ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HuveGuard MMAT suspension for oral suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.025 ml contains:

Active substances:

Sporulated oocysts derived from precocious strains of *Eimeria* species:

Eimeria acervulina, strain RA 3+20, live	50	-	139 oocysts*
Eimeria maxima, strain MCK+10, live	100	-	278 oocysts*
Eimeria mitis, strain Jormit 3+9, live	100	-	278 oocysts*
Eimeria tenella, strain Rt 3 +15, live	150	-	417 oocysts*

*According to the *in vitro* counting procedure of the manufacturer at the time of blending and at release.

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Potassium chloride
Disodium phosphate
Potassium dihydrogen phosphate
Polysorbate 80
Water for injections

Colourless to white to light beige suspension when shaken.

3. CLINICAL INFORMATION

3.1 Target species

Chickens

3.2 Indications for use for each target species

For the active immunisation of chickens to reduce infection and clinical signs of coccidiosis caused by *E. acervulina*, *E. maxima*, *E. mitis* and *E. tenella.*

Onset of immunity: 21 days post vaccination.
Duration of immunity: has not been established.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The vaccine contains live coccidian oocysts and is dependent upon replication of the vaccinal strains within the chickens for building up of immunity.

It is common to find oocysts in the gastro-intestinal tract of vaccinated birds from 1-3 weeks or more after vaccination. These oocysts are most likely to be vaccinal oocysts which recycle in the birds via the litter. Recycling of oocysts is necessary for the development of immunity and for continued protection.

Since the protection against coccidial infection following vaccination is enhanced by natural challenge, access to any therapeutic agents having anti-coccidial activity at any time following vaccination can adversely affect the development of immunity. This is important throughout the life of the chicken.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Chickens must be strictly floor-reared on litter.
To reduce the chance of coccidial challenge before the onset of immunity, litter should be removed, and chicken housing should be thoroughly cleaned between rearing cycles.

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

When spraying the vaccine onto chicks or onto feed, personal protective equipment consisting of a well-fitting mask and eye protection should be worn by the operator.
Wash and disinfect hands and equipment after use.

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 for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
The safety of the veterinary medicinal product has not been established during lay. Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer any anticoccidial agents, including sulphonamides, before or after vaccination, as doing so will have a negative impact on immunity which is dependent on the recycling of oocysts in the environment.

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

Oral use (spray on birds, spray on feed, in drinking water use).

Vaccination schedule:
Spray on birds and spray on feed: administer one dose of vaccine to each chicken from 1 day of age.
In drinking water use: administer one dose of vaccine to each chicken from 3 days of age.
Once the 30 ml vial containing either 1000 or 5000 doses is opened, the entire contents must be used.

Administration via spray onto feed
Sufficient starter feed for the chicks' first 12-24 hours should be laid out on paper or plastic along the floor of the poultry house.

Shake the vaccine vial vigorously for 30 seconds before use to re-suspend the oocysts. Dilute the vaccine in water at the rate of approximately 1000 doses in 1 litre of water (5000 doses in 5 litres). To ensure that all oocysts are removed from the vial, rinse it out 3 times with water. Spray the oocyst suspension evenly over the surface of the feed using a coarse spray. Ensure a controlled even coverage of the total surface area of the feed available to the chickens. Agitate the applicator reservoir regularly throughout spraying to avoid settling-out of oocysts. Ensure that all available feed is treated and that the total number of doses dispensed matches the number of birds in the house.

Once the vaccine has been diluted for use it should be sprayed immediately onto feed and birds should be placed with access to the feed immediately.

When the treated allocation of feed has been consumed, routine feeding may continue.

It is recommended to monitor the feed intake and behaviour of the birds and to apply the vaccine by this method only after an adequate feed intake is expected.

Administration via in drinking water use
For the administration of the vaccine, drinkers must be used.
Provide an adequate number of drinkers and drinking space so that all chicks have access to the vaccinal water and thus can receive the correct dose.
Place the drinkers evenly in the area where chicks are housed.

Water should be withheld for 2 - 4 hours before vaccination.

