ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac TRT lyophilisate for oculonasal suspension for turkeys

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Turkey rhinotracheitis virus, strain clone K, Live $10^{3.2}$ - $10^{4.5}$ *$CCID_{50}$

* $CCID_{50}$ = Cell Culture Infectious Dose 50%.

Excipients:

Qualitative composition of excipients and other constituents
Mannitol
NZ Case Plus
Gelatin
Inositol

Cream coloured lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Turkeys.

3.2 Indications for use for each target species

For active immunisation of turkeys to reduce clinical signs associated with infection with TRT virus.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 14 weeks after vaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The use of the vaccine in turkeys older than 10 days does not induce sufficient protection due to the resistance against TRT increasing with age.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In order to prevent risks of dissemination of the vaccine in the site, all the birds at the same site should be correctly vaccinated.

Do not vaccinate in mixed breeding farms where turkeys and other avian species, except chickens, are raised. The virus contained in the vaccine was shown to spread for approximately 10 days. This spreading appeared to be without any consequence for chickens.

There is a possibility that the virus may be disseminated to other avian species and care should be taken to avoid contact with other birds.

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

If the vaccine is administered by spray, personal protective equipment consisting of safety goggles and a dust mask or a helmet with filtered air circulation should be worn.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Turkeys:

Rare (1 to 10 animals / 10,000 animals treated):	Nasal discharge[1], Respiratory tract disorder[2]

[1]Mild, may occur from day 7 to 8 post vaccination.
[2]May occur between day 10 and 21 post vaccination for 1-2 days.

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 <or 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

Do not use in turkeys in 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 made on a case by case basis.

3.9 Administration routes and dosage

One dose per bird from one day of age for oculonasal use to be administered by spray, eye drop or nose drop.
Only disinfectant-free and/or antiseptic free materials should be used for the preparation of vaccine suspension.

Spray:
The vaccine should be reconstituted with water of good quality at room temperature, e.g. deionised water or good quality drinking water. Treat water with milk powder if necessary but ensure there are no particles which may block the spray nozzle.

Remove the aluminium cap from the vaccine vial. To reconstitute the lyophilised vaccine, the rubber stopper should be removed whilst the vial is immersed in a clean plastic measuring jug containing 0.2 - 0.5 litre of water (as noted below for sprayer types). Half fill the vial with water, replace the stopper and shake to reconstitute any remaining lyophilised vaccine.
Pour into the jug and stir carefully to ensure even dispersal of the vaccine.
The vaccine should then be added to the sprayer.

The quantity of water depends on the method of administration:

Hand spray:	0.2 L/1,000 birds.
Knapsack spray:	0.5 L/1,000 birds, if the birds are housed on the ground.
	0.25 L/1,000 birds, if the birds are housed in a battery.
Automatic spray equipment:	0.15 - 0.50 L/1,000 birds (hatchery).

If administered by spray, spray equipment, providing a droplet size of 0.12 - 0.15 mm has to be used (hand spray, knapsack spray, automatic spray equipment). The distance from the spraying head to the birds must be approximately 50 cm. Hold birds in boxes for approximately 30 - 45 minutes. Ensure the temperature of the holding area is 70 - 80 °F and draught free, to avoid chilling.
Spray application is only to be carried out in housings which can be closed properly.
Turn off ventilation fans, if any, to avoid air movement.

Eye drop/nose drop:
30-50 ml/1000 birds, 0.03-0.05 ml/eye or nostril.

Reconstitute vaccine by dissolving in deionised water for eye drop or nose drop at the rate of 30-50 ml to 1,000 doses. The deionised water should be at room temperature. Remove the aluminium cap and rubber stopper from the vaccine vial and add deionised water from 30-50 ml to half fill the vial. Replace the rubber stopper and shake so that all the vaccine material is completely dissolved. Pour the vaccine concentrate into the rest of the 30-50 ml and mix well.

Administer by dropper at the rate of one drop (0.03-0.05 ml) per bird into the eye or nostril. The use of standardised droppers is recommended. Hold the bird so that one eye is pointing upwards and allow one drop of vaccine to fall into the eye or nostril. Ensure that the nasal drop is inhaled. Birds should swallow during vaccination.

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

Administration of a 10-fold overdose does not result in significantly worse adverse events to those seen after administration of a single dose.

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 ATCvet code: QI01CD01

To stimulate active immunity against TRT virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 20 months.
Shelf life after reconstitution according to directions: 4 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep the container in the outer carton.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vials containing freeze dried pellet of 1,000, 2,000 or 5,000 doses, closed with siliconized type I rubber stopper and sealed with an aluminium cap.

Pack sizes:
Cardboard box of 1 x 1,000 doses.
Cardboard box of 1 x 2,000 doses.
Cardboard box of 1 x 5,000 doses.
Cardboard box of 10 x 1,000 doses.
Cardboard box of 10 x 2,000 doses.
Cardboard box of 10 x 5,000 doses.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Date of first authorisation: *To be completed nationally.*

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

To be completed nationally.

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 OR 10 VIALS, EACH CONTAINING 1,000, 2,000 OR 5,000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac TRT lyophilisate for oculonasal suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Turkey rhinotracheitis virus, strain clone K, Live $10^{3.2}$ - $10^{4.5}$ *$CCID_{50}$/dose
* $CCID_{50}$ = Cell Culture Infectious Dose 50%.

