ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Myxo-RHD lyophilisate and solvent for suspension for injection for rabbits

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:
Live myxoma vectored RHD virus strain 009: $\geq 10^{3.0}$ and $\leq 10^{6.1}$ FFU*

*Focus Forming Units

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Rabbits

4.2 Indications for use, specifying the target species

For active immunisation of rabbits from 5 weeks of age onwards to reduce mortality and clinical signs of myxomatosis and to prevent mortality due to rabbit haemorrhagic disease

Onset of immunity: 3 weeks.
Duration of immunity: 1 year.

4.3 Contraindications

None

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy rabbits.
Rabbits that have been vaccinated previously with another myxomatosis vaccine, or that have experienced natural myxomatosis infection in the field, may not develop a proper immune response against rabbit haemorrhagic disease following vaccination.

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

None

4.6 Adverse reactions (frequency and seriousness)

A transient temperature increase of 1-2° C can occur. A small, non-painful swelling (maximum 2 cm diameter) at the injection site is commonly observed within the first two weeks after vaccination. The swelling will resolve completely by 3 weeks after vaccination.

4.7 Use during pregnancy and lactation

Studies involving the use of the vaccine during early pregnancy were inconclusive, therefore vaccination is not recommended during the first 14 days of pregnancy.

No safety study on the reproductive performance has been conducted in male rabbits (bucks). Therefore, the vaccination of breeding bucks is not recommended.

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

After reconstitution, administer 1 dose of vaccine by subcutaneous injection to rabbits from 5 weeks of age onwards.

Revaccinate annually.

Ensure that the lyophilisate is completely reconstituted before use.

Single dose vial
Reconstitute a single dose vial of vaccine with 1 ml of Nobivac Myxo RHD solvent and inject the total contents of the vial.

50-dose vial

Solvent volume	Number of vials of freeze-dried vaccine to be added	Injection volume	Total number of rabbits that can be vaccinated
10 ml	1	0.2 ml	50
50 ml	5	0.2 ml	250

For proper reconstitution of the multidose vial, use the following procedure:
1. Add 1-2 ml of Nobivac Myxo RHD solvent to the 50-dose vaccine vial(s) and ensure that the lyophilisate is fully dissolved.
2. Withdraw the reconstituted vaccine concentrate from the vial(s) and inject it back into the Nobivac Myxo RHD solvent vial.
3. Ensure that the resulting vaccine suspension in the Nobivac Myxo RHD solvent vial is properly mixed.
4. Use the vaccine suspension within 4 hours of reconstitution. Any reconstituted vaccine remaining at the end of this time should be discarded.

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

In addition to the signs observed after single dose vaccination, a mild swelling of the local lymph nodes may be observed within the first 3 days after overdose vaccination.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: live viral vaccine, ATCvet code: QI08AD

To stimulate immunity against myxoma virus and rabbit haemorrhagic disease virus.

The vaccine strain is a myxoma virus expressing the capsid protein gene of rabbit haemorrhagic disease virus. As a consequence rabbits are immunised against both myxoma virus and rabbit haemorrhagic disease virus.

After infection with virulent myxoma virus some vaccinated animals may develop a few very small swellings, especially on hairless places of the body, which quickly form scabs. The scabs usually disappear within 2 weeks after the small swellings have been observed. These scabs are only observed in animals with active immunity and have no influence on the general health, appetite or behaviour of the rabbit.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrolysed gelatine
Pancreatic digest of casein
Sorbitol
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

Shelf-life of the lyophilisate as packaged for sale: 2 years.
Shelf-life of the solvent as packaged for sale:
- 1 ml and 10 ml Glass vials: 4 years.
- 50 ml PET vials: 2 years

Shelf-life after reconstitution according to directions: 4 hours.

6.4. Special precautions for storage

Lyophilisate:
Store in a refrigerator (2°C - 8°C).
Do not freeze.
Protect from light.

Solvent (50 ml PET vial):
Store in a refrigerator (2°C - 8°C).
Do not freeze.

Solvent (1 ml and 10 ml glass vial):
No special precautions for storage.
Do not freeze

6.5 Nature and composition of immediate packaging

Lyophilisate:
Glass vial of 1 or 50 doses with a halogenobutyl rubber stopper and aluminium cap

Solvent:
Glass vial of 1 ml or 10 ml, or polyethylene terephthalate (PET) bottle of 50 ml with a halogenobutyl rubber stopper and aluminium cap

Packaging:
Box with 5 x 1 dose vial of vaccine and 5 x 1 ml vial of solvent.
Box with 25 x 1 dose vial of vaccine and 25 x 1 ml vial of solvent.
Box with 10 x 50 doses vial of vaccine
2 Boxes with 1 x 50 ml vial of solvent
Box with 10 x 10 ml vial of solvent

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

{DD/MM/YYYY}

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Nobivac Myxo-RHD is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use Nobivac Myxo-RHD must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance
Intervet International BV, site De Bilt
Ambachtstraat 4
3732 CN De Bilt
The Netherlands

Name and address of the manufacturer responsible for batch release
Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

B. CONDITIONS OF THE MARKETING AUTHORISATION

- Conditions or restrictions regarding supply and use imposed on the marketing authorisation holder

Veterinary medicinal product subject to prescription

- Conditions or restrictions with regard to the safe and effective use of the medicinal product

Not applicable

- Other conditions

Pharmacovigilance system
The MAH must ensure that the system of pharmacovigilance, as described in Part I of the marketing authorisation application, is in place and functioning before and whilst the product is on the market.

C. STATEMENT OF THE MRLS

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

5 x 1 dose of vaccine including solvent
25 x 1 dose of vaccine including solvent
10 x 50 doses of vaccine - 10 ml glass solvent vials
10 x 50 doses of vaccine - 50 ml PET solvent vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Myxo-RHD lyophilisate and solvent for suspension for injection for rabbits

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Live myxoma vectored RHD virus strain 009, $\geq 10^{3.0}$ FFU*/dose.

