College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A HOMEOPATHIC VETERINARY MEDICINAL PRODUCT

Mamil Phyt Plus

Created: February 2020

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Mamyl Phyt Plus, Intramammary gel for cattle
Applicant	Feed Farm B.V. Bommelsekade 7 5301 KL Zaltbommel
Active substance(s)	Phytolacca 30 CH 100 mg Bryonia 30 CH 100 mg Conium 30 CH 100 mg Lachesis 30 CH 100 mg Belladonna 30 CH 100 mg
Target species	Cattle
Indication for use	Homoeopathic remedy for veterinary use without approved therapeutic indications used according to the principles of homoeopathic medicine.

MODULE 2

The Summary of Product Characteristics for this homeopathic product is available on the Diergeneesmiddeleninformatiebank.

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 17(1) of Directive 2001/82/EC as amended. Based on article 17(1) of Directive 2001/82/EC Homeopathic veterinary medicinal products shall be authorised in accordance with Articles 12, 13a, 13b, 13c, 13d and 14.
Date of authorisation	6 October 2020

I. SCIENTIFIC OVERVIEW

The applicant has submitted data which demonstrate that the product can be safely used in cattle. In addition the applicant has demonstrated that 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 Summary of Product Characteristics.

As an application was made as 'Homoeopathic remedy for veterinary use without approved therapeutic indications used according to the principles of homoeopathic medicine.' assessment of the efficacy was not part of the assessment procedure. Therefore no indication is mentioned in the Summary of Product Characteristics.

In conclusion the data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the quality and safety of the product for cattle, humans and the environment is acceptable.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

10 g of this homoeopathic medicinal product contain 100 mg of each of the active substances Phytolacca 30CH, Bryonia 30CH, Conium 30CH, Lachesis 30CH and Belladonna 30CH. Excipients are purified water, methyl-para-hydroxybenzoate, sodium edetate, sodium hydroxide, carbomer and propylene glycol.

The container/closure system is a 12 ml intramammary injector consisting of low density poly ethylene (LDPE) with a white LDPE dual end cap. The injectors are packed in a carton box containing 4, 8 or 48 intramammary injectors.

The presence of preservative 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 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

The active substances are Phytolacca 30CH, Bryonia 30CH, Conium 30CH, Lachesis 30CH and Belladonna 30CH. The respective raw materials Phytolacca decandra, Bryonia, Conium maculatum, Lachesis mutus and Belladonna are established homoeopathic substances described in the European Pharmacopoeia (Ph. Eur.) or the French Pharmacopoeia (Ph. Fr.).
The active substances are manufactured in accordance with the principles of good manufacturing practice.

The active substances specifications are considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

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

D. Control on intermediate products (pharmaceuticals)

Not applicable.

E. 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.

F. Stability

Stability data on most of the active substances have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions. Where stability data are lacking, the active substance is fully tested to ensure compliance with its specification immediately prior to its use in manufacture of the product.

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.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT

User Safety

Information has been provided which made plausible that the 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 substances are highly diluted natural substances, the use of the highly diluted substances will not alter the concentration or distribution of the substance in the environment.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because all ingredients are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

MRLs

Active substances:

Phytolacca 30CH

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Bryonia 30CH

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Conium 30CH

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Lachesis 30 CH

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Belladonna 30CH

Substances used in homeopathic veterinary medicines, provided that their concentration in the product does not exceed one part per 10000 are included in Table 1 of Regulation (EC) 37/2010 as allowed substance for which no MRL is required for all food producing species.

Withdrawal Periods

Since there are no MRLs required for the active substances or excipients of Mamil Phyt Plus, a withdrawal period of zero days for Mamil Phyt Plus is justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As an application was made as 'Homoeopathic remedy for veterinary use without approved therapeutic indications used according to the principles of homoeopathic medicine.' assessment of the efficacy was not part of the assessment procedure. Therefore no indication is mentioned in the Summary of Product Characteristics.

IV.A Pre-Clinical Studies

Tolerance in the Target Species of Animals

Information has been provided which made plausible that the tolerance in cattle is acceptable.

IV.B Clinical Studies

No clinical studies have been conducted.

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 quality and safety of the product for the target species, humans and the environment is acceptable.