

## NOTICE

### AVIAN INFLUENZA VIRUS H5N9

#### [in the product: POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE]

The Australian Pesticides and Veterinary Medicines Authority (APVMA) has before it an application from Commonwealth Department of Agriculture Fisheries and Forestry, for the approval of a new active constituent, *Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998. The APVMA also has before it an application from the same applicant, for the registration of a new product, 'POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE' containing the above active constituent. The product is for the immunisation of chickens and turkeys against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to these diseases.

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the applications for approval of this active constituent and the application for the registration of the product 'POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE' should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to matters outlined below that the APVMA is required to take into account in deciding whether to grant the approval and registration. Comments must be received by the APVMA within 28 days of the date of this Gazette.

#### **Particulars of Active Constituent**

Common name:	<i>Avian influenza virus H5N9</i>
Strain/serotype:	Strain A/CK/Italy/22A/H5N9/1998
Identity and purity:	Carried out by the OIE Reference Laboratory for Newcastle
Disease and	Avian Influenza,
Sterility:	As per European Pharmacopoeia
Extraneous agents:	As per European Pharmacopoeia
Mycoplasma:	As per European Pharmacopoeia
Mode of action:	Inducing immunological responses
Site of manufacture:	Recognised by the APVMA
Gene technology:	Not applicable
Applicant Name:	Department of Agriculture Fisheries and Forestry Edmund Barton Building Blackall Street Barton ACT 2601
Summary of Use:	This active is to be incorporated in a vaccine for the immunisation of chickens and turkeys against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to this disease.

## **Particulars of the Product**

### **Proposed product name**

POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE

### **Active Constituent**

*Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998

### **Adjuvant**

Liquid light paraffin

### **Pharmaceutical form**

Emulsion for injection

### **Target species**

Chickens and turkeys

### **Indications for use**

For the immunisation of chickens and turkeys against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to these diseases.

### **Directions for use**

Chickens: From 14 days old, two injections of 0.5 mL given intramuscularly at least 14 days between vaccinations. Turkeys: From 8 days old, two injections of 0.5 mL given subcutaneously at approximately 21 days interval.

### **Contraindications**

Do not administer intramuscularly in chickens less than 2 weeks old.

Do not administer to birds in lay or less than 4 weeks before the birds come into lay

### **Caution**

This vaccine has not been tested in other species. The level of efficacy for other species may differ from that observed in chickens and turkey

### **User safety information**

This product contains mineral oil. Extreme caution should be used when administering oil emulsion vaccine to avoid injecting yourself. Accidental-self injection may cause inflammatory reaction, severe pain and swelling that requires correct medical management. Seek medical attention as soon as possible in the event of accidental-self injection.

### **Incompatibilities**

Do not mix with any other medicinal product.

### **Withholding eriod**

Nil

### **Applicant name**

Department of Agriculture Fisheries and Forestry  
Edmund Barton Building

Blackall Street Barton ACT 2601

### **Conditions of supply and use**

POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE' can only be released on the authority of the Chief Veterinary Officer (CVO) in the relevant State or Territory. The product can only be used under the control of the CVO of the jurisdiction in accordance with a decision of the Consultative Committee on Exotic Animal Diseases (CCEAD).

POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE can only be used by authorised personnel or persons otherwise authorised under State/Territory legislation. The product must be used in accordance with the approved label directions/instructions or as specified by the CCEAD, or the CVO of the relevant jurisdiction.

### **Summary of the APVMA's Evaluation of the Active Constituent and the Product**

The chemistry and manufacturing aspects of *Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998 and the product, including starting materials, master seed organism (source, isolation, identification, testing), culture medium, vaccine production, storage, quality control and batch release analysis, have been evaluated and found to be acceptable.

The APVMA is satisfied that the proposed use of *Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998 in POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE for active immunisation of chickens and turkeys against avian influenza type A, subtype H5 serotype to reduce mortality, clinical signs and/ or lesions due to this disease would not be likely to have an effect that is harmful to human beings, environment or trade.

In relation to its assessment of efficacy and safety in target animals the APVMA is satisfied that the data supporting the efficacy and safety of POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE adequately demonstrates that this product is likely to be effective under Australian conditions when used as directed according to the label instructions.

Written submissions on the APVMA's proposal to grant the application for approval of the active constituents *Avian influenza virus H5N9* Strain A/CK/Italy/22A/H5N9/1998, and the registration of the product POULVAC FLUFEND i AI H5N9 (INACTIVATED) VACCINE should be addressed in writing to:

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Manager Vaccines and Antibiotics  
Veterinary Medicines Program  
The Australian Pesticides and Veterinary Medicines Authority  
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