ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE lyophilisate and solvent for suspension for injection for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.01 ml) contains:

Active substances:

Live recombinant fowlpox virus expressing the membrane fusion protein and the encapsidation protein of avian infectious laryngotracheitis virus (rFP-LT)	2.7 to 4.5 log10 TCID50*
Avian encephalomyelitis virus, strain Calnek 1143 (AE)	2.7 to 4.5 log10 EID50**

* 50% Tissue Culture Infective Dose
** 50% Egg Infective Dose

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.
Lyophilisate: whitish-brownish.
Solvent: clear, blue liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For active immunisation of chickens of 8 to 13 weeks of age in order to reduce the skin lesions due to fowlpox, to reduce the clinical signs and tracheal lesions due to avian infectious laryngotracheitis and to prevent egg production losses due to avian encephalomyelitis.

Onset of immunity
Fowlpox and avian infectious laryngotracheitis: 3 weeks after vaccination
Avian encephalomyelitis: 20 weeks after vaccination

Duration of immunity:
Fowlpox: 34 weeks after vaccination.
Avian infectious laryngotracheitis and avian encephalomyelitis: 57 weeks after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

The avian encephalomyelitis virus vaccine strain can spread to unvaccinated chickens. Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated chickens.

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)

Small swelling/scabs typical of folwpox vaccine take are very common and should disappear within 14 days after vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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

Laying birds:
Do not use in birds in lay and within 4 weeks before the start 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

Wing-web-stab use
The vaccine is to be administered once from 8 weeks of age and not later than 4 weeks before the onset of lay.
The injection volume is 0.01 ml (10µl).
The vaccine is delivered by transfixion of inner side of the wing web using the two pronged-applicator supplied with the product. The applicator is inserted from beneath through the wing web and care should be taken to push the feathers aside so as to avoid damaging the blood vessels.
The wing web should be slightly stretched.

Recommended dilutions for administration:

Number of vaccine ampoules	Volume of solvent to be used	Volume of one dose
1 x 1000 doses	10 ml	0.01 ml
1 x 2000 doses	20 ml	0.01 ml

Preparation of vaccine suspension for injection:
1. Using a sterile syringe fitted with at least a 20-18 gauge needle, withdraw 4 to 5 ml of solvent from the solvent vial and inject into the vial containing the lyophilisate (freeze-dried vaccine). Swirl gently until the lyophilisate has dissolved.
2. Draw up all the reconstituted vaccine suspension into the syringe and inject into the solvent vial.
3. Then take 4-5 ml of the diluted vaccine suspension from the solvent vial, use it to rinse the vaccine vial and transfer it back into the solvent vial.

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

Ten times the maximum dose was shown to be safe.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for aves, live viral vaccines for domestic fowls.
ATCvet code: {not yet assigned}

The vaccine is a live recombinant fowlpox virus expressing the membrane fusion protein and the encapsidation protein of avian infectious laryngotracheitis virus and a live avian encephalomyelitis virus. The vaccine induces active immunity against fowlpox, avian infectious laryngotracheitis and avian encephalomyelitis viruses.

For avian encephalomyelitis, serological data suggest that the maximum seroconversion rate is reached between 4 and 7 weeks after vaccination and is maintained until 57 weeks after vaccination.

For fowl pox, increased speed of cicatrisation is observed until 49 weeks after vaccination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate
Dipotassium phosphate
Gelatin
Lactose
Potassium dihydrogen phosphate
Sorbitol
Sucrose
Tryptose Phosphate Broth
Water for injections

Solvent
Glycerol
Patent blue V (E131)
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

6.3 Shelf life

Shelf life of the lyophilisate as packaged for sale: 21 months
Shelf life of the solvent as packaged for sale: 3 years.
Shelf life after reconstitution according to directions: 2 hours.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I glass vial containing 1000 or 2000 doses of vaccine.

Solvent (Cevac Solvent Wingweb):
Type I glass vial containing 10 ml (1000 doses) or 20 ml (2000 doses) of solvent.

