[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dophexine 20 mg/g powder for use in drinking water/milk

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substances:

Bromhexine	18.2 mg
as bromhexine hydrochloride	20.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Citric acid anhydrous
Propylene glycol
Lactose monohydrate

White to off-white powder.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves), pigs, chickens, turkeys, ducks.

3.2 Indications for use for each target species

Mucolytic treatment of congested respiratory tract.

3.3 Contraindications

Do not use in cases of pulmonary oedema.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In case of serious lungworm infection, the drug should not be used until 3 days after the commencement of the anthelmintic treatment.

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

This veterinary medicinal product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to bromhexine or lactose should avoid contact with the veterinary medicinal product.

During preparation and administration inhalation of dust particles should be avoided. Wear an appropriate dust mask (either a disposable half-mask respirator conforming to European Standard EN149) or a non-disposable respirator to European Standard EN 140 with a filter to EN 143), when handling the veterinary medicinal product. If respiratory symptoms develop following exposure, seek medical advice and show this warning to the physician.
This veterinary medicinal product may cause irritation to the skin, eyes and mucous membranes. Avoid direct contact with the veterinary medicinal product. Wear gloves and protective glasses during the use of the veterinary medicinal product. Wash hands and any exposed skin after use. If accidental contact occurs, rinse the affected area with large amounts of clean water.
Do not eat, drink or smoke while handling this veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 or immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have not produced any evidence of foetotoxic effects or effects on fertility at the recommended dose. However this has not been specifically studied in the target species. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product may be used in conjunction with antibiotics and/or sulphonamides and bronchodilators.
Bromhexine modifies the distribution of antibiotics in the organism and increases their concentration in the serum and in the nasal secretions (e.g. spiramycin, tylosin and oxytetracycline). When administered concomitantly with the veterinary medicinal product, antimicrobial agents should, nevertheless, not be underdosed.

3.9 Administration routes and dosage

In drinking water/milk use.

0.45 mg of bromhexine per kg body weight daily, equivalent to 2.5 g of veterinary medicinal product per 100 kg body weight per day administered for 3 to 10 consecutive days.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake of medicated water /milk depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of bromhexine may need to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{25 mg veterinary medicinal product/ kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water/milk intake (l/animal)}} = \ldots \text{ mg veterinary medicinal product per litre of drinking water/milk}$$

The required amount of veterinary medicinal product should be weighed as accurately as possible using suitably calibrated weighing equipment.

The maximum solubility of the veterinary medicinal product is 100 g/L in water at 20ºC. The time required for complete dissolution varies from 3 minutes (10 g/L) to 15 minutes (100 g/L). For stock solutions and when using a proportioner, take care not to exceed the maximum solubility. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated. Any unused medicated water should be discarded after 24 hours.

For the preparation of the medicated milk replacer first dissolve the veterinary medicinal product in water. After dispersion of the milk powder add the solution of Dophexine under vigorous stirring for at least 3 minutes at ca. 40 ºC. The medicated milk should be freshly prepared prior to use and used within 6 hours.

Care should be taken that the intended dose will be completely ingested.

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

None known.

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

Cattle (calves): meat and offal: 2 days.
Not authorised for use in animals producing milk for human consumption.

Pigs: meat and offal: zero days.

Chickens, turkey, ducks: meat and offal: zero days.
Not for use in birds producing eggs for human consumption, during and 4 weeks before the laying period.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QR05CB02

4.2 Pharmacodynamics

Bromhexine is a mucoregulator. By activating the secretion of the seromucous glands, bromhexine helps to re-establish the viscosity and elasticity of bronchial secretions in the tracheobronchial tree. In addition, its expectorant action encourages mobilisation of mucus and enables effective bronchial drainage, thereby improving the functioning and defence capability of the lung.
These two simultaneous actions lead to an abundant discharge and facilitate a productive cough.
It breaks down the network of acid glycoprotein fibres found in mucoid sputum, which are mainly responsible for the characteristic viscosity.

4.3 Pharmacokinetics

In pigs, bromhexine is rapidly absorbed following oral administration with a peak plasma concentrations obtained in one to three hours. The concentration plateau is reached 12 hours after the second or third administration.
In calves, plasma concentrations increase progressively over several hours following administration.
In turkeys or chickens, peak plasma concentrations are reached within 2 to 4 hours of oral administration.
Due to the lipophilic character of bromhexine, it has a strong affinity for lipid tissues and a slow depletion profile from these tissues.
Bromhexine is largely metabolised into more polar compounds.
The apparent half-life of elimination of total plasma radioactivity after the last administration is 20 to 30 hours in a pig, 40 to 50 hours in cattle and 40 to 50 hours in chickens and turkeys.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening of the immediate packaging: 3 months.
Shelf life after dissolution in drinking water according to directions: 24 hours.
Shelf life after dissolution in milk (replacer) according to directions: 6 hours.

5.3 Special precautions for storage

Do not store above 25°C.
Protect from light.

