I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Fort Dodge Animal Health on 10 March 2006, the Committee for Medicinal Products for Veterinary Use (CVMP) accepted on 15 March 2006 that Poulvac FluFend H5N3 RG was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised procedure.

During its meeting of 14-16 March 2006, the CVMP appointed Dr Ivo Claassen from Netherlands as Rapporteur and Dr Jean-Claude Rouby from France as Co-rapporteur for the assessment of the application for Poulvac FluFend H5N3 RG. Due to exceptional circumstances the CVMP decided to appoint J-C Rouby as Rapporteur and I. Claassen as Co-Rapporteur in May 2006. In accordance with Article 39 (8) of Regulation (EC) No 726/2004, the CVMP also accepted the request of Fort Dodge Animal Health for an accelerated assessment procedure on the grounds that Poulvac FluFend H5N3 RG is a veterinary medicinal product of major interest, particularly from the point of view of human and animal health as explained below.

The company Fort Dodge Animal Health submitted an application to the EMEA on 28 April 2006 for the granting of a Community marketing authorisation for Poulvac FluFend H5N3 RG.

The application was validated on 2 May 2006.

2. Steps taken for the assessment of the product

The Rapporteur and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 28 June 2006.

The procedure was finalised with adoption of the opinion according to Article 31 of Regulation (EC) No 726/2004 and Article 39 (7) of Regulation (EC) No 726/2004. The CVMP, in the light of the agreed scientific standards and methods for evaluating veterinary medicinal products at the time of submission of the dossier, issued on 20 July 2006 a positive Opinion for the granting of a Community marketing authorisation for Poulvac FluFend H5N3 RG.

The CVMP considered that due to the current epidemiological situation of Avian Influenza and the consequent threat to both human and animal health there are objective and verifiable reasons for recommending the granting of a Marketing Authorisation in accordance with Article 39 (7) of Regulation (EC) No 726/2004 under exceptional circumstances for this product, namely that

- the period of greatest epidemiological risk for European bird populations is the autumn/winter and there is therefore an urgent and objective need to have authorised products available for use during this period in 2006.
- the application has met the requirements of the EMEA/CVMP/IWP/46853/06 Reflection Paper: Minimum Data Requirements for an Authorisation under Exceptional Circumstances for Vaccines for Emergency Use in Birds Against H5 and/or H7 Highly Pathogenic Avian Influenza Virus.
- the Applicant has agreed to the necessary post authorisation specific obligations, including enhanced pharmacovigilance, to assure the safe use of the product in the field.
- the Applicant cannot reasonably be expected to provide the results from certain trials on the target species for duly substantiated reasons, in particular trials which may not be conducted due to the European Community legislation on the control of Avian Influenza that prohibits vaccination against Avian Influenza except as part of approved control programmes.

II. GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing authorisations and inspection status

Manufacturer of the active substance and responsible for batch release:

Fort Dodge Animal Health Holland
CJ van Houtenlaan 36
1381 CP Weesp
The Netherlands

Fort Dodge Animal Health (Charles City)
2000 Rockford Road
Charles City, Iowa 50616
USA

Fort Dodge Animal Health Holland
CJ van Houtenlaan 36
1381 CP Weesp
The Nederlands

Manufacturing Authorisation issued on 25 September 2003 by the Chief Veterinary Officer in the Netherlands.

2. Proposed conditions or restrictions of supply and use

To be supplied only on veterinary prescription.

According to Article 71 of Directive 2001/82/EC Member States prohibit or may prohibit the import, sale, supply and/or use of the veterinary medicinal product on the whole or part of their territory if it is established that:

a) the administration of the veterinary medicinal product to animals will interfere with the implementation of national programmes for the diagnosis, control and eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals>
b) the disease to which the veterinary medicinal product is intended to confer immunity is largely absent from the territory.

The use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of Avian Influenza.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

2.3. Statement of the MRLs

Annex II of Council Regulation (EEC) No 2377/90

Pharmacologically active substance	Animal Species	Other provisions
Mineral oils	All food producing species	
Arlacel 83V (sorbitan sesquioleate)	All food producing species	
Tween 80 (polyoxyethylene sorbitan monooleate)	All food producing species	
Sodium chloride	All food producing species	
Sodium phosphate dibasic (E339)	All food producing species	
Potassium phosphate monobasic (E340)	All food producing species	
Thiomersal	All food producing species	For use only as preservatives in multidose vaccines at a concentration not exceeding 0.02%(concentration in the product is 0.004%)

