ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD Suspension and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of vaccine contains:

Active substance:

Live vHVT013-69 recombinant virus, at least ..... 3.6 to 5.0 log10 PFU*
Excipients ..... qs 1 dose

Diluent:

Diluent ..... qs 1 dose

*Plaque forming unit

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension and solvent for suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Day-old chickens and 18 days embryonated eggs.

4.2 Indications for use, specifying the target species

For active immunisation of chickens:

- To prevent mortality and to reduce clinical signs and lesions of Infectious Bursal disease.
  The onset of protection is from 2 weeks and the protection extends to 9 weeks.
- To reduce mortality, clinical signs and lesions of Marek's disease.
  The onset of protection is from 4 days. A single vaccination is sufficient to provide protection during the risk period.

4.3 Contraindications

Do not use in birds in lay and breeding birds.

4.4 Special warnings

Vaccinate only healthy birds.

4.5 Special precautions for use

Special precautions for use in animals

Apply the usual aseptic precautions to all administration procedures.
As a live vaccine, the vaccine strain is excreted from vaccinated birds and may spread to turkeys. Safety and reversion to virulence trials have shown that the strain is safe for turkeys. However, precautionary measures have to be followed in order to avoid direct or indirect contact between vaccinated chickens and turkeys.

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

Wear protective gloves and spectacles during the ampoule thawing and opening operations.
Open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not use in breeding birds and birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

For subcutaneous route:

Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Merial attenuated vaccines against Marek's disease Rispens strain.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Merial attenuated vaccines against Newcastle disease and Infectious bronchitis.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

For *in ovo* route:

In the absence of specific studies, no other veterinary medicinal product should be administered concurrently with the product.

4.9 Amounts to be administered and administration route

Reconstitution of the vaccine

- Wear protective gloves and spectacles during the ampoule thawing and opening operations.
- Remove from the liquid nitrogen container only those ampoules which are to be used immediately.
- Thaw the contents of the ampoules rapidly by agitation in water at 25°C-30°C. Proceed immediately to next step.
- As soon as they are thawed, open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.
- Once the ampoule is opened, draw up the contents into a 5 ml sterile syringe.
- Transfer the suspension into the diluent (Do not use if cloudy).

- Draw up 2 ml of the contents of the diluent into the syringe.
- Rinse the ampoule with these 2 ml and then transfer the rinsing liquid into the diluent. Repeat the rinsing operation once or twice.
- Repeat the thawing, opening, transfer and rinsing operations for the appropriate number of ampoules to be reconstituted in the diluent; either 1 ampoule of 1,000 doses of vaccine per 200 ml of diluent (or 1 ampoule of 2,000 doses of vaccine per 400 ml of diluent) for subcutaneous administration, or 4 ampoules of 1,000 doses of vaccine per 200 ml of diluent (or 4 ampoules of 2,000 doses of vaccines per 400 ml of diluent) for *in ovo* administration.
- The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use. It should be used immediately after the preparation (all of the diluted vaccine should be used up within one hour). This is why the vaccine suspension should only be prepared as and when required.

Posology

One single injection of 0.2 ml per chicken at the age of one day, by subcutaneous route.
One single injection of 0.05 ml per chicken egg at 18 days of embryonation, by *in ovo* route.

Method of administration

The vaccine must be administered by subcutaneous route or by *in ovo route*.

For *in ovo* administration, an automated egg injection machine can be used. The device should be proven to safely and effectively deliver the appropriate dose. The instructions for use of this device should be strictly followed.

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

None known.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code QI01AD15

Live recombinant vaccine against Infectious Bursal Disease and Marek's Disease.

The vaccine strain is a recombinant Herpesvirus of turkeys (HVT) expressing the protective antigen (VP2) of the Infectious Bursal Disease Virus (IBDV) strain Faragher 52/70.
The vaccine induces an active immunity and a serological response against Infectious Bursal Disease and Marek's Disease in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Suspension:

Dimethyl sulfoxide
Dilution medium

Diluent:

Sucrose
Casein hydrolysate
Phenol red 1% solution
Salts

6.2 Incompatibilities

Use sterile and antiseptic-free and/or disinfectant-free equipment for injections purposes.
Do not mix with any other veterinary medicinal product except those mentioned in section 4.8 and the diluent supplied for use with the product.

6.3 Shelf life

Shelf life of the non-reconstituted vaccine: 36 months at –196°C
Shelf life of the reconstituted vaccine: up to 2 hours at a temperature below 25°C.
Shelf life of the diluent in polypropylene bottles: 12 months at a temperature below 30°C.
Shelf life of the diluent in polyvinylchloride bags: 36 months at a temperature below 30°C.

