FRENCH AGENCY FOR VETERINARY MEDICINAL PRODUCTS
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"MUTUAL RECOGNITION " PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

MODULE 1

PRODUCT SUMMARY

EU Procedure number	FR/V/0171/002
Name, strength and pharmaceutical form	Hatchpak IB H120 NEO Effervescent tablet for nebulizer suspension 3.7 to 4.7 log10 EID_{50} per dose
Applicant	BOEHRINGER INGELHEIM ANIMAL HEALTH FRANCE 29 Avenue Tony Garnier 69007 Lyon France
Active substance(s)	Life Avian Infectious Bronchitis virus, strain H120
ATC Vetcode	QI01AD07
Target species	One day old chickens.
Indication for use	active immunisation against Infectious Bronchitis in order to reduce infection with Massachusetts serotype of Infectious Bronchitis virus.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the website http://www.anmv.anses.fr/

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Mutual Recognition application in accordance with Article 12 of Directive 2001/82/EC as amended.
Date of completion of the original <mutual recognition> <decentralised>procedure	21/09/2016
Date product first authorised in the Reference Member State (MRP only)	15/03/2016
Concerned Member States for original procedure	AT, BE, CY, DE, DK, EL, FI, IE, IS, IT, NL, SE, SI, ES, UK

I. SCIENTIFIC OVERVIEW

***For public assessment reports for the first authorisation in a range**:*

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; the slight reactions observed are indicated in the SPC
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 of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

The efficacy aspects of this product is identical to Hatchpak H120.

II. QUALITY ASPECTS

A. Composition

The product contains Live Infectious bronchitis virus H120 strain (3.7 ≤ R ≤ 4.7 log10 EID_{50}) and excipients (Sunset Yellow FCF colorant, casein hydrolysate, D-

mannitol, sodium hydroxide, water for injections, citric acid anhydrous, sodium hydrogen carbonate and magnesium stearate).

The container/closure system are aluminium blister consisting of two aluminium foils heat-sealed. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the effervescent tablet formulation is justified. The composition is active substance is not changed compared to Hatchpak H120.

The product is a novel pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

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 and in accordance with the European Pharmacopoeia and relevant European guidelines.

C. Control of Starting Materials

Starting materials of non-biological origin used in production comply with pharmacopoeia monographs and in-house specifications.

Biological starting materials used are in compliance with the relevant Ph. Eur. Monographs and guidelines and are appropriately screened for the absence of extraneous agents according to the Ph. Eur and European Guidelines; 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.

D. Specific Measures concerning the Prevention of the Transmission of Animal Spongiform Encephalopathies

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

E. Control tests during production> (immunologicals)

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

F. 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 include in particular appearance, disintregation time, pH, identification of the active substance, batch titre, sterility and purity tests and residual humidity.
The demonstration of the batch to batch consistency is based on the results of 3 batches produced according to the method described in the dossier. Other supportive data provided confirm the consistency of the production process.

G. Stability

The in-use shelf-life of 24 months of the vaccine is supported by the data provided.

III. SAFETY ASSESSMENT

The safety part of the dossier correspond to the safety part of the dossiers Hatchpak H120. Only the environmental risk assessment and the user risk assessment are documented.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required >. The assessment concluded that the risk posed by the vaccine is identical to the risk posed by Hatchpak H120 and it is effectively zero.

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)

The efficacy part of the dossier correspond to the efficacy part of the dossiers Hatchpak H120.

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 risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 veterinary Heads of Agencies website (HMAv).

This section 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.

1. Refiement of the bacterial and fungal sterility test for the active ingredient authorised on 18/08/2017.

2. Conditions of the bulk active ingredient formulation at the freeze-drying stage authorised on 31/07/2019

3. Extension of the shelf life from 18 to 24 months authorised on 05/06/2021

4. Refinement of the specification of control test for hardness of the tablets authorised on 22/10/2021