ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STARTVAC emulsion for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substances:
Escherichia coli J5 inactivated..... > 50 RED_{60}*
Staphylococcus aureus (CP8) strain SP 140 inactivated, expressing slime associated antigenic complex (SAAC) .....…… > 50 RED_{80}**

* RED_{60}: Rabbit effective dose in 60% of the animals (serology).
** RED_{80}: Rabbit effective dose in 80% of the animals (serology).

Adjuvant:
Liquid paraffin..... 18.2 mg

Excipient:
Benzyl alcohol……..... 21 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
Ivory-coloured homogeneous emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle (cows and heifers).

4.2 Indications for use, specifying the target species

For herd immunisation of healthy cows and heifers, in dairy cattle herds with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis and the incidence and the severity of the clinical signs of clinical mastitis caused by *Staphylococcus aureus*, coliforms and coagulase-negative staphylococci.

The full immunisation scheme induces immunity from approximately day 13 after the first injection until approximately day 78 after the third injection.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The whole herd should be immunised.

Immunisation has to be considered as one component in a complex mastitis control program that addresses all important udder health factors (e.g. milking technique, dry-off and breeding management, hygiene, nutrition, housing, bedding, cow comfort, air and water quality, health monitoring) and other management practices.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate healthy animals only.

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

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

Very rare adverse reactions:

- Slight to moderate transient local reactions may occur after the administration of one dose of vaccine based on post-authorisation pharmacovigilance reporting. They would mainly be: swelling (up to 5 cm^2 on average), which disappears within 1 or 2 weeks at most. In some cases, there may also be pain at the inoculation site that spontaneously subsides in a maximum of 4 days.

- A mean transient increase in body temperature of about 1 °C, in some cows up to 2 °C, may occur in the first 24 hours after injection based on post-authorisation pharmacovigilance reporting.

- Anaphylactic-type reactions may occur in some sensitive animals which might be life-threatening based on post-authorisation pharmacovigilance reporting. Under these circumstances, appropriate and rapid symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

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

Intramuscular use.
The injections should be preferably administered on the alternate sides of the neck. Allow the vaccine to reach a temperature of 15 °C to 25 °C before administration. Shake before use.

Administer one dose (2 ml) by deep intramuscular injection in the neck muscles at 45 days before the expected parturition date and 1 month thereafter administer a second dose (at least 10 days before calving). A third dose should be administered 2 months thereafter.

The full immunisation program should be repeated with each gestation.

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

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a double dose of vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for bovidae, inactivated bacterial vaccines for cattle.
ATCvet code: QI02AB17.

To stimulate active immunity against *Staphylococcus aureus*, coliforms and coagulase-negative staphylococci.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol
Liquid paraffin
Sorbitan monooleate
Polysorbate 80
Sodium alginate
Calcium chloride, dihydrate
Simeticone
Water for injections

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: 18 months.
Shelf life after first opening the immediate packaging: 10 hours stored at 15 ºC to 25 ºC.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type I colourless glass vials of 3, 10 and 50 ml.
Polyethylene (PET) vials of 10, 50 and 250 ml.
The vials are closed with a rubber stopper and aluminium cap.

Pack sizes:
Cardboard box with 1 glass vial of 1 dose.
Cardboard box with 10 glass vials of 1 dose.
Cardboard box with 20 glass vials of 1 dose.
Cardboard box with 1 glass vial of 5 doses.
Cardboard box with 10 glass vials of 5 doses.
Cardboard box with 1 glass vial of 25 doses.
Cardboard box with 10 glass vials of 25 doses.

Cardboard box with 1 PET vial of 5 doses.
Cardboard box with 1 PET vial of 25 doses.
Cardboard box with 1 PET vial of 125 doses.

Not all pack sizes may be marketed.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN
Tel. +34 972 430660
Fax +34 972 430661
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/092/001-010

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11/02/2009
Date of last renewal: 10/02/2014

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 SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

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

Name and address of the manufacturer of the biological active substances

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

Laboratorios Hipra, S.A. (CIAMER)
Carretera C-63, km 48.300,
Polígono Industrial El Rieral
17170 Amer (Girona)
Spain

Name and address of the manufacturer responsible for batch release

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

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

The excipients (including adjuvants) 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 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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes, PET vial (250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STARTVAC emulsion for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

One dose (2 ml) contains:
E. coli J5 inactivated > 50 RED_{60} (Rabbit effective dose in 60% of the animals (serology)).
S. aureus (CP8) strain SP 140 inactivated, expressing slime associated antigenic complex (SAAC) > 50 RED_{80} (In 80% of the animals).
Liquid paraffin: 18.2 mg
Benzyl alcohol: 21 mg.

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

1 vial of 1 dose (2 ml)
10 vials of 1 dose (2 ml)
20 vials of 1 dose (2 ml)
1 vial of 5 doses (10 ml)
10 vials of 5 doses (10 ml)
1 vial of 25 doses (50 ml)
10 vials of 25 doses (50 ml)
1 vial of 125 doses (250 ml)
125 doses (250 ml)

5. TARGET SPECIES

Cattle (cows and heifers).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – read the package leaflet before use.

