EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency reviews hypothesis on Pandemrix and development of narcolepsy

No new concerns for Pandemrix or other vaccines on the basis of available evidence

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) at the request of the Agency's Executive Director Guido Rasi has reviewed preliminary research results by the Finnish National Institute of Health and Welfare (THL) investigating differences in the immunological response triggered by different pandemic influenza vaccines as a potential root cause for the development of narcolepsy in persons vaccinated with Pandemrix.

After careful consideration, the CHMP concluded that the data presented by the Finnish researchers are preliminary and that the evidence presented so far is insufficient to allow conclusions to be drawn, and does not lead to any new concerns regarding Pandemrix or other vaccines, including other influenza vaccines. On the basis of the current evidence, the role of the Pandemrix antigen and its adjuvant on the association between Pandemrix and narcolepsy remains unknown.

The CHMP welcomes the work of academic researchers to understand the biological mechanism for the association between Pandemrix and narcolepsy and has expressed its appreciation to the Finnish research team for making these results available for scrutiny in a timely manner. The Committee also said it would welcome the opportunity to evaluate any further analyses produced by these researchers or others as their work progresses.

The CHMP also expects the marketing authorisation holder for Pandemrix, GSK, to take into account the hypothesis generated by the Finnish research in their experimental research programme into the root cause for the association between Pandemrix and narcolepsy.

Pandemrix was authorised in the EU in September 2009 to protect against influenza (flu) caused by the A (H1N1)v 2009 virus. The vaccine was used extensively during the 2009 (H1N1) pandemic, with at least 30.8 million people vaccinated in the EU. Pandemrix is currently not available in the EU.

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Data in some EU countries have shown an increased risk of narcolepsy in children and adolescents. A similar risk has not been confirmed but cannot be ruled out in other countries. In a 2011 review the Committee therefore concluded that Pandemrix should only be used in persons under 20 years of age if the recommended annual seasonal trivalent influenza vaccine is not available and if immunisation against (H1N1)v is considered necessary.

Notes

1. This press release, together with all related documents, is available on the Agency's website.

2. More information about Pandemrix, including the 2011 review, is available on the Agency's website: http://ema-wip.emea.eu.int/ema/index.jsp?curl=pages/medicines/human/medicines/000832/human_med_000965.jsp&mid=WC0b01ac058001d124

3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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