Preparation of the xanthan gum solution:
Commercially available xanthan gum can be used.
For 1000 doses put 3 litres of clean drinking water at room temperature in a suitable container and dissolve 5 g xanthan gum.
For 5000 doses put 15 litres of clean drinking water at room temperature in a suitable container and dissolve 25 g xanthan gum.

Prepare the vaccine suspension as follows:
To resuspend the oocysts, shake the vaccine vial vigorously. Open the vial and pour the whole contents into clean drinking water at room temperature: 2 litres for 1000 doses and 10 litres for 5000 doses. To ensure that all oocysts are removed from the vial, rinse it out 3 times with water. Shake the obtained 2 litres (1000 doses) or 10 litres (5000 doses) of vaccine suspension and transfer gradually into the prepared xanthan gum solution, mixing thoroughly to ensure a homogeneous suspension.

Mixing the xanthan gum solution together with the vaccine suspension will result in a final quantity of 5 litres (for 1000 doses) or 25 litres (for 5000 doses) vaccine-xanthan gum suspension. Pour the vaccine-xanthan gum suspension into the drinking equipment.

Administration via spray on chickens
For each 100 birds a dose volume of about 24 ml (0.24 ml/bird) of coarse spray suspension has to be prepared.

For spraying on chickens use Brilliant Blue (E133) coloring agent.

Preparation of the coloured diluent:
For 1000 doses, put 240 ml of water in a suitable container and add Brilliant Blue (E133) colorant at a concentration of 0.01% w/v.
For 5000 doses, put 1200 ml of water in a suitable container and add Brilliant Blue (E133) colorant at a concentration of 0.01% w/v.

Preparation and administration of the vaccine suspension:
Shake the 1000- or 5000- doses vial vigorously to re-suspend the oocysts.
Add the entire content of the vial to the diluent and mix thoroughly. Rinse the vial 3 times with diluent to ensure that all oocysts are removed. Fill the vaccine reservoir of the spraying device with the full volume prepared. Continuously maintain homogeneity of the vaccine suspension. The pressure of the spraying device should be at 3 bars. The spraying device must provide a droplet size of ≥100 µm.
To improve the uniformity of the vaccination, maintain the chicks inside the chick box for at least 1 hour in order to let them ingest all the vaccine droplets. Make sure that there is enough light so that the chickens are awake and preen themselves and each other.

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

No adverse effects have been observed following administration of a 10-fold overdose.

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: QI01AN01

To stimulate active specific immunity to wild strains of *E. acervulina*, *E. maxima*, *E. mitis* and *E. tenella* when ingested by chickens.
Vaccination is followed by continuous and lifelong recycling of vaccinal oocysts in birds via the litter. This recycling of oocysts results in the development of immunity and continued protection against wild strains of the four *Eimeria* strains.

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.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 26 weeks.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after dilution according to directions: 4 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Low density polyethylene (LDPE) vial of 30 ml with a grey butyl rubber stopper and aluminium cap containing either 1000 or 5000 doses.
Pack sizes:
Cardboard box with 1 vial of 1000 doses
Cardboard box with 1 vial of 5000 doses
Cardboard box with 5 vials of 1000 doses
Cardboard box with 5 vials of 5000 doses
Cardboard box with 10 vials of 1000 doses
Cardboard box with 10 vials of 5000 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 system applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}><{DD month YYYY}>
To be completed nationally

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

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>
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 II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HuveGuard MMAT suspension for oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:

Eimeria acervulina, strain RA 3+20. live	50	-	139 oocysts
Eimeria maxima, strain MCK+10, live	100	-	278 oocysts
Eimeria mitis, strain Jormit 3+9, live	100	-	278 oocysts
Eimeria tenella, strain Rt 3 +15, live	150	-	417 oocysts

3. PACKAGE SIZE

1000 doses
5 x 1000 doses
10 x 1000 doses
5000 doses
5 x 5000 doses
10 x 5000 doses

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp: <{dd/mm/yyyy}>
Once broached use immediately.
Once diluted use within 4 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
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

Huvepharma NV

14. MARKETING AUTHORISATION NUMBER

To be completed nationally

15. BATCH NUMBER

Lot {number}:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 vial of 1000 doses; 1 vial of 5000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HuveGuard MMAT

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Per dose:

Eimeria acervulina	50	-	139 oocysts
Eimeria maxima	100	-	278 oocysts
Eimeria mitis	100	-	278 oocysts
Eimeria tenella	150	-	417 oocysts

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp: <{dd/mm/yyyy}>
Once broached use immediately.