10. EXPIRY DATE

EXP

Once opened, use within a 10-hour period, stored at 15–25 ºC.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/08/092/001 1 glass vial 1 dose
EU/2/08/092/002 10 glass vials 1 dose
EU/2/08/092/003 20 glass vials 1 dose
EU/2/08/092/004 1 glass vial 5 doses
EU/2/08/092/005 10 glass vials 5 doses
EU/2/08/092/006 1 glass vial 25 doses
EU/2/08/092/007 10 glass vials 25 doses
EU/2/08/092/008 1 PET vial of 5 doses

EU/2/08/092/009 1 PET vial of 25 doses
EU/2/08/092/010 1 PET vial of 125 doses

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

PET vials (10 ml, 50 ml) and glass vials (2 ml, 10 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STARTVAC emulsion for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

One dose contains:
E. coli J5 inactivated; *S. aureus* (CP8) strain SP 140 inactivated.

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

1 dose (2 ml)
5 doses (10 ml)
25 doses (50 ml)

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP
Once opened, use within a 10-hour period, stored at 15–25 ºC.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
STARTVAC emulsion for injection for cattle

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

Marketing authorisation holder and manufacturer responsible for batch release:

Laboratorios Hipra S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

STARTVAC emulsion for injection for cattle

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

One dose (2 ml) contains:
Escherichia coli (J5) inactivated ..... > 50 RED_{60}*
Staphylococcus aureus (CP8) strain SP 140 inactivated, expressing slime associated antigenic complex (SAAC)..... > 50 RED_{80}**
* RED_{60}: Rabbit effective dose in 60% of the animals (serology).
** RED_{80}: Rabbit effective dose in 80% of the animals (serology).
Liquid paraffin: 18.2 mg
Benzyl alcohol: 21 mg.

STARTVAC is an ivory-coloured homogeneous emulsion for injection.

4. INDICATION(S)

For herd immunisation of healthy cows and heifers, in dairy cattle herds with recurring mastitis problems, to reduce the incidence of sub-clinical mastitis and the incidence and the severity of the clinical signs of clinical mastitis caused by *Staphylococcus aureus*, coliforms and coagulase-negative staphylococci.

The full immunisation scheme induces immunity from approximately day 13 after the first injection until approximately day 78 after the third injection.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Very rare adverse reactions:

- Slight to moderate transient local reactions may occur after the administration of one dose of vaccine based on post-authorisation pharmacovigilance reporting. They would mainly be: swelling (up to 5 cm^2 on average), which disappears within 1 or 2 weeks at most. In some cases, there may also be pain at the inoculation site that spontaneously subsides in a maximum of 4 days.

- A mean transient increase in body temperature of about 1 °C, in some cows up to 2 °C, may occur in the first 24 hours after injection based on post-authorisation pharmacovigilance reporting.

- Anaphylactic-type reactions may occur in some sensitive animals which might be life-threatening based on post-authorisation pharmacovigilance reporting. Under these circumstances, appropriate and rapid symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

7. TARGET SPECIES

Cattle (cows and heifers).

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

Intramuscular use. The injections should be preferably administered on the alternate sides of the neck.

Administer one dose (2 ml) by deep intramuscular injection in the neck muscles at 45 days before the expected parturition date and 1 month thereafter administer a second dose (at least 10 days before calving). A third dose should be administered 2 months thereafter.
The full immunisation program should be repeated with each gestation.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the vaccine to reach a temperature of 15 °C to 25 °C before administration. Shake before use.

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). Protect from light.
Do not freeze.

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.
Shelf life after first opening the immediate packaging: 10 hours stored at 15 °C to 25 ºC.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The whole herd should be immunised.

Immunisation has to be considered as one component in a complex mastitis control program that addresses all important udder health factors (e.g. milking technique, dry-off and breeding management, hygiene, nutrition, housing, bedding, cow comfort, air and water quality, health monitoring) and other management practices.

Special precautions for use in animals:
Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

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 (symptoms, emergency procedures, antidotes):
No adverse reactions other than those mentioned in section “Adverse reactions” were observed after the administration of a double dose of vaccine.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

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

15. OTHER INFORMATION

Pack sizes:
- Cardboard box with 1, 10 and 20 glass vials of 1 dose.
- Cardboard box with 1 and 10 glass vials of 5 doses.
- Cardboard box with 1 and 10 glass vials of 25 doses.
- Cardboard box with 1 PET vial of 5 doses.
- Cardboard box with 1 PET vial of 25 doses.
- Cardboard box with 1 PET vial of 125 doses.

Not all pack sizes may be marketed.

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

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Ísland LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60	**Slovenská republika** LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60
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Κύπρος LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60	**Sverige** LABORATORIOS HIPRA, S.A. Tel. (34) 972 43 06 60
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