Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Avishield IB QX Lyophilisate for Oculonasal Suspension/use in Drinking Water for Chickens

Date Created: November 2025

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Avishield IB QX Lyophilisate for Oculonasal Suspension/use in Drinking Water for Chickens, Suspension for use in drinking water
Applicant	Genera d.d., Svetonedeljska cesta 2, Kalinovica, 10436 Rakov Potok, Croatia
Active substance(s)	Live avian infectious bronchitis virus, type QX, strain 1285
ATC Vetcode	QI01AD07
Target species	Chickens
Indication for use	For the active immunisation of chickens (broilers, future layers and future breeders) in order to reduce respiratory signs of avian infectious bronchitis caused by QX-like variants of infectious bronchitis virus (IBV). Onset of immunity: 3 weeks after vaccination. Duration of immunity: 10 weeks after vaccination.

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	28/08/2025

I. SCIENTIFIC OVERVIEW

This is a full application in accordance with Article 8 of Veterinary Medicine Regulations (VMRs) 2013 (Schedule 1, Part 1) as amended in Great Britain (GB). Avishield IB QX Lyophilisate for Oculonasal Suspension/use in Drinking Water for Chickens is indicated for the active immunisation of chickens to reduce respiratory signs of avian infectious bronchitis caused by QX-like variants of infectious bronchitis virus (IBV).

The vaccine contains live avian infectious bronchitis virus, type QX, strain 1285. It is recommended for use from one day of age for the coarse spray or oculonasal route and from 7 days of age in drinking water. The recommended dose depends on the route of administration. The onset of immunity is 3 weeks after vaccination and the duration of immunity is 10 weeks after vaccination.

The product is authorised as POM-V in GB, a prescription only veterinary medicine.

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.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

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

The product contains live avian infectious bronchitis virus, type QX, strain 1285 and the excipients povidone K 25, bacto-peptone, monosodium glutamate, potassium dihydrogen phosphate, potassium hydroxide and dextran 40 000.

The container/closure system consists of colourless glass vials (type I), which are closed with bromobutyl rubber stoppers and sealed with aluminium caps. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the vaccine strain and the absence of preservative are justified.

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 the principles of good manufacturing practice from a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant regulatory guidelines.

II.C. Control of Starting Materials

The active substance is live avian infectious bronchitis virus, type QX, strain 1285, a novel active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

Starting materials of non-biological origin used in production comply with relevant pharmacopoeia monographs. The only starting material of non-biological origin not listed in a pharmacopoeia is Minimal Essential Medium Eagle (MEM), for which a certificate of analysis is provided.

Biological starting materials used are complaint with the relevant Ph. Eur. Monographs and guidelines. They are appropriately screened for the absence of extraneous agents according to the Ph. Eur; any deviation was adequately justified.

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

The vials and rubber stoppers used as part of the container/closure system, are in compliance with the relevant Ph. Eur. requirements. Certificates of analysis for the vials, rubber stoppers and caps are provided.

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 batches, 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. The tests are appearance, identification, virus titre, purity, sterility, mycoplasma, extraneous agents, residual moisture and vacuum.

The demonstration of the batch-to-batch consistency is based on the results of 3 consecutive 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 substance 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 18 months. The shelf life after reconstitution according to directions is 3 hours.

The product should be stored and transported refrigerated (2 °C – 8 °C). It should not be frozen and should be protected from light.

III. SAFETY ASSESSMENT

The safety studies were performed according to the requirements of the relevant monographs.

Laboratory trials

The safety of the product was investigated in ten GLP laboratory safety studies using batches manufactured according to the dossier. Each study used Specific Pathogen Free (SPF) chicks of the appropriate age for the claimed administration routes and virus at the least attenuated passage that will be present in each batch of vaccine.

The safety of the administration of one dose and an overdose in the target animal is demonstrated together in five GLP-compliant studies. The investigations were performed according to the recommendations of Directive 2001/82/EC as amended and the relevant Ph. Eur. The SPC reflects the adverse events observed in the pivotal overdose studies.

The safety of a repeated administration of one (maximum) dose of the vaccine was not tested and no claim for repeated use is made.

The vaccine is not intended for use during lay, and the SPC carries an appropriate warning. However, an examination of reproductive performance was conducted in one study using a single dose in chicks, vaccinated via coarse spray. The study demonstrated the safety of the vaccine for the developing reproductive tract when administered on the first day of life.

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.

Specific studies were carried out to describe the spread, dissemination, reversion to virulence, biological properties and recombination or genetic reassortment of the vaccine strain. The vaccine was shown to disseminate to all organs, apart from spleen and kidney, in the body of the vaccinated birds which can persist for at least 28 days. It was concluded that no reversion to virulence was observed. The SPC contains an appropriate warning regarding the excretion of the vaccine strain.

The excipients used are either allowed substances where no Maximum Residue Limits (MRL) are required or are considered as not falling within the scope of Regulation EC) No 470/2009. Based on this information, no withdrawal period is proposed.

The interaction of the vaccine with Avishield IB H120 and Avishield IB GI-13 was studied. This confirmed the safety of associative mixed use with these two vaccines and appropriate text is included in the SPC regarding this.

Field studies

Two controlled, blinded, GCP clinical trials were performed in broilers to study safety and efficacy. The vaccine was applied via spray or drinking water. The results of the studies confirm the safety of the vaccine.

A further clinical trial in broilers to study the safety of associated use of the vaccine with Avishield IB H120 and Avishield IB GI-13 was also provided. This supported the safety of the mixed use of these vaccines.

Ecotoxicity

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

The product is not expected to pose a risk for the environment when used according to the SPC. No warnings regarding protection of the environment are therefore required.

