ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine oculonasal 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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Modified Frey's medium containing phenol red and swine serum	

Red orange to straw translucent suspension.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each 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.
Duration of immunity to reduce air sac lesions: 40 weeks post vaccination.
Duration of immunity to reduce the number of eggs with abnormal shell formation: has not been established.

3.3 Contraindications

None.
See also section 3.7.

3.4 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.

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

All birds in a flock/common housed group must be vaccinated 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 an indirect diagnostic assay (e.g. the rapid serum agglutination test (RSAT) or ELISA) with blood samples being tested within 24 hours of collection. Testing by a direct diagnostic assay (e.g. PCR) for the presence of M. synoviae is preferable due to the time required for seroconversion after infection.

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, and it is essential that all birds in the flock/common housed group are vaccinated
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:

Personal protective equipment consisting of gloves and safety glasses should be worn when handling the veterinary medicinal product.
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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

3.6 Adverse events

Chickens:

None known.

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 systemhttps://www.ema.europa.eu/documents/template-form/qrd-appendix-i-adverse-event-phv-mss-reporting-details_en.docx. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

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

Oculonasal use.

Chickens from 5 weeks of age

One dose of 30 µl to be administered by the oculonasal route.

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.

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

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

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AE03

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

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: 5 years.
Shelf life after thawing and first opening the immediate packaging: 2 hours.

5.3 Special precautions for storage

Store frozen below -70 °C for a maximum of 5 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.

5.4 Nature and composition of immediate packaging

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

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

Pharmsure Veterinary Products Europe Limited

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/126/001

8. DATE OF FIRST AUTHORISATION

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

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

{MM/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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

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 LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

MS-H Vaccine oculonasal suspension

2. Composition

One dose (30 µl) contains:

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

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

Red orange to straw translucent suspension.

3. Target species

Chickens.

4. Indications for use

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.
Duration of immunity to reduce air sac lesions: 40 weeks post vaccination.
Duration of immunity to reduce the number of eggs with abnormal shell formation: has not been established.

5. Contraindications

None.

6. 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 non mycoplasma activity, such as penicillin, amoxycillin or neomycin. They should not be given within 2 weeks after vaccination.

Special precautions for safe use in the target species:

- All birds in a flock/common housed group must be vaccinated at the same time.

- 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 an indirect diagnostic assay (e.g. the rapid serum agglutination test (RSAT) or ELISA) with blood samples being tested within 24 hours of collection. Testing by a direct diagnostic assay (e.g. PCR) for the presence of *M. synoviae* is preferable due to the time required for seroconversion after infection.
- 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, and it is essential that all birds in the flock/common housed group are vaccinated.
- 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- Personal protective equipment consisting of gloves and safety glasses should be worn when handling the veterinary medicinal product.
- 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.

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

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

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

None known.

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

Oculonasal use.

Chickens should be vaccinated once by applying one 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 30 µl should be administered by the oculonasal route.

- 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 periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Protect from direct sunlight.
Store frozen below -70 °C for a maximum of 5 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 this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 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

EU/2/11/126/001

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

15. Date on which the package leaflet was last revised

<{MM/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:

Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road
Bray
WICKLOW
A98 T6H6
Ireland

Manufacturer responsible for batch release:

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

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

België/Belgique/Belgien
Vetpharm
Oude Iepersestraat 88
BE-8870 Izegem
E-mail: info@vetpharm.be
Tel: + 32 51 30 31 00

Република България
Dremax Kft.
Fehérvári str. 83
HU-1119 Budapest
E-mail: matyas.essosy@dremax.ltd
Тел: +36 30 311 6908

Česká republika
Dremax Kft.
Fehérvári str. 83
HU-1119 Budapest
E-mail: matyas.essosy@dremax.ltd
Tel: +36 30 311 6908

Danmark
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road, Bray
WICKLOW
IE-A98 T6H6
Tlf: +353 86 1784658

Deutschland
Gallicare GbR
Leopoldstraße 116
DE-06366 Köthen
E-mail: info@gallicare.de
Tel: +49 3496 405228

Eesti
UAB Vetmarket
Nemuno g. 4, Virbališkių k., Kaunas
LT-53458
E-mail: info@vetmarket.lt
Tel: +370 37 384003