5. PACKAGE SIZE

1000 doses
5000 doses

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

HuveGuard MMAT suspension for oral suspension for chickens

2. Composition

Each dose of 0.025 ml contains:

Active substances:

Sporulated oocysts derived from precocious strains of *Eimeria* species:

Eimeria acervulina, strain RA 3+20, live	50	-	139 oocysts*
Eimeria maxima, strain MCK+10, live	100	-	278 oocysts*
Eimeria mitis, strain Jormit 3+9, live	100	-	278 oocysts*
Eimeria tenella, strain Rt 3 +15, live	150	-	417 oocysts*

*According to the *in vitro* counting procedure of the manufacturer at the time of blending and at release.

Colourless to white to light beige suspension when shaken.

3. Target species

Chickens

4. Indications for use

For the active immunisation of chickens to reduce infection and clinical signs of coccidiosis caused by *E. acervulina, E. maxima, E. mitis* and *E. tenella.*

Onset of immunity: 21 days post vaccination.
Duration of immunity: has not been established.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
The vaccine contains live coccidian oocysts and is dependent upon replication of the vaccinal strains within the chickens for building up of immunity.
It is common to find oocysts in the gastro-intestinal tract of vaccinated birds from 1-3 weeks or more after vaccination. These oocysts are most likely to be vaccinal oocysts which recycle in the birds via the litter. Recycling of oocysts is necessary for the development of immunity and for continued protection.

Since the protection against coccidial infection following vaccination is enhanced by natural challenge, access to any therapeutic agents having anti-coccidial activity at any time following vaccination can adversely affect the development of immunity. This is important throughout the life of the chicken.

Special precautions for safe use in the target species:
Chickens must be strictly floor reared on litter.
To reduce the chance of coccidial challenge before the onset of immunity, litter should be removed and chicken housing should be thoroughly cleaned between rearing cycles.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
When spraying the vaccine onto chicks or onto feed, personal protective equipment consisting of a well-fitting mask and eye protection should be worn by the operator.
Wash and disinfect hands and equipment after use.

Laying birds:
The safety of the veterinary medicinal product has not been established during lay. Do not use in birds in lay and within 4 weeks before the start of the laying period.

Interaction with other medicinal products and other forms of interaction:
Do not administer any anticoccidial agents, including sulphonamides, before or after vaccination, as doing so will have a negative impact on immunity which is dependent on the recycling of oocysts in the environment.
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:
No adverse effects have been observed following administration of a 10-fold overdose.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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 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

Oral use (spray on birds, spray on feed, in drinking water use).
Vaccination schedule:
Spray on birds and spray on feed: administer one dose of vaccine to each chicken from 1 day of age.
In drinking water use: administer one dose of vaccine to each chicken from 3 days of age.

9. Advice on correct administration

Each method of administration uses 30 ml vials containing either 1000 or 5000 doses of vaccine. Once the vial is opened, the entire contents must be used.

Administration via spray onto feed
Sufficient starter feed for the chicks' first 12-24 hours should be laid out on paper or plastic along the floor of the poultry house.

Shake the vaccine vial vigorously for 30 seconds before use to resuspend the oocysts. Dilute the vaccine in water at the rate of approximately 1000 doses in 1 litre of water (5000 doses in 5 litres). To ensure that all oocysts are removed from the vial, rinse it out 3 times with water. Spray the oocyst suspension evenly over the surface of the feed using a coarse spray. Ensure a controlled even coverage of the total surface area of the feed available to the chickens. Agitate the applicator reservoir regularly throughout spraying to avoid settling-out of oocysts. Ensure that all available feed is treated and that the total number of doses dispensed matches the number of birds in the house.

Once the vaccine has been diluted for use, it should be sprayed immediately onto feed and birds should be placed with access to the feed immediately.

When the treated allocation of feed has been consumed, routine feeding may continue.

It is recommended to monitor the feed intake and behaviour of the birds and to apply the vaccine by this method only after an adequate feed intake is expected.

Administration via in drinking water use
For the administration of the vaccine drinkers must be used.
Provide an adequate number of drinkers and drinking space so that all chicks have access to the vaccinal water and thus can receive the correct dose.
Place the drinkers evenly in the area where chicks are housed.

Water should be withheld for 2 - 4 hours before vaccination.

Preparation of the xanthan gum solution:
Commercially available xanthan gum can be used.
For 1000 doses, put 3 litres of clean drinking water at room temperature in a suitable container and dissolve 5 g xanthan gum.
For 5000 doses, put 15 litres of clean drinking water at room temperature in a suitable container and dissolve 25 g xanthan gum.

Prepare the vaccine suspension as follows:
To re-suspend the oocysts, shake the vaccine vial vigorously. Open the vial and pour the whole contents into clean drinking water at room temperature: 2 litres for 1000 doses and 10 litres for 5000 doses. To ensure that all oocysts are removed from the vial, rinse it out 3 times with water. Shake the obtained 2 litres (1000 doses) or 10 litres (5000 doses) of vaccine suspension and transfer gradually into the prepared xanthan gum solution, mixing thoroughly to ensure a homogeneous suspension. Mixing the xanthan gum solution together with the vaccine suspension will result in a final quantity of 5 litres (for 1000 doses) or 25 litres (for 5000 doses) vaccine-xanthan gum suspension. Pour the vaccine-xanthan gum suspension into the drinking equipment.

Administration via spray on chickens
For each 100 birds, a dose volume of about 24 ml (0,24 ml/bird) of coarse spray suspension has to be prepared.

For spraying on chickens use Brilliant Blue (E133) coloring agent.

Preparation of the coloured diluent:
For 1000,doses, put 240 ml of water in a suitable container and add Brilliant Blue (E133) colorant at a concentration of 0.01% w/v.
For 5000 doses, put 1200 ml of water in a suitable container and add Brilliant Blue (E133) colorant at a concentration of 0.01% w/v.

Preparation and administration of the vaccine suspension:
Shake the 1000- or 5000- doses vial vigorously to re-suspend the oocysts.
Add the entire content of the vial to the diluent and mix thoroughly. Rinse the vial 3 times with diluent to ensure that all oocysts are removed. Fill the vaccine reservoir of the spraying device with the full volume prepared. Continuously maintain homogeneity of the vaccine suspension. The pressure of the spraying device should be at 3 bars. The spraying device must provide a droplet size of ≥100 µm.

To improve the uniformity of the vaccination maintain the chicks inside the chick box for at least 1 hour in order to let them ingest all the vaccine droplets. Make sure that there is enough light so that the chickens are awake and preen themselves and each other.

10. Withdrawal periods

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. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after dilution 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 system. These measures should help to protect the environment. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally

Low density polyethylene (LDPE) vial of 30 ml with a grey butyl rubber stopper and aluminum cap containing either 1000 or 5000 doses.
Pack sizes:
Cardboard box with 1 vial of 1000 doses
Cardboard box with 1 vial of 5000 doses
Cardboard box with 5 vials of 1000 doses
Cardboard box with 5 vials of 5000 doses
Cardboard box with 10 vials of 1000 doses
Cardboard box with 10 vials of 5000 doses

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>
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:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
+32 3 288 18 49
pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

<Local representatives and contact details to report suspected adverse reactions>
To be adjusted nationally

17. Other information

Vaccination is followed by continuous and lifelong recycling of vaccinal oocysts in birds via the litter. This recycling of oocysts results in the development of immunity and continued protection against wild strains of the four *Eimeria* strains.

To be completed nationally