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Public statement

Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostic

Expiry of the marketing authorisation in the European Union

The marketing authorisation for Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostic expired on 28 November 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. The vaccine contained haemagglutinin and neuraminidase of influenza virus H5N1 A/Vietnam/1194/2004.

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

Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostic was granted marketing authorisation in the European Union (EU) on 29 November 2010 for immunisation against the H5N1 subtype of influenza A virus. The marketing authorisation was valid for a 5-year period.

Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostic was a duplicate application to Aflunov, which is authorised in the EU. The marketing authorisation holder (Seqirus) will maintain the marketing authorisation for Aflunov.

The European Public Assessment Report (EPAR) for Prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) Novartis Vaccines and Diagnostic will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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