Paul-Ehrlich-Institut

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Suvaxyn MH-One (all countries, except for France and Denmark)
Emulsion for injection for pigs

Suvaxyn M.Hyo Mono (France and Denmark)
Emulsion for injection for pigs

PRODUCT SUMMARY

EU Procedure number	DE/V/0248/001/MR
Name, strength and pharmaceutical form	Suvaxyn MH-One (all countries, except for France and Denmark) Emulsion for injection for pigs Suvaxyn M.Hyo Mono (France and Denmark) Emulsion for injection for pigs
Applicant	Fort Dodge Animal Health
Active substance(s)	Inactivated *Mycoplasma hyopneumoniae*, strain P-5722-3
ATC Vet code	Q109AB13
Target species	Pigs of a minimum age of 21 days
Indication for use	For active immunisation of pigs of a minimum age of 21 days to reduce lung lesions that are caused by *Mycoplasma hyopneumoniae*. Onset of immunity: 4 weeks following vaccination. Duration of immunity: 6 months.

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	MRP application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition	02. July 2008
Date product first authorised in the Reference Member State (MRP only)	01. April 2005
Concerned Member States for original procedure	AT, BE, BG, CZ, DK, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK

I. SCIENTIFIC OVERVIEW

For public assessment reports for the first authorisation in a range:

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 inactivated *Mycoplasma hyopneumoniae* (RP ≥ 1.00, undiluted) and Carbopol/ MetaStim (adjuvants).

The container/closure system consists of HDPE bottles or LDPE flexible plastic bag closured with Butyl rubber stoppers and aluminium caps.

The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the adjuvants (Carbopol and MetaStim), vaccine strain (P-5722-3), formulation (emulsion), inactivating agent (BEI), presence of preservative (Thiomersal) are justified.

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

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 majority of starting materials used in production comply with pharmacopoeia monographs.

Biological starting materials used are in compliance with the current regulatory texts related to the TSE Note for Guidance (EMEA/410/01-Rev.2) and Commission Directive 2001/82/EEC.

Information to the vaccine strain, their origin, characterisation, passage history, preparation and storage conditions has been provided. The master and working seeds have been produced according to the Seed Lot System.

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

Scientific data 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 tests during production)

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, pH, Viscosity, Volume, Potency, Amount of Carbopol and SP oil, Content of thiomersal, Safety, Sterility and Inactivation.

The demonstration of the batch to batch consistency is based on the results of three batches produced according to the method described in the dossier. Other supportive data provided confirm the consistency of the production process.

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 in-use shelf-life of the broached vaccine is restricted (use immediately).

H. Genetically Modified Organisms

Not applicable.

III. SAFETY ASSESSMENT

Suvaxyn MH-One is an inactivated vaccine intended for the active immunisation of pigs from 21 days of age onwards to reduce lung lesions that are caused by *Mycoplasma hyopneumoniae*. The vaccine is recommended for a one-time intramuscular immunisation.

Batches used in the safety trials were produced according to the manufacturing process described in Part II of the dossier. In laboratory safety tests one vaccine batch with the maximum allowed antigen content has been used.

Laboratory trials

The safety of the administration of one dose, an overdose and the repeated administration of one dose in the target animal is demonstrated in a GLP conform study using serological negative piglets. The majority of pigs in each group were 3 weeks which is the minimum age recommended for vaccination. The investigation was performed according to the recommendations of Directive 2001/82/EC as amended and the relevant guidelines. The reactions observed were limited in severity and duration and are adequately reflected in the relevant SPC sections.

No investigation of effect on reproductive performance was conducted because the vaccine is not intended for this category of animals.

There are no data suggesting that this product might adversely affect the immune system of the vaccinated animal. Since generally no adverse effects of inactivated vaccines on the immune system neither known nor expected, a specific study was not carried out.

The vaccine is inactivated and thus the specific tests to be performed for live vaccines are not applicable.

