20 December 2010
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Human Medicines Development and Evaluation

Public statement on

Arepanrix ([pandemic influenza vaccine (H1N1) (split virion, inactivated, adjuvanted])

Withdrawal of the marketing authorisation in the European Union

On the 23 March 2010 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Arepanrix, pandemic influenza vaccine (H1N1)v (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 Arepanrix was GlaxoSmithKline Biologicals S.A. The European Commission was notified by a letter dated 22 November 2010 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Arepanrix for commercial reasons. Arepanrix was not marketed in any European country.

On 13 December 2010 the European Commission issued a decision to withdraw the marketing authorisation for Arepanrix.

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the European Public Assessment Report for Arepanrix will be updated to reflect that the marketing authorisation is no longer valid.

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