ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PARVOKAN lyophilisate and suspension for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.2 ml) contains:

Active substances:
Suspension:
Muscovy duck parvovirus, strain GM, inactivated ≥ 1.5 $\log_{10}$ SN.U[1]

Lyophilisate:
Derzsy's disease virus, strain H, live attenuated ≥ 2.5 $\log_{10}$ $CCID_{50}$

[1] SN.U: q.s. to obtain a mean seroneutralizing antibody titre of 1 $\log_{10}$ in the vaccinated animal

Adjuvant:
Suspension:
Al^{3+} (as aluminium hydroxide) 0.42 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Lyophilisate:	
Disodium phosphate dihydrate	
Citric acid monohydrate	
Casein hydrolysate	
Water for injection	
Suspension:	
Thiomersal	≤ 20 mcg
Sodium chloride	
Monopotassium phosphate	
Disodium phosphate monohydrate	
Water for injection	

Lyophilisate: whitish homogeneous pellet
Suspension: homogeneous appearance once shaken

3. CLINICAL INFORMATION

3.1 Target species

Muscovy ducks.

3.2 Indications for use for each target species

Active immunisation against Muscovy duck parvovirosis and Derzsy's disease.

Onset of immunity : 14 days.
Duration of immunity: 4 weeks of age (i.e. entire period of susceptibility of ducklings).

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Muscovy ducks:

Very common (> 1 animal / 10 animals treated):	Abnormal histology[1]

[1] In clinical studies, moderate and transient inflammatory reactions at the injection site were observed histologically in 50% of cases. No palpable reactions were observed.

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, its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay.

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 decided on a case by case basis.

3.9 Administration routes and dosage

Subcutaneous use.
One dose of 0.2 ml according to the following vaccination schedule:

First injection: at 1 day of age.
Second injection: 14 to 21 days later.

Apply the usual aseptic procedures.
Only disinfectant-free and/or antiseptic-free equipment should be used for the injection of vaccine solution.

Method of reconstitution:
Shake well the bottle of suspension until resuspension of the deposit.
Push the needle of a 5 ml syringe through the bottle closure of the suspension.
Suck up around 2 ml of suspension.
Push the needle of the filled syringe through the closure of the lyophilisate bottle.
Inject the volume of suspension.
Shake well the bottle of lyophilisate until complete dissolution of the pellet.
Suck up the reconstituted vaccine with the syringe and inject it into the bottle of suspension.
Shake well the bottle of reconstituted suspension before use.

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

No adverse event other than those mentioned in section 3.6 “Adverse events” have been observed after the injection of a 10-fold overdose of vaccine.

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 ATC vet code: QI01BH01.

The vaccine induces a specific protection against Muscovy duck parvovirosis and Derzsy’s disease in the vaccinated animal.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 15 months.
Shelf-life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2°C - 8°C).
Protect from light.

5.4 Nature and composition of immediate packaging

- Lyophilisate: Type I glass bottle closed with a butyl elastomer closure and sealed with an aluminium cap.
- Suspension: Polypropylene bottle closed with nitril elastomer closure and sealed with an aluminium cap.

Pack sizes:
Box containing 1 bottle of 500 doses (100 ml) of suspension and 1 bottle of 500 doses of lyophilisate.
Box containing 1 bottle of 1500 (300 ml) doses of suspension and 3 bottles of 500 doses of lyophilisate.
Box containing 10 bottles of 500 doses (10 x 100 ml) of suspension and 10 bottles of 500 doses of lyophilisate.
Box containing 10 bottles of 1500 doses (10 x 300 ml) of suspension and 30 bottles of 500 doses of lyophilisate.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

{DD/MM/YYYY}

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

{DD/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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 bottle of 500 doses of suspension and 1 bottle of 500 doses of lyophilisate.
Box of 1 bottle of 1500 doses of suspension of 3 bottles of 500 doses of lyophilisate.
Box of 10 bottles of 500 doses of suspension and 10 bottles of 500 doses of lyophilisate.
Box of 10 bottles of 1500 doses of suspension and 30 bottles of 500 doses of lyophilisate.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PARVOKAN lyophilisate and suspension for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (0.2 ml):

Muscovy duck parvovirus, strain GM, inactivated	≥ 1.5 $\log_{10}$ SN.U
Derzsy's disease virus, strain H, live attenuated	≥ 2.5 $\log_{10}$ $CCID_{50}$

