ANNEX I

SCIENTIFIC CONCLUSIONS PRESENTED BY THE EMEA

SCIENTIFIC CONCLUSIONS

The basis for arbitration procedure was the withdrawal period of zero days. Concern was expressed by the Netherlands, that a withdrawal time of zero days would not be acceptable. Considering the product to be a live vaccine with a zoonotic agent and the fact that live Newcastle Disease virus was found in the cloaca and trachea of vaccinated birds up to 8 days after vaccination, a withdrawal period of 7 days was considered acceptable by the Netherlands.

The CVMP considered the written responses provided by the Applicant, the joint Rapporteur-Co-Rapporteur's assessment report on the response of the Applicant and the comments from CVMP members.

Taking into account

- the lower pathogenicity of vaccinal strains of Newcastle Disease virus in comparison to wild-type virus strains,
- the removal of the main sources of virus (i.e. intestines and upper respiratory tract) in the processing plant;
- the likelihood of significant Newcastle disease virus inactivation by proper cooking procedures,
- the absence of confirmed cases of Newcastle Disease in humans following oral ingestion of meat from vaccinated birds,
- that ocular contamination with a significant viral load following handling of meat from a vaccinated bird is unlikely,
- that vaccinated birds are unlikely to be sent for immediate slaughter,

the CVMP agreed that a zero-day withdrawal period is sufficient to protect the consumer from any zoonotic hazard posed by the strain of Newcastle disease virus present in the product Avinew, when used in accordance with the SPC.

Therefore, the CVMP has recommended the granting of the Marketing Authorisation(s) for which the Summary of Product Characteristics is set out in Annex III for Avinew.

ANNEX II

LIST OF THE PHARMACEUTICAL FORMS, STRENGTHS, ROUTES OF ADMINISTRATION, PACKAGING AND PACKAGE SIZES OF THE VETERINARY MEDICINAL PRODUCT IN THE MEMBER STATES

ANNEX II

Marketing Authorisation Holder (Name and address):

Reference Member State: MERIAL
17, rue Bourgelat
69002 LYON

Concerned Member States:

AUSTRIA
Marketing authorization holder :
MERIAL
17, rue Bourgelat
69002 LYON
France

BELGIUM
MERIAL BELGIUM S.A./N.V.
243 Bd Sylvain Dupuislaan
1070 BRUXELLES

FINLAND
MERIAL
17, rue Bourgelat
69002 LYON
FRANCE

GERMANY
MERIAL GmbH
Am Söldnermoos 6
D-85399 HALLBERGMOOS

GREECE
MERIAL
17, rue Bourgelat
69002 LYON
FRANCE

IRELAND
MERIAL ANIMAL HEALTH Limited
PO Box 327
Sandringham House
Harlow Business Park
ESSEX CM 19 5TG
UNITED KINGDOM

LUXEMBURG
MERIAL BELGIUM S.A./N.V.
243 Bd Sylvain Dupuislaan
1070 BRUXELLES
BELGIQUE

NETHERLANDS
MERIAL BV
Bovenkerkerweg 6-8
1185 XE - AMSTELVEEN

PORTUGAL
MERIAL PORTUGUESA SAUDE ANIMAL, LDA
Av. Maria Lamas, Lote 19 - BL. A Piso 2
2635 - 432 RIO DE MOURO

SPAIN
MERIAL LABORATORIOS S.A.
C/Tarragona n° 161
08014 BARCELONE

Presentations:

Tradename	Strength	Pharmaceutical Form	Target Species	Route of administration	Packaging	Content	Package-size
AVINEW	Live Newcastle disease virus, at least 5.5 log10 EID50*	Powder for suspension	Chickens	Ocular use Respiratory use Oral use	Bottle (glass)	1000 doses	1 vial
AVINEW	Live Newcastle disease virus, at least 5.5 log10 EID50*	Powder for suspension	Chickens	Ocular use Respiratory use Oral use	Bottle (glass)	1000 doses	10 vials
AVINEW	Live Newcastle disease virus, at least 5.5 log10 EID50*	Powder for suspension	Chickens	Ocular use Respiratory use Oral use	Bottle (glass)	2000 doses	1 vial
AVINEW	Live Newcastle disease virus, at least 5.5 log10 EID50*	Powder for suspension	Chickens	Ocular use Respiratory use Oral use	Bottle (glass)	2000 doses	10 vials

* EID50: 50 % Embryo-infective dose. The virus titre required to produce infection in 50 % of the embryos inoculated

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS
OF THE REFERENCE MEMBER STATE

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

AVINEW

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Live Newcastle disease virus, VG/GA strain, at least	5.5 $\log_{10}$ EID_{50}
Excipient	q.s. 1 dose

3. PHARMACEUTICAL FORM

Freeze-dried vaccine to be diluted in appropriate diluent (non chlorinated drinking water).

