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Human Medicines Development and Evaluation

Public statement on

Humenza (Pandemic influenza vaccine (H1N1) split virion, inactivated, adjuvanted)

Withdrawal of the marketing authorisation in the European Union

On 8 June 2010 the European Commission issued a conditional marketing authorisation valid throughout the European Union for the medicinal product Humenza (pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted)), which had been approved for prophylaxis of influenza in an officially declared pandemic situation.

The marketing authorisation holder (MAH) responsible for Humenza was Sanofi Pasteur S.A. The European Commission was notified by a letter dated 5 May 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation for commercial reasons. Humenza was not marketed in any EU country.

On 14 June 2011 the European Commission issued a decision to withdraw the marketing authorisation for Humenza.

Pursuant to this decision the European Public Assessment Report for Humenza will be updated to reflect that the marketing authorisation is no longer valid.

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