Presentations:
Cardboard box of 1 vial of 1000 doses of vaccine, 1 vial of 10 ml of solvent and 1 pronged applicator.
Cardboard box of 1 vial of 2000 doses of vaccine, 1 vial of 20 ml of solvent and 1 pronged applicator.
Cardboard box of 5 vials of 1000 doses of vaccine. + Cardboard box of 5 vials of 10 ml of solvent and 5 pronged applicators.
Cardboard box of 5 vials of 2000 doses of vaccine. + Cardboard box of 5 vials of 20 ml of solvent and 5 pronged applicators.
Cardboard box of 10 vials of 1000 doses of vaccine. + Cardboard box of 10 vials of 10 ml of solvent and 10 pronged applicators.
Cardboard box of 10 vials of 2000 doses of vaccine. + Cardboard box of 10 vials of 20 ml of solvent and 10 pronged applicators.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/250/001-006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24/04/2020.

10 DATE OF REVISION OF THE TEXT

MM/YYYY

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

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

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

Ceva-Phylaxia Veterinary Biologicals Co. Ltd
Szállás u. 5
1107 Budapest
HUNGARY

Name and address of the manufacturer(s) responsible for batch release

Ceva-Phylaxia Veterinary Biologicals Co. Ltd
Szállás u. 5
1107 Budapest
HUNGARY

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

C. STATEMENT OF THE MRLs

The active substances being principles of biological origin intended to produce immunity are 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 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

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX (lyophilisate + solvent + applicators)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE lyophilisate and solvent for suspension for injection for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

rFPLT virus	2.7 to 4.5 log10 TCID50
AE virus	2.7 to 4.5 log10 EID50

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

1 x {1000 doses + 10 ml solvent + 1 pronged applicator}
1 x {2000 doses + 20 ml solvent + 1 pronged applicator}

5. TARGET SPECIES

Chickens

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Wing-web-stab use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

12. SPECIFIC 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.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/250/001-006

17. MANUFACTURER'S BATCH NUMBER

Lot {number} *(of the lyophilisate + solvent)*

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX (lyophilisate)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE lyophilisate for suspension for injection for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

rFPLT virus	2.7 to 4.5 log10 TCID50
AE virus	2.7 to 4.5 log10 EID50

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection

4. PACKAGE SIZE

5 x 1000 doses
5 x 2000 doses
10 x 1000 doses
10 x 2000 doses

5. TARGET SPECIES

Chickens

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Wing-web-stab use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

12. SPECIFIC 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.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/250/001-006

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOX (solvent + applicators)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cevac Solvent Wingweb

2. STATEMENT OF ACTIVE SUBSTANCES

3. PHARMACEUTICAL FORM

Solvent for suspension for injection

4. PACKAGE SIZE

5 x 10 ml solvent + 5 pronged applicators
5 x 20 ml solvent + 5 pronged applicators
10 x 10 ml solvent + 10 pronged applicators
10 x 20 ml solvent + 10 pronged applicators

5. TARGET SPECIES

Chickens

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Wing-web-stab use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

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.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/20/250/001-006

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

(LABEL) OF THE LYOPHILISATE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE lyophilisate for suspension for injection for chickens

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

rFPLT virus 2.7 to 4.5 log10 TCID50
AE virus 2.7 to 4.5 log10 EID50

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

1000 doses
2000 doses

4. ROUTE(S) OF ADMINISTRATION

Wing web-stab use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 2 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNIT

(LABEL) OF THE SOLVENT

1. NAME OF THE DILUENT

Cevac Solvent Wingweb

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

10 ml
20 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store and transport refrigerated.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Company logo or name of the company

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Vectormune FP ILT + AE
Lyophilisate and solvent for suspension for injection for chickens

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:

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vectormune FP ILT + AE lyophilisate and solvent for suspension for injection for chickens

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

Each dose (0.01 ml) contains:

Active substances:
Live recombinant fowlpox virus expressing the membrane fusion protein and the encapsidation protein of avian infectious laryngotracheitis virus (rFP-LT) 2.7 to 4.5 log10 TCID50*

Avian encephalomyelitis virus, strain Calnek 1143 (AE) 2.7 to 4.5 log10 EID50**

* 50% Tissue Culture Infective Dose
** 50% Egg Infective Dose

Lyophilisate: whitish-brownish.
Solvent: clear, blue liquid.

