European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 18 December 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
IDflu

International Nonproprietary Name (INN): Influenza vaccine (split virion, inactivated)

On 18 December 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product IDflu, 9 microgram/strain and 15 microgram/strain, suspension for injection intended for prophylaxis of influenza. The applicant for this medicinal product is Sanofi Pasteur SA, 2 avenue Pont Pasteur, 69007 Lyon, France.

The active substance of IDflu is split influenza virus, inactivated, containing influenza antigens of type A (H1N1), type A (H3N2) and type B strains. The composition of the influenza strains will be those officially recommended for the season.

IDflu is a trivalent influenza vaccine (J07BB02) that induces an immune response (circulating antibodies) against the antigens (i.e. A/H3N2, A/H1N1, and B strains). The duration of postvaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6-12 months.

The benefits with IDflu is its protection against seasonal influenza. The most common side effects are local reactions (redness, pain, swelling), headache, myalgia and malaise, usually disappearing within 1-3 days without treatment.

A pharmacovigilance plan for IDflu, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: Prophylaxis of influenza in adults up to 59 years of age, especially in those who run an increased risk of associated complications (9 microgram strength) and prophylaxis of influenza in individuals 60 years of age and over, especially in those who run an increased risk of associated complications (15 microgram strength). The use of IDflu should be based on official recommendations.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and 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 quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for IDflu and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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