4. IMMUNOLOGICAL PROPERTIES

The vaccine contains live Newcastle disease virus, VG/GA strain. The VG/GA strain is lentogenic and naturally apathogenic for chickens. The vaccine induces active immunisation against Newcastle disease, as demonstrated by challenge test.

5. CLINICAL PARTICULARS

5.0 Target species

Chickens.

5.1 Indications for use, specifying the target species

In chickens from the age of one day:
Active immunisation against Newcastle disease to reduce mortality and clinical signs associated with the disease.

Duration of immunity induced by the vaccination scheme described under 5.7 : protection until the age of 6 weeks.

5.2 Contraindications and warnings in respect of other products used in the host, immunological status of host and physiological status of host

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other.

5.3 Undesirable effects in the target species (frequency and seriousness)

None known.

5.4 Special precautions for use

Vaccinate healthy birds only.
Apply the usual aseptic procedures.

5.5 Use during pregnancy and lactation

Vaccination of chickens in lay is not recommended.

5.6 Interaction with other vaccines and medicaments when administered in combination with the product

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is, therefore, recommended that no other vaccines should be administered within 14 days before or after vaccination with Avinew.

5.7 Posology and method of administration

Primary vaccination by ocular route (eye drop application) or oculo-nasal route (coarse spray application): from the age of one day.
Booster vaccinations by oral route (drinking water application) : at the age of 2 to 3 weeks.
The minimal interval between the two vaccinations should be of 2 weeks.

Method of administration:
To reconstitute and prepare the vaccine, use clean cold water. For the preparation and administration of the vaccine, use sterile material free from disinfectant and/or antiseptic. Shake the reconstituted vaccine solution before use.

- Individual vaccination: ocular route

For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 3 to 5 ml of non chlorinated drinking water and subsequently dilute it into 50 ml of non chlorinated drinking water.
Use calibrated dropper, so as to distribute 50 µl-drops.
Place one drop of the vaccine solution on the eye of each bird, allow the drop to spread and release the bird.

- Mass vaccination: oral route

For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 3 to 5 ml of non chlorinated drinking water and subsequently dilute it into the volume of non chlorinated drinking water to be consumed within one to two hours.
When using mains water, treat all water to come into contact with the vaccine with skimmed milk powder at a rate of 2.5 g per litre in order to neutralise traces of chlorine.
Distribute the vaccine solution at the time of use to birds. Birds should be deprived of water for two hours prior to vaccination.

- Mass vaccination: respiratory route

For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 3 to 5 ml of non chlorinated drinking water and subsequently dilute it into the volume of non chlorinated drinking water according to the type of sprayer used (pressure-sprayer or sprayer with rotary cone).
Spray the vaccine solution above the birds using a spray capable of producing micro-droplets (mean diameter 80-100 µm).
For proper vaccine distribution, make sure that birds are closely confined together during spraying.
The ventilation system of the poultry house should be inoperative during the spray administration.

5.8 Overdose (signs, emergency procedures, antidotes) (if necessary)

No side-effect has been observed following administration of 10 times the recommended dose of vaccine.

5.9 Special warnings for each target species

Vaccine virus can spread to unvaccinated birds. Infection of unvaccinated birds with the vaccine virus from vaccinated birds does not induce any sign of disease. Moreover, a reversion to virulence trial carried out in the laboratory has shown that the vaccine virus does not acquire any pathogenic characteristic after 10 passages in chickens. Therefore, spread to unvaccinated birds, in the present state of knowledge, can be considered as safe.

5.10 Withdrawal periods

Zero days.

5.11 Special precautions to be taken by the person administering the product to animals

Care should be taken when handling the vaccine preparation.
Because Newcastle disease virus can cause a transitory conjunctivitis in man, it is recommended to wear respiratory and eye protection in compliance with current European standards.
For more information, contact the manufacturer.
Hands should be washed and disinfected after vaccinating.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities (major)

The presence of disinfectant and/or antiseptic in water and material used for the preparation of vaccine solution is not compatible with an effective vaccination.
Do not mix with other products.

6.2 Shelf-life

16 months.
After reconstitution: 2 hours.

6.3 Special precautions for storage

Store between 2°C and 8°C, protected from light.

6.4 Nature and contents of container

- Type-I glass bottle
  Butyl elastomer closure
  Aluminium cap

- Box of one 1,000-dose bottle
  Box of one 2,000-dose bottle
  Box of ten 1,000-dose bottles
  Box of ten 2,000-dose bottles

6.5 Name or style and permanent address or registered place of business of the holder of the authorisation to place the product on the market

MERIAL
17, rue Bourgelat
69002 LYON
FRANCE

6.6 Special precautions for the disposal of unused product or waste material, if any

Disinfect empty bottles or bottles containing unused product before discarding.
Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7 ADDITIONAL INFORMATION

Marketing Authorisation number:

Date of approval/last revision:

Condition of supply: subject to medical prescription

Authorised pack size: