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Public statement

Pumarix

Withdrawal of the marketing authorisation in the European Union

On 11 February 2015, the European Commission withdrew the marketing authorisation for Pumarix (pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)) in the European Union (EU). The withdrawal was requested by the marketing authorisation holder, GlaxoSmithKline Biologicals, which notified the European Commission that it did not intend to maintain the marketing authorisation for commercial reasons.

Pumarix was granted a marketing authorisation in the EU on 4 March 2011 for prevention of influenza (flu) in an officially declared pandemic situation. The marketing authorisation was valid for a 5-year period, subject to subsequent renewals. Pumarix has never been marketed in the EU, and was intended to be used in an officially declared influenza pandemic following the identification and, if appropriate, the inclusion of the influenza strain causing the pandemic into the vaccine.

Another product, Adjupanrix (pandemic influenza vaccine A/H5N1, split virion, inactivated, adjuvanted) is authorised in the EU for prevention of influenza in an officially declared pandemic situation, and can be used instead of Pumarix. The marketing authorisation holder, GlaxoSmithKline Biologicals, will maintain the marketing authorisation for Adjupanrix.

The European Public Assessment Report (EPAR) for Pumarix will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact