ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate and solvent for suspension for injection for cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Lyophilisate:
Active substances:
Modified live BVDV*-1, non-cytopathic parent strain KE-9: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$**,
Modified live BVDV*-2, non-cytopathic parent strain NY-93: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$**.

* Bovine viral diarrhoea virus
** Tissue culture infectious dose 50%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

Lyophilisate: Off-white colour without foreign matter.
Solvent: Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

For active immunisation of cattle from 3 months of age to reduce hyperthermia and to minimise the reduction of leukocyte count caused by bovine viral diarrhoea virus (BVDV-1 and BVDV-2), and to reduce virus shedding and viraemia caused by BVDV-2.

For active immunisation of cattle against BVDV-1 and BVDV-2, to prevent the birth of persistently infected calves caused by transplacental infection.

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

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
To ensure the protection of animals introduced to the herd where BVDV is circulating, vaccination has to be completed 3 weeks before introduction.

The cornerstone of bovine viral diarrhoea (BVD)-eradication is identification and culling of persistently infected animals. A definitive diagnosis of persistent infection can only be established upon re-testing in blood after an interval of at least 3 weeks. In some limited cases with newborn calves, positive ear notches for BVDV vaccine strain were reported by molecular diagnostic tests. Additional laboratory tests to differentiate vaccine strain virus from field strain are available upon request from the marketing authorisation holder.

The field studies to investigate the efficacy of the vaccine were done in herds where persistently infected animals had been removed.

4.5 Special precautions for use

Special precautions for use in animals:
Longlasting viremia has been observed after vaccination, in particular in pregnant seronegative heifers (10 days in a study). This may result in transplacental transmission on the vaccine virus, but no adverse effects on foetus or pregnancy was observed in studies.

Shedding of the vaccine virus by body fluids cannot be excluded.
The vaccine strains are able to infect sheep and swine when administered intranasally, but no adverse reactions or spreading to in-contact animals has been demonstrated.
The vaccine has not been tested in breeding bulls and should therefore not be used in breeding bulls.

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)

An increase in body temperature within the physiological range is common within 4 hours of vaccination and spontaneously resolves within 24 hours (clinical studies).

Mild swellings or nodules up to 3 cm diameter were observed at the injection site and disappeared within 4 days post vaccination (clinical studies).

Hypersensitivity reactions, including anaphylactic-type reactions, have been reported very rarely (post-marketing safety experience).

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

Pregnancy and lactation:
It is recommended to vaccinate before pregnancy to ensure protection against persistent infection of the foetus. While persistent infection of the foetus caused by the vaccine was not observed, transmission of vaccine virus to the foetus may occur. Therefore, use during pregnancy should only be on a case-by-case basis decided by the responsible veterinarian, taking into consideration e.g. the BVD immunological status of the animal, the time-span between vaccination and mating/insemination, the stage of pregnancy and the risk of infection.

Can be used during lactation.
Studies have shown that vaccine virus may be excreted in milk up to 23 days after vaccination at low amounts (~ 10 $TCID_{50}$/ml), although when such milk was fed to calves, no seroconversion occurred in those calves.

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

Intramuscular use.

Preparation of vaccine for use (reconstitution):
Reconstitute the lyophilisate by adding the full content of the solvent at room temperature.
Ensure that the lyophilisate is completely reconstituted before use.
The reconstituted vaccine is transparent and colourless.
Avoid multiple broaching.

Primary vaccination:
After reconstitution, administer one dose (2 ml) of the vaccine by intramuscular (IM) injection.
It is recommended to vaccinate cattle at least 3 weeks before insemination/mating to provide foetal protection from the first day of conception. Animals which are vaccinated later than 3 weeks before gestation or during the early gestation may not be protected against foetal infection. This should be considered in case of herd vaccination.

Recommended re-vaccination programme:
Revaccination is recommended after 1 year.
12 months after primary vaccination most studied animals still had antibody titres at plateau while some animals had lower titres.

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

Mild swellings or nodules up to 3 cm diameter were observed at the injection site after administration of a 10-fold overdose and disappeared within 4 days post vaccination.

Furthermore, an increase of the rectal body temperature was common within 4 hours following administration and spontaneously resolves within 24 hours (see section 4.6).

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for bovidae, live viral vaccines.
ATCvet code: QI02AD02.

The vaccine is designed to stimulate the development of an active immune response against BVDV-1 and BVDV-2 in cattle.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sucrose
Gelatine
Potassium hydroxide
L-Glutamine acid
Potassium dihydrogen phosphate
Dipotassium phosphate
Sodium chloride
Water for injections

Solvent:
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

Lyophilisate:
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Solvent:
Shelf life of the solvent: 3 years.

