sanofi pasteur

The vaccines division of sanofi-aventis Group

01 December 2010

To Eric Abadie
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
UNITED KINGDOM

Subject: Withdrawal of Emerflu, pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/Vietnam/1194/2004 NIBRG-14, 30 µg of haemagglutinin + aluminium hydroxide adjuvant, suspension for injection - EMEA/H/C/000859

Dear Dr Abadie,

I would like to inform you that, at this point of time, Sanofi Pasteur has taken the decision to withdraw the application for Marketing Authorisation of Emerflu, pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/Vietnam/1194/2004 NIBRG-14, 30 µg of haemagglutinin + aluminium hydroxide adjuvant, suspension for injection, which was intended to be used for prophylaxis of influenza in an officially declared pandemic situation.

This core pandemic dossier was submitted in the context of prevention of influenza in an officially declared pandemic situation, according to the mock-up vaccine procedure (CPMP/VEG/4986/03).

This withdrawal is based on the following reasons:

- The CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance
- If pandemic vaccines are needed in the future, adjuvanted vaccines as developed recently for H1N1 pandemic offer a better solution than aluminium adjuvanted vaccine for antigen sparing

At the present time, there is no on-going clinical trial with Emerflu.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Yours sincerely,