6.4 Special precautions for storage

Store the vaccine in liquid nitrogen.
Store the reconstituted vaccine at a temperature below 25°C.
Store the diluent below 30°C. Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

- (glass) ampoule of 1,000 doses of vaccine, 5-ampoule carrier.
- (glass) ampoule of 2,000 doses of vaccine, 4-ampoule carrier.
  Ampoule carriers are stored in canister, and in liquid nitrogen containers.
- (polypropylene) bottle of 200ml of diluent
- (polyvinylchloride) bag of 200ml, 400ml, 600ml, 800ml, 1000ml, 1200ml, 1400ml, 1600ml, 1800ml or 2400ml of diluent.

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

Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances. Do not re-use opened containers of diluted vaccine.

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

MERIAL
29 Avenue Tony Garnier
69007 LYON,
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/02/032/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09/08/2002
Date of last renewal: 06/07/2012

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. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

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

Name and address of the manufacturers of the biological active substance(s)

Merial Laboratoire Lyon Gerland,
254 rue Marcel Merieux
69007 Lyon
France

Merial Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
France

Name and address of the manufacturer responsible for batch release

Merial Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
France

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, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or 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 product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to 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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{AMPOULE 1000 and 2000 doses}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

1000 doses
2000 doses

4. ROUTE(S) OF ADMINISTRATION

SC or *in ovo* route

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

STERILE DILUENT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

STERILE DILUENT

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

1 bottle of 200 ml

1 bag of 200 ml
1 bag of 400 ml
1 bag of 600 ml.
1 bag of 800 ml.
1 bag of 1000 ml.
1 bag of 1200 ml.
1 bag of 1400 ml.
1 bag of 1600 ml.
1 bag of 1800 ml.
1 bag of 2400 ml

5. TARGET SPECIES

Chickens

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet supplied with the vaccine vial before use.

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Use immediately after preparation.
Do not use if cloudy.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store below 30°C. Do not freeze.

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

Read the package leaflet supplied with the vaccine vial before use.

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

MERIAL
29 Avenue Tony Garnier
69007 Lyon
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/02/032/001
EU/2/02/032/002

17. MANUFACTURER'S BATCH NUMBER

Lot

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Vaxxitek HVT+IBD suspension and solvent for suspension for injection

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

Marketing authorisation holder

MERIAL
29 Avenue Tony Garnier
69007 Lyon, France

Manufacturer responsible for batch release

MERIAL
Laboratory of Lyon Porte des Alpes
Rue de l'Aviation,
69800 Saint-Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vaxxitek HVT+IBD Suspension and solvent for suspension for injection

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

Each dose of vaccine contains:

Active ingredient:

Live vHVT013-69 recombinant virus, at least ..... 3.6 to 5.0 log10 PFU
Excipient ..... qs 1 dose

Diluent:

Diluent ..... qs 1 dose

4. INDICATION(S)

For active immunisation of chickens:

- To prevent mortality and to reduce clinical signs and lesions of Infectious Bursal disease.
  The onset of protection is from 2 weeks and the protection extends to 9 weeks.
- To reduce mortality, clinical signs and lesions of Marek's disease.
  The onset of protection is from 4 days. A single vaccination is sufficient to provide protection during the risk period.

5. CONTRAINDICATIONS

Do not use in birds in lay and breeding birds.

6. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Day-old chickens and 18 days embryonated eggs.

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

Subcutaneous or *in ovo* route.

For *in ovo* administration, an automated egg injection machine can be used. The device should be proven to safely and effectively deliver the appropriate dose. The instructions for use of this device should be strictly followed.

Subcutaneous route: one single injection of 0.2 ml per chicken at the age of one day.

In ovo route: one single injection of 0.05 ml per egg at 18 days of embryonation.

9. ADVICE ON CORRECT ADMINISTRATION

- Wear protective gloves and spectacles during the ampoule thawing and opening operations.
- Remove from the liquid nitrogen container only those ampoules which are to be used immediately.
- Thaw rapidly the contents of the ampoules by agitation in water at 25°C-30°C. Proceed immediately to next step.
- As soon as they are thawed, open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.
- Once the ampoule is opened, draw up the contents into a 5 ml sterile syringe.
- Transfer the suspension into the diluent (Do not use if cloudy).
- Draw up 2 ml of the contents of the diluent into the syringe.
- Rinse the ampoule with these 2 ml and then transfer the rinsing liquid into the diluent. Repeat the rinsing operation once or twice.
- Repeat the thawing, opening, transfer and rinsing operations for the appropriate number of ampoules to be reconstituted in the diluent; either 1 ampoule of 1,000 doses of vaccine per 200 ml of diluent (or 1 ampoule of 2,000 doses of vaccine per 400 ml of diluent) for subcutaneous administration, or 4 ampoules of 1,000 doses of vaccine per 200 ml of diluent (or 4 ampoules of 2,000 doses of vaccine per 400 ml of diluent) for *in ovo* administration.
- The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use. It should be used immediately after the preparation (all of the diluted vaccine should be used up within one hour). This is why the vaccine suspension should only be prepared as and when required

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store the vaccine in liquid nitrogen.