Shelf life after reconstitution according to directions: 8 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the lyophilisate and the solvent vials in the outer carton.

6.5 Nature and composition of immediate packaging

Lyophilisate:
Type I amber glass vials closed with siliconised bromobutyl rubber stopper with lacquered aluminium seal.

Solvent:
High density polyethylene (HDPE) bottles sof solvent, closed with a siliconised chlorobutyl rubber stopper with lacquered aluminium seal.

1 lyophilisate vial of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 1 solvent bottle of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

4 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 4 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

6 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 6 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

10 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 10 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/176/001-016

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22.12.2014
Date of last renewal:

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

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 SUBSTANCE AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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

Name and address of the manufacturer of the biological active substance
Boehringer Ingelheim Animal Health USA Inc.
2621 North Belt Highway, St. Joseph, Missouri, 64506-2002
USA

Name and address of the manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

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 produce active immunity is not in the scope of Regulation (EC) 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.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

Specific pharmacovigilance requirements:

Periodic safety update reports are required at yearly intervals.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box: 5 doses, 10 doses, 25 doses, 50 doses lyophilisate and 10 ml, 20 ml, 50 ml, 100 ml solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate and solvent for suspension for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
Bovine viral diarrhoea virus type 1: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$,
Bovine viral diarrhoea virus type 2: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection

4. PACKAGE SIZES

5 doses (10 ml)
10 doses (20 ml)
25 doses (50 ml)
50 doses (100 ml)
4 x 5 doses (10 ml)
4 x 10 doses (20 ml)
4 x 25 doses (50 ml)
4 x 50 doses (100 ml)
6 x 5 doses (10 ml)
6 x 10 doses (20 ml)
6 x 25 doses (50 ml)
6 x 50 doses (100 ml)
10 x 5 doses (10 ml)
10 x 10 doses (20 ml)
10 x 25 doses (50 ml)
10 x 50 doses (100 ml)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular 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 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Keep the vials in the outer carton.

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. 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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/14/176/001 5 doses and 10 ml
EU/2/14/176/002 5 doses and 10 ml (4 x)
EU/2/14/176/003 5 doses and 10 ml (6 x)
EU/2/14/176/004 5 doses and 10 ml (10 x)

EU/2/14/176/005 10 doses and 20 ml
EU/2/14/176/006 10 doses and 20 ml (4 x)
EU/2/14/176/007 10 doses and 20 ml (6 x)
EU/2/14/176/008 10 doses and 20 ml (10 x)
EU/2/14/176/009 25 doses and 50 ml
EU/2/14/176/010 25 doses and 50 ml (4 x)
EU/2/14/176/011 25 doses and 50 ml (6 x)
EU/2/14/176/012 25 doses and 50 ml (10 x)
EU/2/14/176/013 50 doses and 100 ml
EU/2/14/176/014 50 doses and 100 ml (4 x)
EU/2/14/176/015 50 doses and 100 ml (6 x)
EU/2/14/176/016 50 doses and 100 ml (10 x)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Lyophilisate vials: 50 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate for suspension for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:
BVDV-1: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$,
BVDV-2: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection

4. PACKAGE SIZE

50 doses (100 ml)

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

IM
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: 8 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Keep the vial in the outer carton.

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. 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

Boehringer Ingelheim Vetmedica GmbH
GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/14/176/013 50 doses
EU/2/14/176/014 4 x 50 doses
EU/2/14/176/015 6 x 50 doses
EU/2/14/176/016 10 x 50 doses

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vials: 5 doses, 10 doses and 25 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate for suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (2 ml) contains:
BVDV-1: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$,
BVDV-2: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$.

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

5 doses (10 ml)
10 doses (20 ml)
25 doses (50 ml)

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use within: 8 hours.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent bottles: 10 ml, 20 ml, 50 ml, 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Bovela

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

10 ml
20 ml
50 ml
100 ml

3. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

4. STORAGE CONDITIONS

Store and transport refrigerated.
Keep the bottle in the outer carton.

5. BATCH NUMBER

Lot {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bovela lyophilisate and solvent for suspension for injection for cattle

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:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovela lyophilisate and solvent for suspension for injection for cattle

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

Each dose (2 ml) contains:

Lyophilisate:
Modified live BVDV*-1, non-cytopathic parent strain KE-9: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$**,
Modified live BVDV*-2, non-cytopathic parent strain NY-93: $10^{4.0}$–$10^{6.0}$ $TCID_{50}$**.

* Bovine viral diarrhoea virus
** Tissue culture infectious dose 50%

Lyophilisate: Off-white colour without foreign matter.
Solvent: Clear, colourless solution.

