EUROPEAN MEDICINES AGENCY
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Public Statement

Daronrix (pandemic influenza vaccine (H5N1) (whole virion, inactivated, adsorbed))

Cessation of validity of the marketing authorisation in the European Union

On 21 March 2007, the European Commission granted a marketing authorisation valid throughout the European Union (EU) for the medicinal product Daronrix (pandemic influenza vaccine (H5N1) (whole virion, inactivated, adsorbed)), indicated for the prophylaxis of influenza in an officially declared pandemic situation. The marketing authorisation holder was notified on the 23 March 2007.

Daronrix (pandemic influenza vaccine (H5N1) (whole virion, inactivated, adsorbed)) has not been marketed in Europe since this initial marketing authorisation. In accordance with article 14(4) of Regulation (EC) No 726/2004 ('sunset clause'), the marketing authorisation of a medicinal product lapses if the product has never been marketed in one of the Member States within three years of its initial authorisation.

Because of this, the marketing authorisation for Daronrix is no longer valid.

The Marketing Authorisation Holder of Daronrix has confirmed that the product was not marketed due to lack of demand for this vaccine.

Pursuant to the expiry of the marketing authorisation, the European Assessment Report (EPAR) for Daronrix is updated to reflect that the marketing authorisation is no longer valid.

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