ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC Clostridium Ovino suspension for injection (ES)
Coglavax S suspension for injection (IT)
Panclostil S suspension for injection (EL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition for a 2-ml dose

Active substances:

Alpha toxoid of *Clostridium perfringens* type A	≥ 2.2 IU *
Beta toxoid of *Clostridium perfringens* type C	≥ 20.0 IU *
Epsilon toxoid of *Clostridium perfringens* type D	≥ 10.0 IU *
Toxoid of *Clostridium novyi* type B	≥ 7.0 IU *
Toxoid of *Clostridium septicum*	≥ 5.0 IU *
Toxoid of *Clostridium tetani*	≥ 5.0 IU *
Toxoid of *Clostridium sordellii*	100 % protection **
Anaculture of *Clostridium chauvoei*	≥ 90 % protection ***

* International Units
** Level of protection in control animal (mice)
*** Level of protection in guinea-pigs (in line with Ph. Eur.)

Adjuvant:

Aluminium hydroxide as $Al(OH)_3$	5.19 mg

Excipients:

Formaldehyde	≤ 0.05 % w/v

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
Lacteal suspension more or less coloured in clear brown.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep, pregnant ewe and lamb

4.2 Indications for use, specifying the target species

Active immunisation against enterotoxaemia due to *C. perfringens* type A, B, C and D, and *Clostridium sordellii* and clostridial infections due to *C. novyi* type B*, septicum, chauvoei* and *tetani*.
As primary or unique agents, these pathogens or their toxins cause the following diseases:

Pathogens	Diseases
Alpha toxin of *Clostridium perfringens*	Enterotoxaemia and Yellow Lamb Disease

Type A Beta toxin of *Clostridium perfringens* Type B and Type C	Lamb dysentery Haemorrhagic enteritis of lambs and Infectious Enterotoxaemia in sheep (or Struck)
Epsilon toxin *Clostridium perfringens* Type D	Pulpy kidney disease (Basquilla)
Toxin of *Clostridium septicum*	Bradsot or malignant oedema of abomasum
Toxin of *Clostridium novyi* Type B	Necrotic hepatitis
Toxin of *Clostridium tetani*	Tetanus
Clostridium chauvoei	Blackleg
Toxin of *Clostridium sordellii*	Enterotoxaemia in sheep

Lamb born from non-vaccinated mother: Two administrations of the vaccine at 2 and 6 weeks of age provide a significant immune response against the pathogens listed above, as from 2 weeks after the 2nd vaccination. This level lasts for 6 weeks, except for *C. tetani*.

Booster vaccination (before a risk period): two weeks after vaccination, antibodies against the same components reach a significant level. This level lasts for 4 weeks, except for *C. chauvoei (not tested).*

Lamb born from vaccinated mother: two administrations of the vaccine at 8 and 12 weeks of age provides a significant immune response as from 2 weeks after the 2nd vaccination and lasts for 6 weeks.
Booster vaccination (before a risk period): two weeks after vaccination, antibodies against the same components reach a significant level. This level lasts for 6 weeks, except for *C. chauvoei* (not tested*).*

Pregnant ewe: two administrations of the vaccine at 4 weeks interval age provides a significant immune response as from 2 weeks after the 2nd vaccination against Alpha, Beta, Epsilon toxins of *Clostridium perfringens* type A, B, C and D and toxins of *Clostridium septicum, novyi* type B*,* and *tetani*.

Passive immunisation: after two administrations of the vaccine at 4 weeks interval with the second one administered 2 to 5 weeks before expected lambing date, antibodies against Beta and Epsilon toxins expressed by *Clostridium perfringens* type C and D, are present in the colostrum of the vaccinated ewes.
Passive immunisation against the same pathogens will be transferred to lambs that receive colostrum in the first day after birth.

4.3 Contraindications

None

4.4 Special warnings <for each target species>

None

4.5 Special precautions for use

Special precautions for use in animals

Administer only to healthy animals.

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.

4.6 Adverse reactions (frequency and seriousness)

A mild local reaction at the injection site is commonly expected. According to the safety studies in target species, swelling or a firm nodule appears 2-5 days after administration, reaching a maximum of 18-22 mm around 5 to 7 days after vaccination. It disappears without need for treatment after 20-30 days. In sheep, a slight pain at the injection site is commonly noticed. It disappears in 1 to 7 days.

4.7 Use during pregnancy, lactation or lay

The vaccine can be used during pregnancy. The safety of the veterinary medicinal product has not been established during 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

Warm the vaccine before administration. Shake well before use
Respect normal aseptic conditions

Subcutaneous administration in the axillar region behind the elbow.

