I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by **Intervet International BV** on 2 August 2006, the Committee for Medicinal Products for Veterinary Use (CVMP) accepted on 13 September 2006 that **Nobilis Influenza H5N6** was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Regulation (EC) No. 726/2004.

The CVMP appointed **Dr Martin Ilott** from **United Kingdom** as Rapporteur and **Dr Maria Tollis** from **Italy** as Co-Rapporteur for the assessment of the application for **Nobilis Influenza H5N6** during its meeting of 12-14 September 2006.

The company **Intervet International BV** submitted an application to the EMEA on **30 January 2007** for the granting of a Community marketing authorisation in accordance with Regulation (EC) No. 726/2004.

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 15-16 May 2007 was sent to the Applicant and the clock stopped.
- A CVMP Opinion was adopted on 11 July 2007, recommending the granting of the Marketing Authorisation for the above mentioned product.
- Intervet International BV submitted written notice to the EMEA on 24 July 2007 requesting a re-examination of the Opinion in order to remove one sentence relating to the level of efficacy and its relationship with the degree of antigenic homology between the vaccine strain and circulating field strains.
- On 11 September 2007 the detailed grounds for the re-examination request were received by the EMEA.
- The re-examination procedure started on 12 September 2007.
- An oral hearing was held on 12 December 2007.
- 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 12 December 2007 a positive Opinion for the granting of a Community marketing authorisation for Nobilis Influenza H5N6 with the relevant sentence remaining unchanged.

The CVMP, having considered the application in accordance with Article 32 of Regulation (EC) No 726/2004 of 31 March 2004 as set out in the appended assessment report, recommends the granting of a Marketing Authorisation under exceptional circumstances, in accordance with Article 39 (7) of Regulation (EC) No 726/2004 of 31 March 2004, for the above mentioned veterinary medicinal product for which the draft Summary of Product Characteristics is set out in Annex I.

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 under exceptional circumstances for this product, namely that

- the recent outbreaks of Avian influenza in the Czech Republic, the UK, France and Germany proved the sustained threat of this disease for European bird populations and there is therefore an urgent and objective need to have authorised products available.
- 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.

The European Commission granted a marketing authorisation valid throughout the European Union for Nobilis Influenza H5N6 on 31 January 2008.

A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance

Intervet International BV
Wim de Korverstraat 35
NL-5831 AN Boxmeer
The Netherlands

Laboratorios Intervet SA
Poligono El Montalvo
Apartado 3006
Salamanca 37080
Spain

Intervet International BV, site De Bilt
Ambachtstraat 4
3732 CN De Bilt
The Netherlands

Name and address of the manufacturer responsible for batch release

Intervet International BV
Wim de Korverstraat 35
NL-5831 AN Boxmeer
The Netherlands

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, 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.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable.

D. STATEMENT OF THE MRLs

The following substances contained in the final product are included in Annex II of Council Regulation (EEC) No 2377/90:

Pharmacologically active substance	Animal Species	Other provisions
Light liquid paraffin	All food producing species	
Polysorbate 80	All food producing species	
Sorbitan mono oleate (E494)	All food producing species	
Glycine	All food producing species	