ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVALTO Respi 3 suspension for injection
(In SE NO DK: Bovalto)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substances:

Inactivated bovine respiratory syncytial virus, strain BIO-24	RP* ≥ 1
Inactivated bovine parainfluenza 3 virus, strain BIO-23	RP* ≥ 1
Inactivated *Mannheimia haemolytica*, serotype A1 strain DSM 5283	RP* ≥ 1

* Relative potency (RP) in comparison with the reference serum obtained after vaccination of guinea pigs with a vaccine batch that has successfully passed the challenge test in the target animals.

Adjuvants:

Aluminium hydroxide	8.0 mg
Quillaja saponin (Quil A)	0.4 mg

Excipients:

Thiomersal	0.2 mg
Formaldehyde	1.0 mg at most.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Appearance: pinkish liquid with sediment.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle.

4.2 Indications for use, specifying the target species

For active immunisation of cattle in the absence of maternally derived antibodies against:
- parainfluenza 3 virus, to reduce virus excretion due to infection,
- bovine respiratory syncytial virus, to reduce virus excretion due to infection,
- *Mannheimia haemolytica* serotype A1, to reduce clinical signs and lung lesions.

Onset of immunity: 3 weeks.
Duration of immunity: 6 months.

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
Safety and efficacy studies were performed in sero-negative calves. The efficacy of the vaccination has not been demonstrated in presence of antibodies. The level of antibody response may be reduced by the presence of maternal antibodies. In the presence of maternal antibodies, timing of initial vaccination of calves should be planned accordingly.

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)

A localised swelling may be very commonly observed at the injection site after vaccination. This swelling could reach up to 10 cm or more in diameter and may be associated with pain, and usually progressively reduces and disappears within 6 weeks after vaccination.
A transient slight increase in body temperature may commonly appear which is higher after the second injection (1.5 °C at most) lasting up to 3 days after vaccination.
Anaphylactic-type reactions may very rarely occur after vaccination. In such cases, appropriate symptomatic treatment should be administered.

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

Can be used during pregnancy and lactation.

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

Subcutaneous use.
Dose: 2 ml administered subcutaneously.
Warm before use to a temperature of 15 °C to 25 °C and shake the contents of the bottle.

Primary vaccination
Calves from non-immune dams: two doses three weeks apart from 2 weeks of age.

For calves from immune dams or where the immune status of the dam is unknown, the vaccination scheme should be adapted at the discretion of the veterinarian to take into account potential interference of maternally derived antibodies with the response to vaccination.

Revaccination
Administer one dose six months after completion of the primary vaccination scheme.

The efficacy of revaccination was demonstrated by measurement of the serological response and has not been assessed by challenge.

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

No adverse effects other than those mentioned in section 4.6 (Adverse Reactions) were observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Bovidae; inactivated viral and bacterial vaccines for cattle.
ATCvet code: QI02AL.

The vaccine induces an active immunity against bovine respiratory syncytial virus, parainfluenza 3 virus and *Mannheimia haemolytica*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Formaldehyde
Quillaja saponin (Quil A)
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass bottle of 10 ml with chlorobutyl elastomer closure (5 doses).
Type II glass bottle of 50 or 100 ml with chlorobutyl elastomer closure (25 or 50 doses).
Translucent HDPE plastic bottle of 10, 50 or 100 ml with chlorobutyl elastomer closure (5, 25 or 50 doses).
Bottle is secured with an aluminium cap.

Cardboard box of 1 bottle of 5 doses (10 ml).
Covered plastic box of 10 bottles of 5 doses (10 x 10 ml).
Cardboard box of 1 bottle of 25 doses (50 ml).
Cardboard box of 1 bottle of 50 doses (100 ml).

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

To be completed locally

8. MARKETING AUTHORISATION NUMBER

To be completed locally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed locally.

10 DATE OF REVISION OF THE TEXT

To be completed locally.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.