Do not use after the expiry date stated on the ampoule.

Shelf life of the reconstituted vaccine: up to 2 hours at a temperature below 25°C.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccinate only healthy birds.
Apply the usual aseptic precautions to all administration procedures.
As a live vaccine, the vaccine strain is excreted from vaccinated birds and may spread to turkeys. Safety and reversion to virulence trials have shown that the strain is safe for turkeys. However, precautionary measures have to be followed in order to avoid direct or indirect contact between vaccinated chickens and turkeys.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wear protective gloves and spectacles during the ampoule thawing and opening operations.
Open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.

Lay:
Do not use in breeding birds and birds in lay.

Interaction with other medicinal products and other forms of interaction:

For subcutaneous route:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed with Merial attenuated vaccines against Marek's disease Rispens strain.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Merial attenuated vaccines against Newcastle disease and Infectious bronchitis.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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.

For *in ovo* route:
In the absence of specific studies, no other veterinary medicinal product should be administered concurrently with the product.

Use sterile and antiseptic-free and/or disinfectant-free equipment for injections purposes.
Do not mix with any other veterinary medicinal product except those mentioned in the above paragraph and the diluent supplied for use with the product.

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

Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.
Do not re-use opened containers of diluted vaccine.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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

Live recombinant vaccine against Infectious Bursal Disease and Marek's Disease.

The vaccine strain is a recombinant Herpesvirus of turkeys (HVT) expressing the protective antigen (VP2) of the Infectious Bursal Disease Virus (IBDV) strain Faragher 52/70.
The vaccine induces an active immunity and a serological response against Infectious Bursal Disease and Marek's Disease in chickens.

- (glass) ampoule of 1,000 doses of vaccine, 5-ampoule carrier.
- (glass) ampoule of 2,000 doses of vaccine, 4-ampoule carrier.
  Ampoule carriers are stored in canister, and in liquid nitrogen containers.
- (polypropylene) bottle of 200ml of diluent.
- (polyvinylchloride) bag of 200ml, 400ml, 600ml, 800ml, 1000ml, 1200ml, 1400ml, 1600ml, 1800ml or 2400ml of diluent

Not all pack sizes may be marketed.

Veterinary medicinal product subject to prescription.

PACKAGE LEAFLET FOR
STERILE DILUENT

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

Marketing authorisation holder:

MERIAL
29 avenue Tony Garnier
69007 Lyon, France

Manufacturer responsible for batch release:

MERIAL
Laboratory of Lyon Porte des Alpes
Rue de l'Aviation,
69800 Saint-Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

STERILE DILUENT

3. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

4. TARGET SPECIES

Chickens.

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

Read the package leaflet supplied with the vaccine vial.

6. ADVICE ON CORRECT ADMINISTRATION

Frozen vaccines:

- Wear protective gloves and spectacles during the ampoule thawing and opening operations.
- Remove from the liquid nitrogen container only those ampoules which are to be used immediately.
- Thaw rapidly the contents of the ampoules by agitation in water at 25°C-30°C. Proceed immediately to next step.
- As soon as they are thawed, open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.
- Once the ampoule is opened, draw up the contents into a 5 ml sterile syringe.
- Transfer the suspension into the diluent.

- Draw up 2 ml of the contents of the diluent into the syringe.
- Rinse the ampoule with these 2 ml and then transfer the rinsing liquid into the diluent. Repeat the rinsing operation once or twice.
- Repeat the thawing, opening, transfer and rinsing operations for the appropriate number of ampoules to be reconstituted in the diluent; either 1 ampoule of 1,000 doses of vaccine per 200 ml of diluent (or 1 ampoule of 2,000 doses of vaccine per 400 ml of diluent) for subcutaneous administration, or 4 ampoules of 1,000 doses of vaccine per 200 ml of diluent (or 4 ampoules of 2,000 doses of vaccine per 400 ml of diluent) for *in ovo* administration.
- The diluted vaccine prepared as described is mixed by gentle agitation so as to be ready for use. It should be used immediately after the preparation (all of the diluted vaccine should be used up within one hour). This is why the vaccine suspension should only be prepared as and when required.

7. WITHDRAWAL PERIOD

Zero days.

8. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 30°C. Do not freeze.

9. SPECIAL WARNING(S)

Use immediately after preparation.
Do not use if cloudy.

10. 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 products should be disposed of in accordance with local requirements.

11. 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/.

12. OTHER INFORMATION

This diluent may be used with the following products:
Vaxxitek HVT+IBD (EU/2/02/032/001-002)