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. Laboratory studies investigated the onset of immunity for oculonasal, drinking water and spray routes of administration and duration of immunity for oculonasal use and drinking water routes.

Dose confirmation studies

The pivotal efficacy studies were performed in SPF and Maternally Derived Antibody positive (MDA+) broiler chicks to test the efficacy of the vaccine at a minimum dose of 3.7 $\log_{10}$ EID_{50}.

Onset of Immunity

Two studies investigated onset of immunity following administration of the vaccine by the spray, eye-nose drop and oral routes of administration.

The first study evaluated onset of immunity of 14 and 21 days, following oculonasal vaccination by coarse spray. 60 one-day-old SPF layer chicks were administered either Avishield IB QX vaccine by coarse spray or left unvaccinated as a control. Challenge was performed at either day 14 or day 21. In the vaccinated group that were challenged on day 14, 50% were protected. In the vaccinated group that were challenged on day 21, 80% were protected.

The second study evaluated onset of immunity of 21 days, following oculonasal vaccination by the eye-nose drop method at one-day of age and by the oral route at seven days of age. 65 SPF layer chicks, were administered either Avishield IB QX vaccine at one or seven days of age or left unvaccinated as a control. Challenge was performed at day 21. Results showed a protection level at 21 days post vaccination of 85% for the oculonasal route in one-day old chicks and of 80% for the oral route in seven-day old chicks.

Efficacy and the claim of reduction in respiratory signs were demonstrated following administration of the vaccine to one-day old and seven-day old SPF chicks, challenged three weeks after oculonasal (spray or eye-nose drop) and oral vaccination, respectively.

Therefore, the onset of immunity was concluded to be three weeks post vaccination when administered by the oculonasal (spray or eye-nose drop) route in one day old chicks and by the oral route in seven-day old chicks.

Duration of Immunity

One study investigated duration of immunity following administration of vaccine by the spray and oral routes of administration.

The study evaluated duration of immunity of nine and ten weeks, following oculonasal vaccination by the spray method at one day of age and by the oral route at seven days of age.

110 SPF layer chicks were administered either Avishield IB QX vaccine at one or seven days of age, depending on the route of administration, or left unvaccinated as controls. Results showed a protection level at 63 days (nine-week duration of immunity) post vaccination of 80% for both the oculonasal route (spray method) in one-day old chicks and the oral route in seven-day old chicks. At 70 days (ten-week duration of immunity) post vaccination, 60% and 70% protection was shown for the oculonasal route (spray method) in one-day old chicks and the oral route in seven-day old chicks, respectively.

In conclusion, efficacy and the claim of reduction in clinical signs have been demonstrated following administration of the vaccine to one-day old and seven-day old SPF chicks, challenged ten weeks after oculonasal (spray method) and oral vaccination respectively. The duration of immunity of ten weeks post vaccination, for the oculonasal route in one day old chicks and for the oral route in seven-day old chicks, was supported.

Associated Use Studies

Two pivotal studies investigated efficacy of the vaccine (oculonasal route by spray method) in associated use with Avishield IB GI-13 and Avishield IB H120. These were performed in SPF chicks, vaccinated at one-day of age.

Appropriate challenge testing was performed and the results of vaccinated chicks were compared with the results of non-vaccinated chicks. Overall, the studies showed no evidence that associated use would interfere with the efficacy Avishield IB QX.

Maternally Derived Antibodies (MDA)

Three studies (coarse spray, eye-nose drop and oral methods of administration) were provided to investigate interference of MDA on the efficacy of Avishield IB QX.

In these studies, efficacy was demonstrated following administration of Avishield IB QX vaccine to one- and seven-day old commercial broiler MDA+ chicks. Chicks were challenged three weeks after oculonasal (spray method and eye-nose drop) and oral vaccination, respectively. An onset of immunity of three weeks post vaccination for Avishield IB QX administered by the oculonasal route in one day old and by the oral route in seven-day old MDA+ commercial broiler chicks was supported.

Field Trials

Two field studies were performed in broilers in Slovenia, one using spray administration of the vaccine and one using oral administration. A positive comparator vaccine was used as a control.

The first study evaluated the efficacy, in the field, of Avishield IB QX by spray administration in commercial one day old broilers. This was a comparative, randomised, blinded field trial with one treatment group (one broiler flock of 20,033) and one comparative group (one broiler flock). Blood tests were taken at day 1, day 22 and day 40 for antibody evaluation by ELISA. On day 40, the Avishield IB QX vaccinated chicks had a significantly higher antibody response compared to the comparator group. As no natural challenge occurred, a select group of chicks were transported to the laboratory for challenge. Results showed a protection level at 21 days post vaccination of 70% for the oculonasal route in one-day old MDA+ broiler chicks.

The second study evaluated the efficacy, in the field, of Avishield IB QX by oral administration, in commercial seven-day old broilers. This was a comparative, randomised, blinded field trial with one treatment group (one broiler flock of 19,519) and one comparative group (one broiler flock of 23,600). Blood tests were taken for analysis. On the day of vaccination and three weeks after vaccination, there was no significant difference in the titre of specific antibodies to IBV between both groups. On day 41/42, significantly higher antibody response was confirmed in the comparator group, compared to the treatment group. As no natural challenge occurred, a select group of chicks were transported to the laboratory for challenge. Results following the administration of the vaccine showed a protection level at 21 days post vaccination of 85%, for the oral route in seven-day old MDA+ broiler chicks.

In conclusion, efficacy has been demonstrated following administration of Avishield IB QX vaccine to one and seven-day old broilers, vaccinated in the field and challenged three weeks after oculonasal (spray) and oral vaccination, respectively. Studies were performed using the proposed minimum IBV antigen content of 3.7 $\log_{10}$ $TCID_{50}$. The results from both field trials support the laboratory findings.

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 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.

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

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.

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