4. INDICATION(S)

For active immunisation of chickens of 8 to 13 weeks of age in order to reduce the clinical signs (skin lesions) due to fowlpox, to reduce the clinical signs and tracheal lesions due to avian infectious laryngotracheitis and to prevent egg production losses due to avian encephalomyelitis.

Onset of immunity
Fowlpox and avian infectious laryngotracheitis: 3 weeks after vaccination
Avian encephalomyelitis: 20 weeks after vaccination

Duration of immunity:
Fowlpox: 34 weeks after vaccination
Avian infectious laryngotracheitis and avian encephalomyelitis: 57 weeks after vaccination.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Small swelling/scabs typical of folwpox vaccine take are very common and should disappear within 14 days after vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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 side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens

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

Wing web-stab use
The vaccine is to be administered once from 8 weeks of age and not later than 4 weeks before the onset of lay. The injection volume is 0.01 ml (10µl). The vaccine is delivered by transfixion of the inner side of the wing web with the help of a pronged-applicator. The applicator is inserted from beneath through the wing web and care should be taken to push the feathers aside so as to avoid damaging the blood vessels.
The wing web should be slightly stretched.

Proposed dilutions for administration:

Number of vaccine ampoules	Volume of solvent to be used	Volume of one dose
1 x 1000 doses	10 ml	0.01 ml
1 x 2000 doses	20 ml	0.01 ml

9. ADVICE ON CORRECT ADMINISTRATION

Preparation of vaccine suspension for injection:
1. Using a sterile syringe fitted with at least a 20-18 gauge needle, withdraw 4 to 5 ml of solvent from the solvent vial and inject into the vial containing the lyophilisate (freeze-dried vaccine). Swirl gently until the lyophilisate has dissolved.
2. Draw up the reconstituted vaccine suspension into the syringe and inject into the solvent vial.
3. Then take 4-5 ml of the diluted vaccine suspension from the solvent vial, use it to rinse the vaccine vial and transfer it back into the solvent vial.

10. WITHDRAWAL PERIOD(S)

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 use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after reconstitution according to directions: 2 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy birds only.

Special precautions for use in animals:
The avian encephalomyelitis virus vaccine strain can spread to unvaccinated chickens. Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated chickens.

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.

Lay:
Do not use in birds in lay or within 4 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 (symptoms, emergency procedures, antidotes):
Ten times the maximum dose was shown to be safe.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

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

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

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

For avian encephalomyelitis, serological data suggest that the maximum seroconversion rate is reached between 4 and 7 weeks after vaccination and is maintained until 57 weeks after vaccination.

For fowlpox, increased speed of cicatrisation is observed until 49 weeks after vaccination.

Lyophilisate: Type I glass vial containing, 1000 or 2000 doses of vaccine.
Solvent (Cevac Solvent Wingweb): Type I glass vial containing 10 ml (1000 doses) or 20 ml (2000 doses) of solvent
Presentations:
Cardboard box of 1 vial of 1000 doses of vaccine, 1 vial of 10 ml of solvent and 1 pronged applicator.
Cardboard box of 1 vial of 2000 doses of vaccine, 1 vial of 20 ml of solvent and 1 pronged applicator.
Cardboard box of 5 vials of 1000 doses of vaccine. + Cardboard box of 5 vials of 10 ml of solvent and 5 pronged applicators.
Cardboard box of 5 vials of 2000 doses of vaccine. + Cardboard box of 5 vials of 20 ml of solvent and 5 pronged applicators.
Cardboard box of 10 vials of 1000 doses of vaccine. + Cardboard box of 10 vials of 10 ml of solvent and 10 pronged applicators.
Cardboard box of 10 vials of 2000 doses of vaccine. + Cardboard box of 10 vials of 20 ml of solvent and 10 pronged applicators.

Not all pack sizes may be marketed.