Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Nobilis Multriva RT+IBm+ND+EDS Emulsion for Injection for Chickens

Date Created: June 2026

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Nobilis Multriva RT+IBm+ND+EDS Emulsion for Injection for Chickens
Applicant	MSD Animal Health UK
Active substance(s)	• Avian metapneumovirus, strain BUT1 #8544, inactivated ≥ 19.0 U1 • Infectious bronchitis virus, strain M41, inactivated ≥ 4.8 log2 HI2 • Infectious bronchitis virus, strain 4/91, inactivated ≥ 5.7 log2 HI2 • Newcastle disease virus, strain Ulster, inactivated ≥ 5.9 U1 • Egg drop syndrome 1976 virus, strain BC14, inactivated ≥ 368.3 U[1]
ATC vet code	QI01AA18
Target species	Chickens
Indication(s) for use	For the active immunisation of chickens for: • reduction of egg drop caused by avian metapneumovirus (AMPV); • reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype) and 4/91-793B; • reduction of mortality and clinical signs caused by Newcastle disease virus (NDV); • reduction of egg drop and eggshell defects caused by egg drop syndrome 1976 virus (EDSV).

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Full application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Part 1) as amended.
Date of conclusion of the procedure	15/04/2026

I. SCIENTIFIC OVERVIEW

This is a full application for Nobilis Multriva RT+IBm+ND+EDS in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Part 1) as amended. It's based on the parent vaccine Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS, with the exception that it does not include avian infectious bursal disease virus strains GB02 and 89/03 or avian reovirus strains ARV-1 and ARV-4.

The product is an emulsion for injection for the active immunisation of chickens for reduction of egg drop caused by avian metapneumovirus (AMPV), reduction of respiratory signs and egg drop caused by infectious bronchitis virus (IBV) strains Massachusetts (GI-1 genotype), 4/91-793B (GI-13 genotype), reduction of mortality and clinical signs caused by Newcastle disease virus (NDV), and reduction of egg drop and eggshell defects caused by egg drop syndrome-1976 virus (EDSV).

The onset of immunity is AMPV 5 weeks post-vaccination; IBV, NDV and EDSV 4 weeks post-vaccination. The proposed duration of immunity for AMPV, IBV, NDV and EDSV is 80 weeks post-vaccination.

The distribution category for this product in GB is POM-V.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released on the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC[1]. The product is safe for the user, the consumer of foodstuffs from treated animals, and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy[2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

[1] SPC – Summary of Product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains inactivated Avian metapneumovirus strain BUT1 #8544, inactivated infectious bronchitis virus strain M41, inactivated infectious bronchitis virus strain 4/91, inactivated Newcastle disease virus strain Ulster, and inactivated egg drop syndrome 1976 virus strain BC14 as active ingredients.

The product also contains the excipients polysorbate 80, sorbitan oleate, PBS solution, and light liquid paraffin as an adjuvant.

The container/closure system consists of a bottle of polyethylene terephthalate (PET) closed with a rubber stopper and aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the adjuvant is justified.

The inactivation process and the detection limit of the control of inactivation are correctly validated.

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant regulatory guidelines.

II.B. Method of Preparation of the Product

The product is manufactured fully in accordance with good manufacturing practice (GMP) principles from a licensed manufacturing site.

The product is manufactured in accordance with the European Pharmacopoeia and relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substances are novel, however not listed in a pharmacopoeia. The active substances are manufactured in accordance with the principles of good manufacturing practice.

Starting materials of non-biological origin used in production are not listed in a pharmacopoeia.

PBS solution is used in the manufacture of the finished product

Biological starting materials used are in compliance with the relevant European Pharmacopoeia monographs and guidelines and are appropriately screened for the absence of extraneous agents; any deviation was adequately justified.

The master and working seeds have been produced according to the Seed Lot System as described in the relevant guidelines.

II.C.4. Substances of Biological Origin

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

II.E. Control Tests on the Finished Product

The tests performed on the final product conform to the relevant requirements; any deviation from these requirements is justified. Tests were conducted on appearance, viscosity, accelerated stability, identity and potency, emulsion type, free formaldehyde content, and sterility.

The demonstration of the batch-to-batch consistency is based on the results of 2 batches produced according to the method described in the dossier. Other supportive data provided confirm the consistency of the production process.

II.F. Stability

Stability data on the active substances have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable regulatory guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

The in-use shelf-life of the reconstituted vaccine is supported by the data provided.

G. Other Information

The shelf life of the product as packaged for sale is 2 years. The shelf life after first opening the immediate packaging is 10 hours.

The product should be stored in a refrigerator (2 °C – 8 °C) and not frozen. The product must also be protected from direct sunlight.

III. SAFETY ASSESSMENT

Laboratory trials

The safety of the administration of one dose in the target animal is demonstrated. No adverse reactions were detected, and all clinical signs seen during the study were attributable to causes other than the vaccine. The results of the studies are appropriately reflected by the SPC.

Effects on reproductive performance were examined. The SPC has been updated to state do not use in birds in lay and within 4 weeks of the start of lay.

There are no data suggesting that this product might adversely affect the immune system of the vaccinated animal or its progeny therefore a specific study was not carried out.