Lamb from non-vaccinated mother as from 2 weeks of age:
Vaccination: twice 2 ml 4 weeks apart, at two and six weeks of age
Re-vaccination: booster vaccination should be programmed 2 to 4 weeks before any period of risk.
Lamb from vaccinated mother as from 8 weeks of age:
Vaccination: twice 2 ml 4 weeks apart, at eight and twelve weeks of age
Re-vaccination: booster vaccination should be programmed 2 to 4 weeks before any period of risk.
Pregnant ewe:
Vaccination: twice 2 ml with 4 weeks interval, the second vaccine dose is administered 2 to 5 weeks before expected lambing date.
Re-vaccination: booster vaccination should be programmed 2 to 4 weeks before any period of risk. When a new pregnancy is programmed, re-vaccination should be carried out 2 to 5 weeks before the expected date of lambing.
Lambs should drink the colostrum during the day following birth.

Vaccination should also be carried out taking into account with great care the risk period or lambing date. The adequate vaccination program should be applied so that the peak of antibodies will be present in the animals during the risk period or at time of lambing.

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

Studies on the effect of the administration of a two-fold overdose in different sensitive categories (pregnant ewes, 2 and 8 week-old lambs) have shown that a mild local reaction at the injection site is expected. Swelling or a firm nodule appears 2-6 days after administration, reaching a maximum of 23-27 mm around 5 to 8 days after vaccination. It disappears without need for treatment after 20-30 days. In sheep, an overdose commonly triggers a slight pain at the injection site. It disappears in 1 to 8 days.

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sheep, inactivated clostridium vaccine
ATCvet code: QI04AB01

Summary presentation of active ingredients
The active ingredients (a mixture of toxoids and whole inactivated culture) present in the vaccine are aiming at the immunisation of sheep against the pathogens involved in diseases (as primary or unique agents), listed in section 4.2.

The vaccine provides active or passive immunisation against those pathogens.
The action of neutralising antibodies is known to be determinant in the protection of sheep against enterotoxaemia due to *C. perfringens* type A, B, C and D and *Clostridium sordellii* and clostridial infections due to *C. novyi* type B*, septicum, tetani* and *chauvoei*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide as $Al(OH)_3$
Trometamol
Maleic acid
Sodium chloride
Free formaldehyde
Water for injection

6.2 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: 21 months
Shelf-life after first opening the immediate packaging: use immediately

6.4. Special precautions for storage

The product must be stored between +2°C and +8°C protected from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Carton box with 1 LDPE (Low Density Polyethylene Eur. Ph. 3.1.4) bottle of 50, 100 or 250 ml with 20 mm H 4001/A grey brombutyl (Eur. Ph. 3.2.2 type I.) stopper and aluminium cap.
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 should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

04/2014

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX LABEL – 50 ml, 100 ml, 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC Clostridium Ovino suspension for injection (ES)
Coglavax S suspension for injection (IT)
Panclostil S suspension for injection (EL)
Inactivated bacterial vaccine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition for 2 ml dose

Alpha toxoid of *Clostridium perfringens* type A	≥ 2.2 IU *
Beta toxoid of *Clostridium perfringens* type C	≥ 20.0 IU *
Epsilon toxoid of *Clostridium perfringens* type D	≥ 10.0 IU *
Toxoid of *Clostridium novyi* type B	≥ 7.0 IU *
Toxoid of *Clostridium septicum*	≥ 5.0 IU *
Toxoid of *Clostridium tetani*	≥ 5.0 IU *
Toxoid of *Clostridium sordellii*	100 % protection **
Anaculture of *Clostridium chauvoei*	≥ 90 % protection ***

* International Units
** Level of protection in control animal (mice)
*** Level of protection in guinea-pigs (in line with Ph. Eur.)

Aluminium hydroxide as $Al(OH)_3$ (adjuvant)	5.19 mg
Formaldehyde	≤ 0.05 % w/v

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml, 100 ml, 250 ml

5. TARGET SPECIES

Sheep , pregnant ewe and lamb

6. INDICATIONS

Active immunisation against enterotoxaemia due to *C. perfringens* type A, B,C and D, and *Clostridium sordellii* and clostridial infections due to *C. novyi* type B*, septicum, chauvoei* and *tetani*.
As primary or unique agents, these pathogens or their toxins cause the following diseases:

- Enterotoxaemia and Yellow Lamb Disease
- Lamb dysentery

- Haemorrhagic enteritis of lambs and Infectious Enterotoxaemia in sheep (or Struck)
- Basquilla (Pulpy kidney disease)
- Bradsot or malignant oedema of abomasum
- Necrotic hepatitis
- Tetanus
- Blackleg
- Enterotoxaemia in sheep

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous administration in the axillar region behind the elbow.
Warm the vaccine before administration. Shake well before use.
Respect normal aseptic conditions.
For detailed description see the package insert.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Administer only to healthy animals. If the vaccine is accidentally injected to the operator, urgent medical attention is required.

