EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 September 2010
EMA/CHMP/487326/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Aflunov

Influenza virus surface antigens*, inactivated: A/Viet Nam/1194/2004 (H5N1) * produced in eggs /Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)

On 23 September 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product AFLUNOV, 7.5 µg Haemagglutinin/dose, suspension for injection in pre-filled syringe intended for the active immunisation against H5N1 subtype of Influenza A virus in adults. The applicant for this medicinal product is Novartis Vaccines and Diagnostics S.r.l. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Aflunov is Influenza virus surface antigens (produced in eggs) inactivated derived from the strain A/Viet Nam/1194/2004 (H5N1)-like strain (NIBRG-14), ATC Code J07BB02. Aflunov is an adjuvanted vaccine that induces an immune response (circulating antibodies) against H5N1 antigens.

The benefits with Aflunov are its ability to mount an appropriate immune response in individuals that are immunologically naïve against the vaccine strain. The most common side effects are injection site reactions, myalgia, headache and fatigue.

A pharmacovigilance plan for Aflunov will be implemented as part of the marketing authorisation.

The approved indication is: "Active immunisation against H5N1 subtype of Influenza A virus. This indication is based on immunogenicity data from healthy subjects from the age of 18 years onwards following administration of two doses of the vaccine containing A/Vietnam/1194/2004 (H5N1)-like strain".

It is proposed that Aflunov should be used in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of the quality, safety and efficacy data submitted, considers there is a favourable benefit to risk balance for Aflunov and therefore recommends the granting of the marketing authorisation.