*Focus Forming Units

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZE

5x 1 dose of vaccine including solvent
25 x 1 dose of vaccine including solvent
10 x 50 doses of vaccine 10 ml glass solvent vials
10 x 50 doses of vaccine 50 ml PET solvent vials

5. TARGET SPECIES

Rabbits

6. INDICATION(S)

Live vaccine against myxomatosis and rabbit haemorrhagic disease

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Not applicable.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

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

Read the package leaflet 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 REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
NL - 5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/001
EU/0/00/000/002
EU/0/00/000/003
EU/0/00/000/004

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS - Vaccine

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Myxo-RHD

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Live myxoma vectored RHD virus

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

1 dose
50 doses

4. ROUTE(S) OF ADMINISTRATION

s.c.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT

1ml and 10 ml glass vials

1. NAME OF THE SOLVENT

Nobivac Myxo-RHD - Solvent

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

1 ml
10 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT

50 ml PET vials

1. NAME OF THE SOLVENT

Nobivac Myxo RHD - Solvent

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

50 ml

3. STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C)
Do not freeze.

4. BATCH NUMBER

Lot {number}

5. EXPIRY DATE

EXP {month/year}

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Nobivac Myxo-RHD, lyophilisate and solvent for suspension for injection, for rabbits

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

Intervet International B.V.
Wim de Körverstraat 35
NL- 5831 AN Boxmeer

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobivac Myxo-RHD lyophilisate and solvent for suspension for injection for rabbits

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

Each dose of reconstituted vaccine contains:

Live myxoma vectored RHD virus strain 009: $\geq 10^{3.0}$ and $\leq 10^{6.1}$ FFU*

*Focus Forming Units

4. INDICATION(S)

For active immunisation of rabbits to reduce mortality and clinical signs of myxomatosis and to prevent mortality due to rabbit haemorrhagic disease.

Onset of immunity: 3 weeks.
Duration of immunity: 1 year.

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A transient temperature increase of 1-2° C can occur. A small, non-painful swelling (max. 2 cm diameter) at the injection site is commonly observed within the first two weeks after vaccination. The swelling will resolve completely by 3 weeks after vaccination.

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

7. TARGET SPECIES

Rabbits

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

After reconstitution, administer 1 dose of vaccine by subcutaneous injection to rabbits from 5 weeks of age onwards.

Revaccinate annually.

Single-dose Vials
Reconstitute a single dose vial of vaccine with 1 ml of Nobivac Solvent and inject the total contents of the vial.

Multi-dose Vials

Solvent volume	Number of vials of freeze-dried vaccine to be added	Injection volume	Total number of rabbits that can be vaccinated
10 ml	1	0.2 ml	50
50 ml	5	0.2 ml	250

For proper reconstitution of the multidose vial, use the following procedure:
1. Add 1-2 ml of Nobivac Myxo RHD solvent to the 50-dose vaccine vial(s) and ensure that the lyophilisate is fully dissolved.
2. Withdraw the reconstituted vaccine concentrate from the vial(s) and inject it back into the Nobivac Myxo RHD solvent vial.
3. Ensure that the resulting vaccine suspension in the Nobivac Myxo RHD solvent vial is properly mixed.
4. Use the vaccine suspension within 4 hours of reconstitution. Any reconstituted vaccine remaining at the end of this time should be discarded.

9. ADVICE ON CORRECT ADMINISTRATION

Ensure that the lyophilisate is completely reconstituted before use.

10. WITHDRAWAL PERIOD

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Vaccine: Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light.
Solvent:
- Glass vials (1 ml or 10 ml): No special precautions for storage. Do not freeze.
- PET vials (50 ml): Store in a refrigerator (2°C - 8°C). Do not freeze.

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

Shelf-life after reconstitution according to directions: 4 hours

12. SPECIAL WARNING(S)

Vaccinate only healthy rabbits.

Studies involving the use of the vaccine during early pregnancy were inconclusive, therefore vaccination is not recommended during the first 14 days of pregnancy.

No safety study on the reproductive performance has been conducted in male rabbits (bucks). Therefore, the vaccination of breeding bucks is not recommended.

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.

Rabbits that have been vaccinated previously with another myxomatosis vaccine, or that have experienced natural myxomatosis infection in the field, may not develop a proper immune response against rabbit haemorrhagic disease following vaccination.

In addition to the signs observed after single dose vaccination, a mild swelling of the local lymph nodes may be observed within the first 3 days after overdose vaccination.

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

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To stimulate immunity against myxoma virus and rabbit haemorrhagic disease virus.
The vaccine strain is a myxoma virus expressing the capsid protein gene of rabbit haemorrhagic disease virus. As a consequence rabbits are immunised against both myxoma virus and rabbit haemorrhagic disease virus.

The vector technology used to develop the vaccine strain allows the RHD virus component to be produced *in vitro* instead of using live rabbits for cultivation.

After infection with virulent myxoma virus some vaccinated animals may develop a few very small swellings, especially on hairless places of the body, which quickly form scabs. The scabs usually disappear within 2 weeks after the small swellings have been observed. These scabs are only observed in animals with active immunity and have no influence on the general health, appetite or behaviour of the rabbit.

Single dose
Box with 5 x 1 dose vial of vaccine and 5 x 1 ml vial of solvent
Box with 25 x 1 dose vial of vaccine and 25 x 1 ml vial of solvent

Multi-dose
Box with 10 x 50 doses vial of vaccine
2 Boxes with 1 x 50 ml vial of solvent

Box with 10 x 10 ml vial of solvent

Not all pack sizes may be marketed.