3. PACKAGE SIZE

500 doses
1 x 500 doses (lyophilisate)
1 x 100 ml (suspension)

1 500 doses
3 x 500 doses (lyophilisate)
1 x 300 ml (suspension)

5 000 doses
10 x 500 doses (lyophilisate)
10 x 100 ml (suspension)

15 000 doses
30 x 500 doses (lyophilisate)
10 x 300 ml (suspension)

4. TARGET SPECIES

Muscovy ducks

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

14. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 500 doses of suspension
Bottle of 1500 doses of suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PARVOKAN suspension for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (0.2 ml):
Muscovy duck parvovirus, strain GM, inactivated ≥ 1.5 $\log_{10}$ SN.U

500 doses (100 ml)
1500 doses (300 ml)

3. TARGET SPECIES

Muscovy ducks

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days.

6. EXPIRY DATE

Exp. {dd/mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PARVOKAN lyophilisate

2. QUANTITATIVE PARTICULARSOF THE ACTIVE SUBSTANCES

500 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

PARVOKAN lyophilisate and suspension for suspension for injection

2. Composition

Each dose (0.2 ml) contains:

Active substances:

Suspension:	
Muscovy duck parvovirus, strain GM, inactivated	≥ 1.5 $\log_{10}$ SN.U[1]
Lyophilisate:	
Derzsy's Disease virus, strain H, live attenuated	≥ 2.5 $\log_{10}$ $CCID_{50}$

[1] SN.U: q.s. to obtain a mean seroneutralizing antibody titre of 1 $\log_{10}$ in the vaccinated animal

Adjuvant:

Suspension:	
Al3+ (as aluminium hydroxide)	0.42 mg

Excipient:

Suspension:	
Thiomersal	≤ 20 mcg

Lyophilisate: whitish homogeneous pellet
Suspension: homogeneous appearance once shaken

3. Target species

Muscovy ducks.

4. Indications for use

Active immunisation against Muscovy duck parvovirosis and Derzsy's disease.
Onset of immunity: 14 days.
Duration of immunity: 4 weeks of age (i.e. entire period of susceptibility of ducklings).

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.

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.

Laying birds:
The safety of the veterinary medicinal product has not been established during lay.

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 decided on as case by case basis.

Overdose:
No adverse event other than those mentioned in section "Adverse events" have been observed after the injection of a 10-fold overdose of vaccine.

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

7. Adverse events

Muscovy ducks:
Very common (> 1 animal / 10 animals treated): Abnormal histology[1]
[1] In clinical studies, moderate and transient inflammatory reactions at the injection site were observed histologically in 50% of cases. No palpable reactions were observed.

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

Subcutaneous use.
One dose of 0.2 ml according to the following vaccination schedule:

First injection: at 1 day of age.
Second injection: 14 to 21 days later.

9. Advice on correct administration

Apply the usual aseptic procedures.
Only disinfectant-free and/or antiseptic-free equipment should be used for the injection of vaccine solution.

Shake well the bottle of suspension until resuspension of the deposit.
Push the needle of a 5 ml syringe through the bottle closure of the suspension.
Suck up around 2 ml of suspension.
Push the needle of the filled syringe through the closure of the lyophilisate bottle.
Inject the volume of suspension.
Shake well the bottle of lyophilisate pellet until complete dissolution of the pellet.
Suck up the reconstituted vaccine with the syringe and inject it into the bottle of suspension.
Shake well the bottle of reconstituted suspension 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 use this veterinary medicinal product after the expiry date which is stated on the label after "Exp.".
Shelf-life after reconstitution according to directions: 2 hours.

12. Special precautions for the disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Pack sizes:
Box containing 1 bottle of 500 doses (100 ml) of suspension and 1 bottle of 500 doses of lyophilisate.
Box containing 1 bottle of 1500 doses (10 x 100 ml) of suspension of 3 bottles of 500 doses of lyophilisate.
Box containing 10 bottles of 500 doses (300 ml) of suspension and 10 bottles of 500 doses of lyophilisate.
Box containing 10 bottles of 1500 doses (10 x 300 ml) of suspension and 30 bottles of 500 doses of lyophilisate.

Not all pack sizes may be marketed.

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 and contact details to report suspected adverse reactions:
To be completed nationally.

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse reactions:
To be completed nationally.

17. Other information

The vaccine induces a specific protection against Muscovy duck parvovirosis and Derzsy's disease in the vaccinated animal.