ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M Hyo Suspension for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose contains:

Active substance:

Mycoplasma hyopneumoniae, strain P-5722-3, inactivated RP* ≥ 1

* Relative Potency unit determined by ELISA antigen quantification (*in vitro* potency test) of undiluted serials compared to a reference vaccine.

Adjuvant:

Carbopol 941 4 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	50-115 ppm
EDTA	
Amaranth	
Sodium chloride	
Sodium phosphate dibasic heptahydrate	
Water for injections	

Pinkish aqueous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Pigs for fattening.

3.2 Indications for use for each target species

Active immunisation against *Mycoplasma hyopneumoniae* infection in pigs to reduce the frequency and severity of lung lesions.

Onset and duration of immunity: not established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid stress in the animals around the time of vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling[1]

[1]Transient, of 2 cm in diameter, spontaneously resolving within a few days.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Not applicable.

Fertility:

Not applicable.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

Intramuscular use.

A dose of 2 ml must be administered intramuscularly in the neck behind the ear twice with an interval of 2 weeks, to pigs from the age of 1 week and before the age of 10 weeks.

Shake vaccine well before administration and intermittently during the process of vaccination.
It is good practice to allow the vaccine to warm to body temperature in the hand or pocket before administration, to avoid the discomfort of injection of a cold liquid.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The administration of an overdose may very commonly result in the same type of reaction as seen after administration of a single dose (see section 3.6).

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

To be completed nationally.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI09AB13

The vaccine stimulates active immunity against *Mycoplasma hyopneumoniae*.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 27 months.

Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze. Protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles containing 100 ml (50 doses) or 250 ml (125 doses) of vaccine closed with chlorobutyl rubber stoppers and sealed with aluminium caps.

Pack sizes:
Carton box containing 1 bottle of 50 or 125 doses.
Carton box containing 10 bottles of 50 or 125 doses.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}><{DD month YYYY}>.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

To be complete nationally.

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON BOX:
1 x 100 ml (50 doses) or 250 ml (125 doses)
10 x 100 ml (50 doses) or 250 ml (125 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M Hyo Suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Mycoplasma hyopneumoniae, strain P-5722-3, inactivated RP ≥ 1

3. PACKAGE SIZE

1 x 100 ml (50 doses)
1 x 250 ml (125 doses)
10 x 100 ml (50 doses)
10 x 250 ml (125 doses)

4. TARGET SPECIES

Pigs for fattening

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml (50 doses) HDPE bottle
250 ml (125 doses) HDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Suvaxyn M Hyo Suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Mycoplasma hyopneumoniae, strain P-5722-3, inactivated RP ≥ 1

3. TARGET SPECIES

Pigs for fattening

4. ROUTES OF ADMINISTRATION

i.m.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Suvaxyn M Hyo Suspension for injection for pigs

2. Composition

Each 2 ml dose contains:

Active substance:

Mycoplasma hyopneumoniae, strain P-5722-3, inactivated	RP* ≥ 1

* Relative Potency unit determined by ELISA antigen quantification (*in vitro* potency test) of undiluted serials compared to a reference vaccine.

Adjuvant:

Carbopol 941	4 mg

Excipient:

Thiomersal	50-115 ppm

Pinkish aqueous suspension.

3. Target species

Pigs for fattening.

4. Indications for use

Active immunisation against *Mycoplasma hyopneumoniae* infection in pigs to reduce the frequency and severity of lung lesions.

Onset and duration of immunity: not established.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate only healthy animals.

Special precautions for safe use in the target species:
Avoid stress in the animals around the time of vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose:
The administration of an overdose may very commonly result in the same type of reaction as seen after administration of a single dose (see section 7 "Adverse events").

Special restrictions for use and special conditions for use:
To be completed nationally.

Major incompatibilities:
Do not mix with any other vaccine or immunological product.

7. Adverse events

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling[1]

[1]Transient, of 2 cm in diameter, spontaneously resolving within a few days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intramuscular use.
A dose of 2 ml must be administered intramuscularly in the neck behind the ear twice with an interval of 2 weeks, to pigs from the age of 1 week and before the age of 10 weeks.

9. Advice on correct administration

Shake vaccine well before administration and intermittently during the process of vaccination.
It is good practice to allow the vaccine to warm to body temperature in the hand or pocket before administration, to avoid the discomfort of injection of a cold liquid.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the vial after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Carton box containing 1 bottle of 50 or 125 doses.
Carton box containing 10 bottles of 50 or 125 doses.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
To be completed nationally.

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

<Local representatives <and contact details to report suspected adverse reactions>:>
To be completed nationally (if needed).

17. Other information

The vaccine stimulates active immunity against *Mycoplasma hyopneumoniae*.