ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine eye drops suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

One dose (30 µl) contains:
Mycoplasma synoviae strain MS-H live attenuated thermosensitive, at least $10^{5.7}$ CCU*

* colour changing units

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye drops, suspension.
Red orange to straw translucent suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For active immunisation of future broiler breeder chickens, future layer breeder chickens and future layer chickens from 5 weeks of age to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by *Mycoplasma synoviae.*

Onset of immunity: 4 weeks after vaccination.
The duration of immunity to reduce air sac lesions has been demonstrated to be 40 weeks post vaccination.
The duration of immunity to reduce the number of eggs with abnormal shell formation has not yet been demonstrated

4.3 Contraindications

None.

See also section 4.7

4.4 Special warnings

Do not use antibiotics with anti-Mycoplasma activity 2 weeks before or 4 weeks after vaccination. Such antibiotics include e.g. tetracycline, tiamulin, tylosin, quinolones, lincospectin, gentamicin or macrolide antibiotics.
Where antibiotics must be used, preference should be given to agents with no anti-mycoplasma activity, such as penicillin, amoxicillin or neomycin. They should not be given within 2 weeks after vaccination.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate all birds in a flock at the same time.
Only flocks with no antibodies to *M. synoviae* should be vaccinated. Vaccination should be carried out on *M. synoviae* -free birds at least 4 weeks before expected exposure to virulent *M. synoviae*. Pullets should first be tested for *M. synoviae* infection. Testing for the presence of *M. synoviae* in the flock is normally by way of the rapid serum agglutination test (RSAT) with blood samples being tested within 24 hours of collection.

The vaccine strain can spread from vaccinated to unvaccinated birds, including wild species. This may occur during the whole life of the vaccinated bird. Special precautions should be taken to avoid spreading of the vaccine strain to other bird species.
The vaccine strain can be detected in respiratory tract of the chickens until 55 weeks after vaccination.

Distinguishing between field strains and the vaccine strain of *M. synoviae* can be performed by Hammond classification or High Resolution Melt (HRM) testing by a laboratory.
Infection with *M. synoviae* induces a transient positive antibody response to *Mycoplasma gallisepticum*. Although no data are available on the matter, it is likely that vaccination with this product will also induce a positive antibody response to *Mycoplasma gallisepticum* and may therefore interfere with the serological monitoring of *Mycoplasma gallisepticum*. If necessary, further differentiation of the 2 Mycoplasma species can be done by using PCR in a laboratory. Samples that can be used for PCR include swabs taken from pathological sites such as trachea, palatine cleft, air sacs or joints.

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

To avoid skin and eye injuries which may occur by manipulating the frozen bottle, personal protective equipment consisting of gloves and safety glasses should be worn.
If vaccine is accidentally splashed into the operator's eyes, the eyes and face should be thoroughly washed with water to avoid any potential reaction to culture medium constituents.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay and within 5 weeks before the onset of the laying period.

4.8 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.

4.9 Amounts to be administered and administration route

Ocular use.

Chickens from 5 weeks of age

One dose of 30 µl to be administered by eye drop.

Thaw the unopened bottle rapidly between 33-35°C for a time period of 10 minutes in a thermostatic water bath. Do not thaw at higher temperatures or for longer time periods. Use at room temperature (22-27°C) within 2 hours after thawing. Mix the contents of the bottle by gentle agitation during thawing. Invert the bottle repeatedly following thawing to ensure the content has been resuspended. Remove the aluminium seal and rubber stopper before using a plastic dropper tip or other administration device. Use calibrated dropper or device, so as to distribute 30 µl drop of vaccine. Avoid introduction of contamination.

Hold the bird with its head tilted to one side. Invert the dropper bottle or prepare the device allowing a single drop to form at the tip and fall freely into the open eye, gently flooding it. The drop (before release) and tip should not touch the eye surface.
Allow the bird to blink before releasing it.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions have been noted following an 8-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Aves, live bacterial vaccines
ATCvet code: QI01AE03

The vaccine induces an active immunity against *Mycoplasma synoviae* in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Modified Frey's medium containing phenol red and swine serum.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf life after thawing and first opening the immediate packaging: 2 hours.

6.4. Special precautions for storage

Store frozen below -70°C for a maximum of 4 years.
After removal from the deep freeze, further short term storage is allowed at or below -18°C for no more than 4 weeks. Vaccine should not be stored back in -70°C after storage at or below -18°C.

Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

Plastic LDPE bottle of 30 ml (1,000 doses) with butyl rubber stopper sealed with an aluminium cap.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Pharmsure Veterinary Products Europe Limited
4 Ormond Quay Upper
Dublin
DO7 PF53
Ireland

8. MARKETING AUTHORISATION NUMBER

EU/2/11/126/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14/06/2011
Date of last renewal: 17/05/2016

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Glenorie Manufacturing Facility
Bioproperties Pty Ltd
11-13 Moores Rd, Glenorie, NSW, 2157
Australia

Name and address of the manufacturer responsible for batch release

Laboratoire LCV
Z.I. du Plessis Beuscher
35220 Chateaubourg
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The components of the excipient listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or are considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

NOTE: There is no outer carton

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LDPE BOTTLE 30 ml LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine eye drops suspension

M. synoviae strain MS-H

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1000 doses

4. ROUTE OF ADMINISTRATION

Ocular use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch{number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
MS-H Vaccine eye drops suspension

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Pharmsure Veterinary Products Europe Limited
4 Ormond Quay Upper
Dublin
DO7 PF53
Ireland

Manufacturer responsible for batch release:

Laboratoire LCV
Z.I. du Plessis Beuscher
35220 Chateaubourg
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine eye drops suspension

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Eye drops, suspension.
Red orange to straw translucent suspension.