3. PACKAGE SIZE

1 x 1,000 doses
1 x 2,000 doses
1 x 5,000 doses
10 x 1,000 doses
10 x 2,000 doses
10 x 5,000 doses

4. TARGET SPECIES

Turkeys.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oculonasal use (spray, eye drop or nose drop administration).

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

To be completed nationally.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

GLASS VIAL WITH 1,000, 2,000 OR 5,000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac TRT

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Turkey rhinotracheitis virus, strain clone K, Live $10^{3.2}$ - $10^{4.5}$ $CCID_{50}$/dose

1,000 doses
2,000 doses
5,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Poulvac TRT lyophilisate for oculonasal suspension for turkeys

2. Composition

Each dose contains:

Active substance:

Turkey rhinotracheitis virus, strain clone K, Live $10^{3.2}$ - $10^{4.5}$ *$CCID_{50}$

* $CCID_{50}$ = Cell Culture Infectious Dose 50%.

Cream coloured lyophilisate.

3. Target species

Turkeys.

4. Indications for use

For active immunisation of turkeys to reduce clinical signs associated with infection with TRT virus.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: 14 weeks after vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

The use of the vaccine in turkeys older than 10 days does not induce sufficient protection due to the resistance against TRT increasing with age.

Special precautions for safe use in the target species:
In order to prevent risks of dissemination of the vaccine in the site, all the birds at the same site should be correctly vaccinated.

Do not vaccinate in mixed breeding farms where turkeys and other avian species, except chickens, are raised. The virus contained in the vaccine was shown to spread for approximately 10 days. This spreading appeared to be without any consequence for chickens.

There is a possibility that the virus may be disseminated to other avian species and care should be taken to avoid contact with other birds.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
If the vaccine is administered by spray, personal protective equipment consisting of safety goggles and a dust mask or a helmet with filtered air circulation should be worn.

Laying birds:
Do not use in turkeys in 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 made on a case by case basis.

Overdose:
Administration of a 10-fold overdose does not result in significantly worse adverse events to those seen after administration of a single dose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Turkeys:

Rare (1 to 10 animals / 10,000 animals treated):
Nasal discharge[1], Respiratory tract disorder[2]

[1]Mild, may occur from day 7 to 8 post vaccination.
[2]May occur between day 10 and 21 post vaccination for 1-2 days.

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

One dose per bird from one day of age for oculonasal use to be administered by spray, eye drop or nose drop.

Spray:
The vaccine should be reconstituted with water of good quality at room temperature, e.g. deionised water or good quality drinking water. Treat water with milk powder if necessary but ensure there are no particles which may block the spray nozzle.

Remove the aluminium cap from the vaccine vial. To reconstitute the lyophilised vaccine, the rubber stopper should be removed whilst the vial is immersed in a clean plastic measuring jug containing 0.2 - 0.5 litre of water (as noted below for sprayer types). Half fill the vial with water, replace the stopper and shake to reconstitute any remaining lyophilised vaccine.
Pour into the jug and stir carefully to ensure even dispersal of the vaccine.
The vaccine should then be added to the sprayer.

The quantity of water depends on the method of administration:

Hand spray:	0.2 L/1,000 birds.
Knapsack spray:	0.5 L/1,000 birds, if the birds are housed on the ground.
	0.25 L/1,000 birds, if the birds are housed in a battery.
Automatic spray equipment:	0.15 - 0.50 L/1,000 birds (hatchery).

If administered by spray, spray equipment, providing a droplet size of 0.12 - 0.15 mm has to be used (hand spray, knapsack spray, automatic spray equipment). The distance from the spraying head to the birds must be approximately 50 cm. Hold birds in boxes for approximately 30 - 45 minutes. Ensure the temperature of the holding area is 70 – 80 °F and draught free, to avoid chilling.
Spray application is only to be carried out in housings which can be closed properly.
Turn off ventilation fans, if any, to avoid air movement.

Eye drop/nose drop:
30-50 ml/1000 birds, 0.03-0.05 ml/eye or nostril.

Reconstitute vaccine by dissolving in deionised water for eye drop or nose drop at the rate of 30-50 ml to 1,000 doses. The deionised water should be at room temperature. Remove the aluminium cap and rubber stopper from the vaccine vial and add deionised water from 30-50 ml to half fill the vial. Replace the rubber stopper and shake so that all the vaccine material is completely dissolved. Pour the vaccine concentrate into the rest of the 30-50 ml and mix well.

Administer by dropper at the rate of one drop (0.03-0.05 ml) per bird into the eye or nostril. The use of standardised droppers is recommended. Hold the bird so that one eye is pointing upwards and allow one drop of vaccine to fall into the eye or nostril. Ensure that the nasal drop is inhaled. Birds should swallow during vaccination.

9. Advice on correct administration

Only disinfectant-free and/or antiseptic free materials should be used for the preparation of vaccine suspension.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC – 8 ºC).
Do not freeze.
Keep the container in the outer carton.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the vial after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 4 hours.

12. Special precautions for 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.

Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

The vaccine is supplied in quantities of 1,000, 2,000 or 5,000 doses per vial in boxes of 1 or 10 vials.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

To be completed nationally.

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 responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

<Local representatives <and contact details to report suspected adverse reactions>:>
To be completed nationally (if applicable).

17. Other information

To stimulate active immunity against TRT virus.