10. EXPIRY DATE

EXP {month/year}
After puncture of the stopper, use immediately.

11. SPECIAL STORAGE CONDITIONS

The product must be stored between +2°C and +8°C protected from light. Do not freeze.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

16. MARKETING AUTHORISATION NUMBER(S)

Marketing authorization number:

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE LABEL 50 ml, 100 ml, 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC Clostridium Ovino suspension for injection (ES)
Coglavax S suspension for injection (IT)
Panclostil S suspension for injection (EL)
Inactivated bacterial vaccine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition for 2 ml dose:

Alpha toxoid of *Clostridium perfringens* type A	≥ 2.2 IU *
Beta toxoid of *Clostridium perfringens* type C	≥ 20.0 IU *
Epsilon toxoid of *Clostridium perfringens* type D	≥ 10.0 IU *
Toxoid of *Clostridium novyi* type B	≥ 7.0 IU *
Toxoid of *Clostridium septicum*	≥ 5.0 IU *
Toxoid of *Clostridium tetani*	≥ 5.0 IU *
Toxoid of *Clostridium sordellii*	100 % protection **
Anaculture of *Clostridium chauvoei*	≥ 90 % protection ***

* International Units
** Level of protection in control animal (mice)
*** Level of protection in guinea-pigs (in line with Ph. Eur.)

Aluminium hydroxide as $Al(OH)_3$ (adjuvant)	5.19 mg
Formaldehyde	≤ 0.05 % w/v

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

50 ml, 100 ml, 250 ml

5. TARGET SPECIES

Sheep, pregnant ewe and lamb

6. INDICATIONS

Active immunisation against enterotoxaemia due to *C. perfringens* type A, B,C and D, and *Clostridium sordellii* and clostridial infections due to *C. novyi* type B*, septicum, chauvoei* and *tetani*.

7. METHOD AND ROUTE OF ADMINISTRATION

Subcutaneous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
After puncture of the stopper, use immediately.

11. SPECIAL STORAGE CONDITIONS

The product must be stored between +2°C and +8°C protected from light. Do not freeze.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorization holder

16. MARKETING AUTHORISATION NUMBER(S)

Marketing authorization number:

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET
CEVAC Clostridium Ovino
Inactivated bacterial vaccine
Suspension for injection
50, 100 or 250 ml

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

Marketing authorisation holder:

Marketing authorization holder

Manufacturer for the batch release:

CZ Vaccines S.A.U.
A Relva s/n - Torneiros 36410 O Porriño, Pontevedra
España

Ceva-Phylaxia Co. Ltd.
1107 Budapest Szállás u. 5.
Hungary

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

CEVAC Clostridium Ovino suspension for injection (ES)
Coglavax S suspension for injection (IT)
Panclostil S suspension for injection (EL)
Inactivated bacterial vaccine

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

Composition for 2 ml dose:

Alpha toxoid of *Clostridium perfringens* type A	≥ 2.2 IU *
Beta toxoid of *Clostridium perfringens* type C	≥ 20.0 IU *
Epsilon toxoid of *Clostridium perfringens* type D	≥ 10.0 IU *
Toxoid of *Clostridium novyi* type B	≥ 7.0 IU *
Toxoid of *Clostridium septicum*	≥ 5.0 IU *
Toxoid of *Clostridium tetani*	≥ 5.0 IU *
Toxoid of *Clostridium sordellii*	100 % protection **
Anaculture of *Clostridium chauvoei*	≥ 90 % protection ***

* International Units
** Level of protection in control animal (mice)
*** Level of protection in guinea-pigs (in line with Ph. Eur.)

Aluminium hydroxide as $Al(OH)_3$ (adjuvant)	5.19 mg
Formaldehyde	≤ 0.05 % w/v

Lacteal suspension more or less coloured in clear brown.

4. INDICATIONS

Active immunisation against enterotoxaemia due to *C. perfringens* type A, B, C and D, and *Clostridium sordellii* and clostridial infections due to *C. novyi* type B*, septicum, chauvoei* and *tetani*.
As primary or unique agents, these pathogens or their toxins cause the following diseases:

Pathogens	Diseases
Alpha toxin of *Clostridium perfringens* Type A	Enterotoxaemia and Yellow Lamb Disease
Beta toxin of *Clostridium perfringens* Type B and Type C	Lamb dysentery Haemorrhagic enteritis of lambs and Infectious Enterotoxaemia in sheep (or Struck)
Epsilon toxin *Clostridium perfringens* Type D	Pulpy kidney disease (Basquilla)
Toxin of *Clostridium septicum*	Bradsot or malignant oedema of abomasum
Toxin of *Clostridium novyi* Type B	Necrotic hepatitis
Toxin of *Clostridium tetani*	Tetanus
Clostridium chauvoei	Blackleg
Toxin of *Clostridium sordellii*	Enterotoxaemia in sheep

Lamb born from non-vaccinated mother: two administrations of the vaccine at 2 and 6 weeks of age provide a significant immune response against the pathogens listed above as from 2 weeks after the 2nd vaccination. This level lasts for 6 weeks, except for C. tetani.
Booster vaccination (before a risk period): two weeks after vaccination, antibodies against the same components reach a significant level. This level lasts for 4 weeks, except for C. chauvoei (not tested).

