasture animals are below 100 µg/kg.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because of the type of application (generic application), and because od the route of administration (intravaginal route).

Withdrawal Periods

Withdrawal periods of zero days for meat & offal and zero hours for milk in bovine species are justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

IV.A Pre-Clinical Studies

Pharmacology

The applicant has conducted a bioequivalence study between the candidate product and the reference product. Bioequivalence with the reference product has been demonstrated.

Tolerance in the Target Species of Animals

A GLP local tolerance study was provided.
The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

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.