4. INDICATION(S)

For active immunisation of cattle from 3 months of age to reduce hyperthermia and to minimise the reduction of leukocyte count caused by bovine viral diarrhoea virus (BVDV-1 and BVDV-2), and to reduce virus shedding and viraemia caused by BVDV-2.

For active immunisation of cattle against BVDV-1 and BVDV-2, to prevent the birth of persistently infected calves caused by transplacental infection.

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

5. CONTRAINDICATION

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. ADVERSE REACTIONS

An increase in body temperature within the physiological range is common within 4 hours of vaccination and spontaneously resolves within 24 hours (clinical studies).

Mild swellings or nodules up to 3 cm diameter were observed at the injection site and disappeared within 4 days post vaccination (clinical studies).

Hypersensitivity reactions, including anaphylactic-type reactions, have been reported very rarely (post-marketing safety experience).

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

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

Intramuscular use.

Primary vaccination:
After reconstitution, administer one dose (2 ml) of the vaccine by intramuscular (IM) injection.
It is recommended to vaccinate cattle at least 3 weeks before insemination/mating to provide foetal protection from the first day of conception. Animals which are vaccinated later than 3 weeks before gestation or during the early gestation may not be protected against foetal infection. This should be considered in case of herd vaccination.

Recommended re-vaccination programme:
Revaccination is recommended after 1 year.
12 months after primary vaccination most studied animals still had antibody titres at plateau while some animals had lower titres.

9. ADVICE ON CORRECT ADMINISTRATION

Preparation of vaccine for use (reconstitution):
Reconstitute the lyophilisate by adding the full content of the solvent at room temperature.
Ensure that the lyophilisate is completely reconstituted before use.
The reconstituted vaccine is transparent and colourless.
Avoid multiple broaching.

10. WITHDRAWAL PERIOD(S)

Withdrawal period: 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 freeze.
Keep the vials in the outer carton.

Shelf life after reconstitution: 8 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after the abbreviation EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.
To ensure the protection of animals introduced to the herd where BVDV is circulating, vaccination has to be completed 3 weeks before introduction.

The cornerstone of bovine viral diarrhoea (BVD)-eradication is identification and culling of persistently infected animals. A definitive diagnosis of persistent infection can only be established upon re-testing in blood after an interval of at least 3 weeks. In some limited cases with newborn calves, positive ear notches for BVDV vaccine strain were reported by molecular diagnostic tests. Additional laboratory tests to differentiate vaccine strain virus from field strain are available upon request from the marketing authorisation holder.

The field studies to investigate the efficacy of the vaccine were done in herds where persistently infected animals had been removed.

Special precautions for use in animals:
Longlasting viremia has been observed after vaccination, in particular in pregnant seronegative heifers (10 days in a study). This may result in transplacental transmission on the vaccine virus, but no adverse effects on foetus or pregnancy was observed in studies.

Shedding of the vaccine virus by body fluids cannot be excluded.
The vaccine strains are able to infect sheep and swine when administered intranasally, but no adverse reactions or spreading to in-contact animals occurred.
The vaccine has not been tested in breeding bulls and should therefore not be used in breeding bulls.

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.

Pregnancy and lactation:
It is recommended to vaccinate before pregnancy to ensure protection against persistent infection of the foetus. While persistent infection of the foetus caused by the vaccine was not observed, transmission of vaccine virus to the foetus may occur.. Therefore, use during pregnancy should only be on a case-by-case basis decided by the responsible veterinarian, taking into consideration e.g. the BVD immunological status of the animal, the time-span between vaccination and mating/insemination, the stage of pregnancy and the risk of infection.

Can be used during lactation.
Studies have shown that vaccine virus may be excreted in milk up to 23 days after vaccination at low amounts (~ 10 $TCID_{50}$/ml), although when such milk was fed to calves, no seroconversion occurred in those calves.

Interaction with other medical 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):
Mild swellings or nodules up to 3 cm diameter were observed at the injection site after administration of a 10-fold overdose and disappeared within 4 days post vaccination.

Furthermore, a increase of the rectal body temperature was common within 4 hours following administration and spontaneously resolves within 24 hours (see section “Adverse reactions”).

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

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

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

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

The vaccine is designed to stimulate the development of an active immune response against BVDV-1 and BVDV-2 in cattle.

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.

Package sizes:
1 lyophilisate vial of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 1 solvent bottle of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

4 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 4 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

6 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 6 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

10 lyophilisate vials of 10 ml (5 doses), 20 ml (10 doses), 50 ml (25 doses) or 100 ml (50 doses) and 10 solvent bottles of 10 ml, 20 ml, 50 ml or 100 ml packed in one cardboard box.

Not all pack sizes may be marketed.