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Public statement

Pandemrix

Expiry of the marketing authorisation in the European Union

The marketing authorisation for the vaccine Pandemrix expired on 13 August 2015 following the decision of the marketing authorisation holder, GlaxoSmithKline Biologicals, not to apply for a renewal of the marketing authorisation. Pandemrix is a split virion, inactivated, adjuvanted pandemic influenza vaccine containing A/California/7/2009 (H1N1)v like strain (X-179A).

GlaxoSmithKline Biologicals confirmed that it did not apply for a renewal of the authorisation due to lack of demand for the vaccine.

Pandemrix was granted marketing authorisation in the European Union (EU) on 12 August 2010 for prophylaxis of influenza caused by A (H1N1)v 2009 virus. The marketing authorisation was valid for 5 years.

Pandemrix was used extensively during the 2009 (H1N1)v pandemic, with over 30 million people vaccinated in the EU. Cases of narcolepsy were reported in people who had received the vaccine during the 2009 pandemic. Understanding the link between narcolepsy and Pandemrix remains the subject of investigations and may have implications for the future use of similar vaccines. Therefore, irrespective of the expiry of the marketing authorisation for Pandemrix, the marketing authorisation holder agreed with the Agency to continue to investigate narcolepsy in association with vaccination and will submit to the Agency for evaluation any relevant data generated by the company as well as independent parties.

GlaxoSmithKline Biologicals is the marketing authorisation holder for another pandemic vaccine, Adjupanrix, which is authorised in the EU for pandemic preparedness. GlaxoSmithKline Biologicals will maintain the marketing authorisation for Adjupanrix.

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Report (EPAR) for Pandemrix will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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