The vaccine is inactivated and thus the specific tests to be performed for live vaccines are not applicable.

The adjuvant and excipients used are either allowed substances or not falling within the scope of regulations. Based on this information, a withdrawal period of zero days is proposed.

No specific assessment of the interaction of this product with other medicinal product was made. Therefore, an appropriate warning in the SPC is included.

Field studies

Four GCP field studies were conducted, each using a standard batch of the parent vaccine Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS given on a single occasion intramuscularly into the breast. Two studies were conducted in broiler breeders and two in layers. A total of 67176 birds were vaccinated, and a similar number of control chicken were included. Birds were monitored for a minimum of two weeks after vaccination for local reactions, general health status and feed intake.

In conclusion, there were no evident differences in overall health or production between the control and vaccinated flocks for either broilers or layers following inoculation of a target antigen blend of Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS (the parent vaccine). Injection site reactions, although uncommon, were seen. These observations are used to inform the SPC.

Ecotoxicity

The applicant provided a Phase 1 environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required/further assessment was required.

Warnings and precautions as listed on the product literature are adequate to ensure safety to the environment when the product is used as directed.

IV. CLINICAL ASSESSMENT (EFFICACY)

Clinical Studies

Laboratory Trials

The efficacy of the product has been demonstrated in laboratory studies in accordance with the relevant requirements. Studies have been conducted in chickens from 12-16 weeks of age, however this has been appropriately justified and can be accepted.

The vaccine is recommended for use as a single intramuscular (IM) booster injection (0.3 ml) into the breast or thigh muscle of healthy chickens following mandatory priming with either live or inactivated vaccines particularly against IBV from 8 weeks of age, but no later than 4 weeks before the onset of lay. All vaccine batches are formulated with a fixed antigen content designated as a 100% batch. In general, laboratory challenge studies were conducted for each antigen to determine the onset and duration of immunity of vaccinated birds (SPF chickens) under laboratory conditions.

Onset and Duration of Immunity

Four preclinical laboratory studies were provided to support the onset and duration of immunity against AMPV, although two studies were considered invalid due to insufficient challenge. The proposed onset of immunity (OOI) for AMPV as 5 weeks post vaccination is accepted. The proposed duration of immunity (DOI) for AMPV is 80 wpv.

A total of 11 preclinical laboratory studies has been provided to support efficacy against IBV, although four studies were considered invalid due to insufficient challenge. In the studies, groups were included with or without priming prior to administering Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS. Challeneg studies were conducted on SPF chickens which were given the vaccine at 15 weeks of age and challenged with IBV MA41 at 45 and 81 weeks after vaccination. Protection against reduction in egg production was demonstrated in the vaccinated groups and hence an OOI for IBV of 4 weeks and a DOI of 80 weeks is accepted.

A total of 5 preclinical laboratory studies has been provided to support efficacy against NDV. In the studies, groups were included with or without priming prior to administering Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS. A serological response was seen from 4 to 88 weeks post vaccination in birds with or without priming prior to vaccination. An immunogenicity study and an OOI study were conducted, both of which supported a 4-week OOI with reduction in mortality and clinical signs caused by NDV. Challenge studies were provided in SPF chickens,

which were challenged at 48 and 88 weeks after vaccination. Protection against a reduction in mortality and clinical signs caused by NDV was demonstrated in the vaccinated groups (with and without live priming) compared to the controls and therefore an 80-week DOI is accepted.

A total of 5 preclinical laboratory studies has been provided to support efficacy against EDSV. A serological response was seen from 4 – 74 weeks post vaccination, at 16 weeks of age. Two valid immunogenicity studies were provided to meet the requirements of the Ph. Eur. specific monograph to evaluate efficacy at peak of lay and towards the end of lay, and no marked reduction in egg drop was seen in vaccinated birds. From these studies, a DOI of 80 weeks with a reduction in egg drop is accepted.

Field Trials

Four GCP trials were conducted in the Netherlands to evaluate safety and efficacy of Nobilis Multriva RT+IBm+ND+Gm+REOm+EDS: two on a layer farm and two on a broiler breeder farm, with birds vaccinated at 12, 12, 14 and 15 weeks of age, respectively. All studies were conducted on older birds instead of the minimum age of 8 weeks, however this has been appropriately justified and can be accepted.

In each of the field studies, samples were collected to evaluate serological response following vaccination. These were tested for the presence of antibodies against AMPV, IBV, EDSV, ARV, IBDV and NDV. Routine management practices were performed at each study site, and birds were administered a range of vaccines, some of which had a priming effect prior to administration of the vaccine. Some birds were removed from the field and underwent challenge testing. A serological response to vaccination was seen against all antigens included in the vaccine as follows: AMPV which continued until 80 wpv; IBV strains which continued till 100 wpv; NDV which continued until 88 wpv; and EDS 4 wpv which continued until 88 wpv.

Challenge studies were performed using birds from the field studies and in general results support the laboratory challenge studies although in the AMPV challenge study, efficacy was not demonstrated in commercial layer birds. The challenge at 82 weeks after intramuscular vaccination, was not sufficient to induce clinical signs or viraemia in the control group. No field challenge studies were performed for EDSV in broiler breeder birds.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that, when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the product(s) is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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