08 October 2014
EMA/622936/2014
Committee for Medicinal Products for Human Use (CHMP)

Public statement

Fluenz

Withdrawal of the marketing authorisation in the European Union

On 1st October 2014, the European Commission withdrew the marketing authorisation for Fluenz (influenza vaccine (live attenuated, nasal)) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, MedImmune LLC, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Fluenz was granted marketing authorisation in the EU on 27 January 2011 for the prevention of influenza (flu). The marketing authorisation was initially valid for a 5-year period. The product had not been marketed in the EU since the 2013-14 influenza season.

Fluenz is a trivalent (containing three strains of flu virus) influenza vaccine. It will be replaced by Fluenz Tetra, a tetravalent (four-strain) influenza vaccine which is authorised in the EU since 04 December 2013 for the same indication as Fluenz, i.e. prevention of influenza. MedImmune LLC will maintain the marketing authorisation for Fluenz Tetra.

The European Public Assessment Report (EPAR) for Fluenz will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.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 5520
Send a question via our website www.ema.europa.eu/contact