Ελλάδα
Ελάνκο Ελλάς AEBE
Μεσογείων 335
EL-152 31 Χαλάνδρι, Αττική
Τηλ: +302130065000
E-mail: contact@elanco.gr

Lietuva
UAB Vetmarket
Nemuno g. 4, Virbališkių k., Kaunas
LT-53458
E-mail: info@vetmarket.lt
Tel: +370 37 384003

Luxembourg/Luxemburg
Vetpharm
Oude Iepersestraat 88
BE-8870 Izegem
E-mail: info@vetpharm.be
Tel: + 32 51 30 31 00

Magyarország
Dremax Kft.
Fehérvári str. 83
HU-1119 Budapest
E-mail: matyas.essosy@dremax.ltd
Tel: +36 30 311 6908

Malta
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road, Bray
WICKLOW
IE-A98 T6H6
Tel: +353 86 1784658

Nederland
Vetpharm
Oude Iepersestraat 88
BE-8870 Izegem
E-mail: info@vetpharm.be
Tel: + 32 51 30 31 00

Norge
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road, Bray
WICKLOW
IE-A98 T6H6
Tlf: +353 86 1784658

Österreich
Gallicare GbR
Leopoldstraße 116
DE-06366 Köthen
E-mail: info@gallicare.de
Tel: +49 3496 405228

España
Ceva Salud Animal, S.A.
Avenida Diagonal, 609-615, 9ª planta
ES-08028 Barcelona
E-mail: ceva-salud-animal@ceva.com
Tel: + 34 93 2920660

France
Laboratoire L.C.V.
ZI Plessis Beucher
FR-35220 Châteaubourg
Tél : + 33 (0)2 99 00 92 92

Hrvatska
Dremax Kft.
Fehérvári str. 83
HU-1119 Budapest
e-mail: matyas.essosy@dremax.ltd
Tel: +36 30 311 6908

Ireland
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road, Bray
WICKLOW
IE-A98 T6H6
Tel: +353 86 1784658

Ísland
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road, Bray
WICKLOW
IE-A98 T6H6
Tel: +353 86 1784658

Italia
Boehringer-Ingelheim Animal Health Italia S.p.a.
Via Vezza d'Oglio-3
IT-20139 Milan
E-mail: BIAHitalia@legalmail.it
Tel: +39 02 5355821

Polska
B4Vet Sp. z o.o.
Ul. Wodna 26, Lubawka, Dolnoslaskie
PL-58-420
E-mail: gabor.kis@B4Vet.com
Tel: +48 728 884 232

Portugal
Ceva Saúde Animal
Rua Dr. António Loureiro Borges, 9/9A - 9º A
PT-1495-131 Algés
E-mail: cevaportugal@ceva.com
Tel: + 351 214 228 400
Fax: (+351) 214 228 422

România
Dremax Kft.
Fehérvári str. 83
HU-1119 Budapest
E-mail: matyas.essosy@dremax.ltd
Tel: +36 30 311 6908

Slovenija
Dremax Kft.
Fehérvári str. 83
HU-1119 Budapest
E-mail: matyas.essosy@dremax.ltd
Tel: +36 30 311 6908

Slovenská republika
Dremax Kft.
Fehérvári str. 83
HU-1119 Budapest
E-mail: matyas.essosy@dremax.ltd
Tel: +36 30 311 6908

Suomi/Finland
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road, Bray
WICKLOW
IE-A98 T6H6
Tel: +353 86 1784658

Κύπρος
Activet
Viomichanias 10D
CY-2671, Agioi Trimithias
Τηλ: +357 22 591918
φαξ: +357 22 591917
κινητός: +357 99 615105
E-mail: costas.activet@cytanet.com.cy

Latvija
UAB Vetmarket
Nemuno g. 4, Virbališkių k., Kaunas
LT-53458
E-mail: info@vetmarket.lt
Tel: +370 37 384003

Sverige
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road, Bray
WICKLOW
IE-A98 T6H6
Tel: +353 86 1784658

United Kingdom (Northern Ireland)
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road, Bray
WICKLOW
IE-A98 T6H6
Tel: +353 86 1784658