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Public statement

Focetria

Expiry of the marketing authorisation in the European Union

The marketing authorisation for Focetria (influenza vaccine H1N1v (surface antigen, inactivated, adjuvanted)) expired on 13 August 2015 following the decision of the marketing authorisation holder, Novartis Vaccines and Diagnostics S.r.l., not to apply for a renewal of the marketing authorisation.

Novartis Vaccines and Diagnostics S.r.l. confirmed that it did not apply for renewal of the authorisation due to lack of demand for this product.

Focetria was granted marketing authorisation in the European Union (EU) on 12 August 2010 for prophylaxis of influenza caused by A/H1N1v 2009 virus. The marketing authorisation was valid for a 5-year period.

Novartis Vaccines and Diagnostics S.r.l. (now named Seqirus) is the marketing authorisation holder for another pandemic vaccine, Foclivia, which is authorised in the EU for pandemic preparedness. Seqirus will maintain the marketing authorisation for Foclivia.

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Report (EPAR) for Focetria will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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