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Human Medicines Development and Evaluation

Public statement on

Prepandemic influenza vaccine (H5N1) GlaxoSmithKline Biologicals [Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14]

Withdrawal of the marketing authorisation in the European Union

On the 26 September 2008 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Prepandemic influenza vaccine (H5N1) GlaxoSmithKline Biologicals, prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) A/VietNam/1194/2004 NIBRG-14, which had been approved as for prophylaxis of influenza in an officially declared pandemic situation.

The marketing authorisation holder (MAH) responsible for Prepandemic influenza vaccine (H5N1) GlaxoSmithKline Biologicals was GlaxoSmithKline Biologicals S.A. The European Commission was notified by a letter dated 12 August 2011 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Prepandemic influenza vaccine (H5N1) GlaxoSmithKline Biologicals for commercial reasons. Prepandemic influenza vaccine (H5N1) GlaxoSmithKline Biologicals was not marketed in any country of the European Union.

On 3 October 2011 the European Commission issued a decision to withdraw the marketing authorisation for Prepandemic influenza vaccine (H5N1) GlaxoSmithKline Biologicals.

Pursuant to this decision the European Public Assessment Report for Prepandemic influenza vaccine (H5N1) GlaxoSmithKline Biologicals will be updated to reflect that the marketing authorisation is no longer valid.

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