One dose (30 µl) contains:

Active substance:
Mycoplasma synoviae strain MS-H live attenuated thermosensitive, at least $10^{5.7}$ CCU*
*colour changing units

Other ingredients:
Modified Frey's medium containing phenol red and swine serum

4. INDICATION(S)

For vaccination of future broiler breeder chickens, future layer breeder chickens and future layer chickens from 5 weeks of age to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by *Mycoplasma synoviae.*

Onset of immunity: 4 weeks after vaccination.
The animal will be immune for 40 weeks after the vaccination.
The duration of immunity to reduce the number of eggs with abnormal shell formation has not yet been demonstrated.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Ocular use.

Chickens should be vaccinated once by applying one eye drop (30 µl) from 5 weeks of age and at least 5 weeks before the onset of the laying period.

9. ADVICE ON CORRECT ADMINISTRATION

Chickens from 5 weeks of age

One dose of 30µl should be administered by eye drop.

- Thaw unopened bottles rapidly between 33-35°C for a time period of 10 minutes in a thermostatic water bath. Do not thaw at higher temperatures or for longer time periods. Use at room temperature (22-27°C) within 2 hours after thawing. Mix the contents of the bottle by gentle agitation during thawing. Invert the bottle repeatedly following thawing to ensure the contents have resuspended.
- Remove the aluminium seal and rubber stopper before using a plastic dropper tip or other administration device. Use calibrated dropper or device, so as to distribute 30 µl drop of vaccine. Avoid introduction of contamination.
- Hold the bird with its head tilted to one side. Invert the dropper bottle or prepare the device allowing a single drop to form at the tip and fall freely into the open eye, gently flooding it. The drop (before release) and tip should NOT touch the eye surface.

Allow the bird to blink before releasing it.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

The MS-H vaccine should always be protected from direct sunlight. Store frozen below -70°C for a maximum of 4 years. After removal from the deep freeze, further short term storage is allowed at or below -18°C for no more than 4 weeks. Vaccine should not be stored back in -70°C after storage at or below -18°C. Once thawed, use within 2 hours.

Do not use after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Do not use in birds in lay and within 5 weeks before the onset of the laying period. Vaccinate all birds in a flock at the same time.
Do not use antibiotics with anti-Mycoplasma activity 2 weeks before or 4 weeks after vaccination. Such antibiotics include e.g. tetracycline, tiamulin, tylosin, quinolones, lincospectin, gentamicin or macrolide antibiotics.

Where antibiotics must be used, preference should be given to agents with non mycoplasma activity, such as penicillin, amoxycillin or neomycin. They should not be given within 2 weeks after vaccination.

- Only flocks with no antibodies to MS (*M. synoviae*) should be vaccinated. Vaccination should be carried out on MS-free birds at least 4 weeks before expected exposure to virulent MS.
- Pullets should first be tested for MS infection. Testing for the presence of *M. synoviae* in the flock is normally by way of the rapid serum agglutination test (RSAT) with blood samples being tested within 24 hours of collection.
- The vaccine strain can spread from vaccinated to unvaccinated birds, including wild species. This may occur during the whole life of the vaccinated bird. Special precautions should be taken to avoid spreading of the vaccine strain to other bird species.
- Distinguishing between field strains and the vaccine strain of *M. synoviae* can be performed by Hammond classification or High Resolution Melt (HRM) testing by a laboratory.
- Infection with *M. synoviae* induces a transient positive antibody response to *Mycoplasma gallisepticum*. Although no data are available on the matter, it is likely that vaccination with this product will also induce a positive antibody response to *Mycoplasma gallisepticum* and may therefore interfere with the serological monitoring of *Mycoplasma gallisepticum*. If necessary, further differentiation of the 2 Mycoplasma species can be done by using PCR in a laboratory. Samples that can be used for PCR include swabs taken from pathological sites such as trachea, palatine cleft, air sacs or joints.
- The vaccine strain can be detected in respiratory tract of the chickens until 55 weeks after vaccination.
- 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 decided on a case-by-case basis.
- Do not mix with any other veterinary medicinal product.

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

- To avoid skin and eye injuries which may occur by manipulating the frozen bottle, personal protective equipment consisting of gloves and safety glasses should be worn.

- If vaccine is accidentally splashed into the operator's eyes, the eyes and face should be thoroughly washed with water to avoid any potential reaction to culture medium constituents.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Plastic LDPE bottle of 30 ml (1,000 doses) with butyl rubber stopper and sealed with an aluminium cap.

MAH Number: EU/2/11/126/001

To be supplied only on veterinary prescription.