European Medicines Agency
Directorate

London, 21 July 2006
Doc. Ref. EMEA/281078/2006

Questions and answers on the CVMP positive opinions for avian influenza vaccines for use in birds

On 20 July 2006 the European Medicines Agency's Committee for Medicinal Products for Veterinary Use (CVMP) adopted positive opinions for two vaccines against avian influenza ('bird flu') in birds, **Nobilis Influenza H5N2,** from Intervet International BV, and **Poulvac FluFend H5N3 RG,** from Fort Dodge Animal Health BV, recommending the granting of a marketing authorisation under exceptional circumstances.

What are Nobilis Influenza H5N2 and Poulvac FluFend H5N3 RG used for?
Nobilis Influenza H5N2 and Poulvac FluFend H5N3 RG are vaccines to be used in certain types of poultry to protect against avian influenza, Nobilis Influenza H5N2 can be used in chickens and Poulvac FluFend H5N3 RG in chickens and Pekin ducks. Both vaccines reduce the signs of flu and the excretion (shedding) of the virus by the infected birds.
The strains present in the vaccines (H5N2 in Nobilis Influvac and H5N3 in Poulvac FluFend) have been chosen to protect birds against exposure to virulent H5N1 field strains and to allow differentiation of vaccinated from infected birds. When birds are vaccinated with the vaccines, they develop antibodies (a special type of protein) against H5N2 or H5N3. For that reason vaccinated birds can be differentiated from infected birds by a diagnostic test for antibodies against the N2 or N3 components. This differentiation is important for disease surveillance and control.

Does the Committee's positive opinion mean that avian influenza vaccines have been authorised at Community level?
No. The CVMP is a scientific committee, not a decision-making committee. The CVMP assessed the application for marketing authorisation for each vaccine and decided, based on the information provided, that the benefits of the products outweigh potential risks. These opinions will now be passed to the Commission to be transformed, according to the legal decision-making process, into marketing authorisations valid throughout the European Union.

What steps did the Committee take before recommending marketing authorisation under exceptional circumstances?

- There is an urgent need to have vaccines against avian influenza in birds authorised in time for the next period of high risk, which will be this autumn and winter. The World Health Organization (WHO) places a high priority on control of avian influenza in birds not only for reasons of animal health but also to reduce the likelihood of the emergence of a human pandemic strain. In recognition of this urgency, the CVMP adopted at its February 2006 meeting a reflection paper on the minimum data requirements for authorisation of avian influenza vaccines under exceptional circumstances.
- Having assessed the applications for marketing authorisation for Nobilis Influenza H5N2 and Poulvac FluFend H5N3 RG, the EMEA agreed that both applications met these requirements allowing positive opinions to be reached.
- The Committee assessed the two applications under an accelerated timetable. The active review time was only 79 days.
- The assessment concluded that the information provided was sufficient to give adequate assurance that the benefits of the products outweigh their potential risks.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.eu.int http://www.emea.eu.int

- Certain field trials for avian influenza vaccines cannot be conducted within the EU because EU legislation does not allow vaccination except as part of approved control programmes. The CVMP recommended that the authorisations be issued 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.

How and when will these vaccines be used once they have been authorised?
Vaccination of birds against avian influenza is controlled by Community legislation. A marketing authorisation decision for these two veterinary medicinal products will mean that centrally authorised vaccines will be available for use in birds, thereby promoting harmonisation and quality assurance of vaccines within the EU. The decision whether or not to use the vaccines will be made according to the epidemiological situation of avian influenza in birds by Member States in consultation with the European Commission.