5.4 Nature and composition of immediate packaging

- Composite can: three-layered rectangular container, which consists of a cardboard base with an inner lining of aluminium-paper, covered with a low-density polyethylene lid.
The composite can contains of 1 kg of veterinary medicinal product.
- Securitainer: white cylindrical polypropylene container, covered with a low-density polyethylene lid.
The securitainer contains 1 kg of veterinary medicinal product.
- Bucket: white polypropylene square container provided with a polypropylene lid.
The bucket contains 1, 2.5 or 5 kg of veterinary medicinal product.

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

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IT, LT, LU, LV, NL, NO, PT, RO, SK).
Veterinary medicinal product subject to prescription (IE, PL, SE).

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 IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

Composite can, securitainer and bucket

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dophexine 20 mg/g powder for use in drinking water/milk

2. COMPOSITION

Each gram contains:

Active substances:

Bromhexine	18.2 mg
as bromhexine hydrochloride	20.0 mg

White to off-white powder.

3. PACKAGE SIZE

1 kg, 2.5 kg, 5 kg.

4. TARGET SPECIES

For cattle (calves) pigs, chickens, turkeys, ducks.

5. INDICATIONS FOR USE

Indications for use

Mucolytic treatment of congested respiratory tract.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of pulmonary oedema.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

<u>Special precautions for safe use in the target species:</u>
In case of serious lungworm infection, the drug should not be used until 3 days after the commencement of the anthelmintic treatment.

<u>Special precautions to be taken by the person administering the veterinary medicinal product to animals:</u>
This veterinary medicinal product may cause hypersensitivity reactions (allergy). People with known hypersensitivity to bromhexine or lactose should avoid contact with the veterinary medicinal product.

During preparation and administration inhalation of dust particles should be avoided. Wear an appropriate dust mask (either a disposable half-mask respirator conforming to European Standard EN149) or a non-disposable respirator to European Standard EN 140 with a filter to EN 143), when handling the veterinary medicinal product. If respiratory symptoms develop following exposure, seek medical advice and show this warning to the physician.
This veterinary medicinal product may cause irritation to the skin, eyes and mucous membranes. Avoid direct contact with the veterinary medicinal product. Wear gloves and protective glasses during the use of the veterinary medicinal product. Wash hands and any exposed skin after use. If accidental contact occurs, rinse the affected area with large amounts of clean water.
Do not eat, drink or smoke while handling this veterinary medicinal product.

Pregnancy, lactation and lay:
Studies in laboratory animals have not produced evidence of foetotoxic effects or effects on fertility at the recommended dose. However this has not been specifically studied in the target species.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interactions with other medicinal products and other forms of interaction:
The veterinary medicinal product may be used in conjunction with antibiotics and/or sulphonamides and bronchodilators.
Bromhexine modifies the distribution of antibiotics in the organism and increases their concentration in the serum and in the nasal secretions (e.g. spiramycin, tylosin and oxytetracycline). When administered concomitantly with the veterinary medicinal product, antimicrobial agents should, nevertheless, not be underdosed.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed on this label, 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 its local representative using the contact details on this label, or via your national reporting system.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

In drinking water/milk use.

0.45 mg of bromhexine per kg body weight daily, equivalent to 2.5 g of veterinary medicinal product per 100 kg body weight per day administered for 3 to 10 consecutive days.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake of medicated water /milk depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of bromhexine may need to be adjusted accordingly.

Based on the recommended dose and the number and weight of animals to be treated, the exact daily concentration of the veterinary medicinal product should be calculated according to the following formula:

$$\frac{\text{25 mg veterinary medicinal product/ kg body weight per day} \times \text{average body weight (kg) of animals to be treated}}{\text{average daily water/milk intake (l/animal)}} = \ldots \text{ mg veterinary medicinal product per litre of drinking water/milk}$$

The required amount of veterinary medicinal product should be weighed as accurately as possible using suitably calibrated weighing equipment.

The maximum solubility of the veterinary medicinal product is 100 g/L in water at 20ºC. The time required for complete dissolution varies from 3 minutes (10 g/L) to 15 minutes (100 g/L). For stock solutions and when using a proportioner, take care not to exceed the maximum solubility. Adjust flow rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated. Any unused medicated water should be discarded after 24 hours.

For the preparation of the medicated milk replacer first dissolve the veterinary medicinal product in water. After dispersion of the milk powder add the solution of Dophexine under vigorous stirring for at least 3 minutes at ca. 40 ºC. The medicated milk should be freshly prepared prior to use and used within 6 hours.

Care should be taken that the intended dose will be completely ingested.

11. WITHDRAWAL PERIODS

Withdrawal periods

Cattle (calves): meat and offal: 2 days.
Not authorised for use in animals producing milk for human consumption.
Pigs: meat and offal: zero days.
Chickens, turkey, ducks: meat and offal: zero days.
Not for use in birds producing eggs for human consumption, during and 4 weeks before the laying period.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
Protect from light.