There is no residue risk with this vaccine and therefore, no withdrawal period is proposed.

No specific assessment of the interaction of this product with other medicinal product was made. Therefore, an appropriate warning in the SPC is included.

Field studies

Field studies are carried out in Spain and France in conformity with GCP. The vaccine is well tolerated, inducing no local reaction that would lead to condemnations and no growth retardation. The general reactions observed are adequately reported in the SPC. With respect to the mortality rate no statistical significant difference between vaccinated and non-vaccinated pigs has been determined.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is 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)

Clinical Studies

Laboratory Trials

For the three laboratory trials on efficacy a vaccine batch with minimal antigen content was used.

The efficacy of the product has been demonstrated in laboratory studies in accordance with the relevant requirements, i.e:

- in seronegative piglets and piglets with maternally derived antibodies (MDA) vaccinated at the minimum age recommended and according to the recommended schedule
- by challenge of target animals using a strain different from the one used in the production of the vaccine
- inclusion of control groups (non-vaccinated challenge controls and non-vaccinated, non-challenged controls).

Statistical analysis was performed for the parameter of lung lesions.

A statistical significant reduction in average lung lesion score was observed in all trials. The results demonstrated that a reliable immunity has been developed after 4 weeks and lasts for 6 months. Maternal antibodies do not impair the onset of immunity.

Field Trials

The results from laboratory trials were supplemented with data from two field trials.
The double-blinded studies were conducted on 4 fattening pig farms and on 3 farrow-to-finish piggeries identified as suffering from chronic enzootic pneumonia caused by *Mycoplasma hyopneumoniae*, through serological analysis and/or lesion observation at slaughter. The study periods were 6.5 -7 and 8 months, respectively.

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 benefit-risk 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 PROCEDURES

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/labelling/package leaflet is/are available in the Union Product Database (UPD).

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

Sequence of significant variations

Summary of change (Application number)	Approval date
Transfer Marketing Authorisation Holder (DE) from Fort Dodge GmbH to Pfizer GmbH	09.07.2010
Change in shape or dimensions of the container or closure (immediate packaging) - EMEA/V/C/xxxx/WS/0230	14.06.2012
Reduction of Onset of Immunity from 4 to 2 weeks when the vaccine is administered to 3 weeks-old pigs - DE/V/0248/001/II/004	27.07.2012
Reduction of the minimum age from 21 to 7 days of age; reduction of Onset of Immunity from 4 to 2 weeks when the vaccine is administered to 1 weeks-old pigs, tightening of the specification limits for the antigen content per dose - DE/V/0248/001/II/007/G	07.11.2012
Removal of target animal safety test (TABST)	18.01.2013
Transfer Marketing Authorisation Holder (DE) from Pfizer GmbH to Zoetis Deutschland GmbH	15.10.2013
Change of the in-vitro potency test and deletion of 50 doses presentation (LDPE sachets) - DE/V/0248/001/II/010/G	29.05.2014
Extension of final product shelf life and increase of minimum release specification for the in-vitro potency test - DE/V/0248/001/IB/011/G	16.10.2014
Removal of the in-vivo potency test - DE/V/0248/001/IB/013	16.01.2015
Change the site for sterility testing (IPC) - DE/V/0248/001/IB/014	22.01.2015
Change the site for testing of starting materials of biological origin - EMEA/V/C/xxxxxx/WS/0649/G	10.04.2015

Extension of the shelf-life of the finished product (2 years) - DE/V/0248/001/IB/017	12.06.2015
Update quality part - DE/V/0248/001/II/019/G	02.02.2017
Withdrawal from CMS (EE)	24.03.2017
CMS (Repeat-Use): CY, HR, SE - DE/V/0248/001/E/001	04.07.2018
QRD update - DE/V/0248/001/A/028	14.12.2023
Withdrawal from CMS (LT and LV)	27.01.2025
Withdrawal from CMS (DK and SE)	04.02.2025