Lamb born from vaccinated mother: two administrations of the vaccine at 8 and 12 weeks of age provides a significant immune response as from 2 weeks after the 2nd vaccination and lasts for 6 weeks
Booster vaccination (before a risk period): two weeks after vaccination, antibodies against the same components reach a significant level. This level lasts for 6 weeks, except for *C. chauvoei* (not tested).

Pregnant ewe: two administrations of the vaccine at 4 weeks interval age provides a significant immune response as from 2 weeks after the 2nd vaccination against Alpha, Beta, Epsilon toxins of *Clostridium perfringens* type A, B, C and D and toxins of *Clostridium septicum, novyi* type B*,* and *tetani*.

Passive immunisation: after two administrations of the vaccine at 4 weeks interval with the second one administered 2 to 5 weeks before expected lambing date, antibodies against Beta and Epsilon toxins expressed by *Clostridium perfringens* type C and D, are present in the colostrum of the vaccinated ewes.
Passive immunisation against the same pathogens will be transferred to lambs that receive colostrum in the first day after birth.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A mild local reaction at the injection site is commonly expected. According to the safety studies in target species, swelling or a firm nodule appears 2-5 days after administration, reaching a maximum of 18-22 mm around 5 to 7 days after vaccination. It disappears without need for treatment after 20-30 days. In sheep, a slight pain at the injection site is commonly noticed. It disappears in 1 to 7 days.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep, pregnant ewe and lamb

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

Subcutaneous administration in the axillar region behind the elbow.

Lamb from non-vaccinated mother as from 2 weeks of age:
Vaccination: twice 2 ml 4 weeks apart, at two and six weeks of age
Re-vaccination: booster vaccination should be programmed 2 to 4 weeks before any period of risk.
Lamb from vaccinated mother as from 8 weeks of age and sheep:
Vaccination: twice 2 ml 4 weeks apart, at eight and twelve weeks of age
Re-vaccination: booster vaccination should be programmed 2 to 4 weeks before any period of risk.
Pregnant ewe:
Vaccination: twice 2 ml with 4 weeks interval, the second vaccine dose is administered 2 to 5 weeks before expected lambing date.
Re-vaccination: booster vaccination should be programmed 2 to 4 weeks before any period of risk. When a new pregnancy is programmed, re-vaccination should be carried out 2 to 5 weeks before the expected date of lambing.
Lambs should drink the colostrum during the day following birth.

Vaccination should also be carried out taking into account with great care the risk period or lambing date. The adequate vaccination program should be applied so that the peak of antibodies will be present in the animals during the risk period or at time of lambing.

9. ADVICE ON CORRECT ADMINISTRATION

- Warm the vaccine before administration.
- Shake well before use.
- Respect normal aseptic conditions.
- Administer only to healthy animals.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

The product must be stored between +2°C and +8°C protected from light.
Do not freeze. Use immediately after the puncture of the product.
Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Interaction with other medicaments 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.

Do not mix with any other veterinary medicinal product.

Overdose
Studies on the effect of the administration of a two-fold overdose in different sensitive categories (pregnant ewes, 2 and 8 week-old lambs) have shown that a mild local reaction at the injection site is expected. Swelling or a firm nodule appears 2-6 days after administration, reaching a maximum of 23-27 mm around 5 to 8 days after vaccination. It disappears without need for treatment after 20-30 days. In sheep, an overdose commonly triggers a slight pain at the injection site. It disappears in 1 to 8 days.

Use during pregnancy and lactation
The vaccine can be used during pregnancy. The safety of the veterinary medicinal product has not been established during lactation.

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.

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

Any unused product or waste material should be disposed of in accordance with local requirements. Medicines should not be disposed of via wastewater or household waste.
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

dd-mm-yy

15. OTHER INFORMATION

Marketing authorization number:
For animal treatment only:
To be supplied only on veterinary prescription.
Pack sizes:

Cardboard box containing one 50 ml bottle

Cardboard box containing one 100 ml bottle

Cardboard box containing one 250 ml bottle

Not all pack sizes may be marketed.