Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

PGF Veyx forte
0.250 mg/ml Solution for Injection

Date: 25 June 2012

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0146/002/DC
Name, strength and pharmaceutical form	PGF Veyx forte **0.250 mg/ml Solution for Injection**0.250mg/ml, Solution for Injection
Applicant	Veyx-Pharma GmbH Söhreweg 6 D-34639 Schwarzenborn Germany
Active substance(s)	Cloprostenol Sodium
ATC Vetcode	QG02AD90
Target species	Cattle, Pig
Indication for use	Cattle (heifers, cows): To schedule the time of oestrous and ovulation and for cycle synchronization in animals with an ovulatory cycle when applied during the diestrus (induction of oestrus in non-detected oestrus, synchronisation of oestrus); anoestrus and uterine disorders caused by a progesterone-induced oestrous cycle blockade (induction of oestrous in anoestrus, endometritis, pyometra, corpus luteal cysts, follicular luteal cysts, shortening of the sexual rest period) Induction of abortion up to day 150 of pregnancy; mummified foetuses; induction of parturition Pigs (sows): Induction or synchronisation of farrowing from day 114 of pregnancy onwards (day 1 of

	pregnancy is the last day of insemination)

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13(3) of Directive 2001/82/EC as amended.
Date of completion of the original Mutual recognition procedure Decentralised procedure	26 March 2012
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	AT, BE, BG, CZ, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, 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 overall risk/benefit analysis is in favour of granting a marketing authorisation.

The safety and efficacy aspects of this product are identical to the reference product. The initial application for the reference product 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. Composition

The product contains 0.250 mg Cloprostenol (corresponding to 0.263 mg Cloprostenol sodium) per ml and the excipients Chlorocresol, Citric acid monohydrate, Trisodium citrate dihydrate, Sodium chloride, Sodium hydroxide 20 %, and Water for injections.

The container/closure system comprises colourless glass vials of 10 ml, 20 ml and 50 ml with bromobutyl rubber stoppers and aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the presence of the preservative are 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 Cloprostenol sodium, an established substance described in the British 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.

Information on the active substance been submitted in form of an Active Substance Master File (ASMF).

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 (pharmaceuticals)

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 site have been provided demonstrating compliance with the specification.

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.

The claim of 28 days stability after broaching is based on the demonstration of stability for a batch broached and stored 28 days at 25°C.

H. Genetically Modified Organisms

Not applicable.

J. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

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

The pharmacological and toxicological aspects of this product are identical to the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users / the environment / consumers.

User Safety

The applicant has provided a user safety assessment. The potential hazard of the product will not be any greater for the user than that posed by the reference product. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline. All PECsoil remain below the trigger value of 100 µg/kg. However, because of the endocrine properties of the active ingredient, a phase II environmental fate and effect analysis has been provided which was based on literature and exposure calculations. From the results it was concluded that further experimental assessment of fate and effects for cloprostenol is not necessary. The product is not expected to pose a risk to the environment when used according to the SPC.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted as bioequivalence of the product and the reference product was confirmed on the basis of their similar formulations and identical dose regimes.

MRLs

Cloprostenol
Cloprostenol is listed in Table 1 of Commission Regulation (EU) No 37/2010 for pigs and cattle. In accordance with Council Regulation (EC) No 470/2009 no MRL is required.

Pharmacologically active substance(s)	Animal species	Other provisions
Cloprostenol	Bovine, porcine, equidae	

Chlorocresol
Maximum residues limits (MRL) for chlorocresol are published in Table 1 of Commission Regulation (EU) No 37/2010. In accordance with Council Regulation (EC) No 470/2009 no MRL is required.

Pharmacologically active substance(s)	Animal species	Other provisions
Chlorocresol	All food-producing species	

Withdrawal Periods

Based on the data provided above, the following withdrawal periods are justified:

Cattle:	Meat and offal	2 days
	Milk:	Zero days
Pigs:	Meat and offal	2 days

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.

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 Medicinal 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.

<None>