Agencia Española de Medicamentos y Productos Sanitarios

C/Campezo 1, Edificio 8
28022 – Madrid
España
(Reference Member State)

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

HIPRAPOX lyophilisate and solvent for suspension for injection

CORREO ELECTRÓNICO

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MODULE 1

PRODUCT SUMMARY

EU Procedure number	ES/V/0258/001/MR
Name, strength and pharmaceutical form	HIPRAPOX lyophilisate and solvent for suspension for injection
Applicant	Laboratorios Hipra, S.A. Avda. la Selva, 135 Postcode: 17170 Amer (Gerona) Spain
Active substance(s)	Live attenuated Fowl Pox Virus, strain FPV-92
ATC Vet code	QI01AD12
Target species	Chickens and turkeys
Indication for use	For active immunization of chickens and turkeys to reduce clinical signs after infection with Fowl Pox Virus. Onset of immunity: 21 days after vaccination. The duration of immunity is not established.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Medicines Agencies website (http://www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Mutual Recognition application in accordance with Article 12 (3) of Directive 2001/82/EC as amended.
Date of completion of the original mutual recognition procedure	21/10/2015
Date product first authorised in the Reference Member State (MRP only)	27/09/1955
Concerned Member States for original procedure	DE

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.

II. QUALITY ASPECTS

A. Composition

The product contains live attenuated Fowl Pox Virus, strain FPV-92, 104.0 -104.4 EID50, and excipients:

Lyophilisate:
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride

Potassium chloride
Povidone
Sucrose
Sodium glutamate

Solvent:
Disodium hydrogen phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Potassium chloride
Water for injections

The container/closure system is type I, neutral glass vials; Type I bromobutyl rubber closures and aluminium cap. The particulars of the containers and controls performed are provided and conform to the regulation.

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

The product is an established 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.

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

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

C. Control of Starting Materials

The active substance is Live attenuated Fowl Pox Virus, strain FPV-92, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

Starting materials of non-biological origin used in production comply with pharmacopoeia monographs or 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 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

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.

E. Control tests during production

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 finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site<s> have been provided demonstrating compliance with the specification.

The tests performed on the final product conform to the relevant requirements; any deviation from these requirements is justified. The tests include in particular potency test.

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

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

III. SAFETY ASSESSMENT

Laboratory trials

The safety of the administration of one dose, an overdose and the repeated administration of one dose in the target animal according to the recommendations of the Guideline on Data requirements for Immunological veterinary medicinal products intended for minor use or minor species/limited markets, as amended, have been reduced, and data supported by bibliographycal data.

Effects on reproductive performance were examined: the safety information provided assessing the key safety issues, together with the high number of years of commercial experience on the vaccine, fully supports that this vaccine is a safe product.

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 conceived to be administered in future layers and breeders. In line with this, a study was conducted considering the possible risk that the administration conditions may entail on the reproductive performance, that is on the egg production.

Specific studies were carried out to describe dissemination, reversion to virulence, biological properties, recombination or genetic reassortment of the vaccine strain. No reversion or increase to virulence was shown by the vaccine strain. Nevertheless, the dissemination of the vaccine strain was not specifically assessed in any trial. As established by the guideline on data requirements for veterinary immunological products intended for MUMS, the study of dissemination is not necessary if the agent does not spread from animal to animal. As aforementioned, no spreading was demonstrated for the vaccine strain. Thus, no dissemination study was conducted

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

None field trial was carried out. This approach is included and accepted in the guideline for MUMS products, in the case that laboratory studies sufficiently show no safety risk.

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 vaccine is safe to environment.

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)

IV.B Clinical Studies

Laboratory Trials

According to the Guideline on Data Requirements for Immunological veterinary medicinal products intended for minor use or minor species/limited markets (EMA/CVMP/IWP/123243-Rev.2) vaccines against avian Poxvirus are classified as immunological veterinary medicinal products intended for minor use and/or minor species/limited markets. Therefore some reductions in requirements has been considered for this product.

The efficacy studies were also performed on the nineties, thus they are quite old. However, the vaccine is being commercialized in Spain since 1955, and no efficacy concerns have arisen from its use under the recommended conditions during its whole life cycle. No suspected lack of efficacy cases have ever been reported through the pharmacovigilance system for this product. Therefore, the product has sufficiently demonstrated to be efficacious.

Field Trials

The applicant has provided bibliographical data which show the vaccine efficacy for the active immunization of chickens and turkeys to prevent infection by Fowl Pox virus.

In addition, the efficacy of the vaccine was assessed by challenging the birds with a virulent strain. A strain virulent enough as to cause clinical signs in the 100 % of non-vaccinated birds and a high mortality was used.
The clinical benefit of vaccination was confirmed by the results obtained because relevant differences were found when compared the vaccinated and infected groups with the non-vaccinated infected groups.

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 (www.hma.eu).

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.

None

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