European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency adopts positive opinion for avian influenza vaccines for use in birds

The European Medicines Agency has adopted the first positive opinions recommending the granting of community authorisations for avian influenza vaccines for use in birds. The two vaccines concerned, Nobilis Influenza H5N2 from Intervet International BV, and Poulvac FluFend H5N3 RG, from Fort Dodge Animal Health, are both inactivated, adjuvanted avian influenza vaccines for administration by injection. Nobilis Influenza H5N2 is for use in chickens and Poulvac FluFend H5N3 RG is for use in both chickens and Pekin ducks. Both vaccines reduce mortality and virus excretion in vaccinated chickens exposed to infection. The use of these products will be restricted to administration as part of disease control campaigns carried out by national competent authorities in compliance with European Community legislation on the control of avian influenza.

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) adopted positive opinions at its meeting of 18-20 July 2006, recommending that these vaccines should be authorised under exceptional circumstances and subject to specific obligations that will be reviewed annually. The CVMP concluded that the benefits from immediate authorisation in preparation for the upcoming period of high risk for incursion of avian influenza virus during the autumn and winter of 2006 outweigh the potential risks. The specific obligations are intended to provide additional assurance in relation to the products and to ensure that the applicant has in place a programme of active pharmacovigiliance (i.e. reporting of adverse reactions) should they be used in the field.

Authorisation of these products provides assurance to national authorities of the quality of the vaccines should vaccination be used as a measure to control avian influenza in birds. Effective control of avian influenza in birds is considered to be particularly important at the present time not only in the interests of animal health but also to reduce the likelihood of the emergence of a human pandemic strain of the virus.

The CVMP began its work on avian influenza preparedness in 2005 and issued its reflection paper on data requirements for avian influenza vaccines in February 2006 in direct response to the incursion of the disease into the European Union. The CVMP also adopted a guideline on accelerated assessment and, by granting positive opinions for these two products, the Committee has fulfilled its previously stated commitment to review applications as quickly as possible, whilst ensuring a scientifically sound and thorough assessment.

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NOTES:

1. A question and answer document and summaries of opinion with more details on the positive opinions are available on the EMEA website. The question and answer document can be found here and the summaries of opinion can be found here.
2. The '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' can be found here.
3. The 'Guideline on the procedure for accelerated assessment pursuant to Article 39 (8) of Regulation (EC) No 726/2004' can be found here.
4. This press release, together with other information on the work of the EMEA, can be found on the EMEA website at http://www.emea.eu.int

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