Do not use this veterinary medicinal product after the expiry date stated which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

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.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product not subject to prescription (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IT, LT, LU, LV, NL, NO, PT, RO, SK).
Veterinary medicinal product subject to prescription (IE, PL, SE).

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
- Composite can: 1 kg
- Securitainer: 1 kg.
- Bucket: 1, 2.5, 5 kg.

Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
Tel. +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24

NL-4941 VX Raamsdonksveer

Local representatives and contact details to report suspected adverse events:

Name}
<{Address}
{Country} - {Town} {Code}>
Tel: + {Telephone number}
<{E-mail}>

18. OTHER INFORMATION

Other information

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19. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

20. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by …

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dissolution according to directions: 24 hours in drinking water.
6 hours in milk replacer.

21. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Composite can, securitainer and bucket

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dophexine 20 mg/g powder for use in drinking water/milk

2. STATEMENT OF ACTIVE SUBSTANCES

Bromhexine 18.2 mg/g
as bromhexine hydrochloride 20.0 mg/g

3. PACKAGE SIZE

1 kg, 2.5 kg, 5 kg.

4. TARGET SPECIES

For cattle (calves) pigs, chickens, turkeys, ducks.

5. INDICATIONS

<Mucolytic treatment of congested respiratory tract.> (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IT, LT, LU, LV, NL, NO, PT, RO, SK).

6. ROUTES OF ADMINISTRATION

In drinking water/milk use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle (calves): meat and offal: 2 days.
Not authorised for use in animals producing milk for human consumption.

Pigs: meat and offal: zero days.
Chickens, turkey, ducks: meat and offal: zero days.
Not for use in birds producing eggs for human consumption, during and 4 weeks before the laying period.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by …

Shelf life after first opening the immediate packaging: 3 months
Shelf life after dissolution according to directions: 24 hours in drinking water.
6 hours in milk replacer.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. 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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Dophexine 20 mg/g powder for use in drinking water/milk

2. Composition

Each gram contains:

Active substances:

Bromhexine	18.2 mg/g
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White to off-white powder.

3. Target species

Cattle (calves) pigs, chickens, turkeys, ducks.

4. Indications for use

Mucolytic treatment of congested respiratory tract.

5. Contraindications

Do not use in cases of pulmonary oedema.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
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Do not eat, drink or smoke while handling this veterinary medicinal product.

Pregnancy, lactation and lay:
Studies in laboratory animals have not produced evidence of foetotoxic effects or effects on fertility at the recommended dose. However this has not been specifically studied in the target species.
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Interaction with other medicinal products and other forms of interaction:
The veterinary medicinal product may be used in conjunction with antibiotics and/or sulphonamides and bronchodilators.
Bromhexine modifies the distribution of antibiotics in the organism and increases their concentration in the serum and in the nasal secretions (e.g. spiramycin, tylosin and oxytetracycline). When administered concomitantly with the veterinary medicinal product, antimicrobial agents should, nevertheless, not be underdosed.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
No information is available on potential interactions or incompatibilities of this veterinary medicinal product administered orally by mixing into drinking water containing biocidal products, feed additives or other substances used in drinking water.

7. Adverse events

None known.

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 its local representative 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

In drinking water/milk use.

0.45 mg of bromhexine per kg body weight daily, equivalent to 2.5 g of veterinary medicinal product per 100 kg body weight per day administered for 3 to 10 consecutive days.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
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The required amount of product should be weighed as accurately as possible using suitably calibrated weighing equipment.

The maximum solubility of the veterinary medicinal product is 100 g/L in water at 20ºC. The time required for complete dissolution varies from 3 minutes (10 g/L) to 15 minutes (100 g/L). For stock solutions and when using a proportioner, take care not to exceed the maximum solubility. Adjust flow

rate settings of the dosing pump according to concentration of the stock solution and water intake of the animals to be treated. Any unused medicated water should be discarded after 24 hours.

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Care should be taken that the intended dose will be completely ingested.

10. Withdrawal periods

Cattle (calves): meat and offal: 2 days.
Not authorised for use in animals producing milk for human consumption.
Pigs: meat and offal: zero days.
Chickens, turkey, ducks: meat and offal: zero days.
Not for use in birds producing eggs for human consumption, during and 4 weeks before the laying period.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25°C.
Protect from light.

Do not use this veterinary medicinal product after the expiry date stated which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months.
Shelf life after dissolution in drinking water according to directions: 24 hours.
Shelf life after dissolution in milk (replacer) according to directions: 6 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 not subject to prescription (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IT, LT, LU, LV, NL, NO, PT, RO, SK).
Veterinary medicinal product subject to prescription (IE, PL, SE).

14. Marketing authorisation numbers and pack sizes

Pack sizes
- Composite can: 1 kg
- Securitainer: 1 kg.

- Bucket: 1, 2.5, 5 kg.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 events:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
Tel. +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer

Local representatives and contact details to report suspected adverse events:
{Name}
{Address}
{Country} – {Town} – {Code}
Tel + {Telephone number}
{E-mail}

17. Other information

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