



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency starts review of Pandemrix

Agency is investigating whether there is a link between vaccine and cases of narcolepsy

The European Medicines Agency has launched a review of Pandemrix on the request of the European Commission to investigate whether there is a link between cases of narcolepsy and vaccination with Pandemrix. A limited number of cases was reported, all collected through spontaneous reporting systems, mainly in Sweden and Finland. Pandemrix, an influenza vaccine, has been used since September 2009 for vaccination against H1N1 influenza in at least 30.8 million Europeans.

Narcolepsy is a rare sleep disorder that causes a person to fall asleep suddenly and unexpectedly. Its precise cause is unknown, but it is generally considered to be triggered by a combination of genetic and environmental factors, including infections.

Although the cases of narcolepsy have been reported in temporal association with the use of Pandemrix, it is at present not known if the vaccine caused the disorder. The Agency's Committee for Medicinal Products for Human Use (CHMP) will look carefully at all of the available data to determine whether there is evidence for a causal association. As part of this evaluation the Committee will also consider the so-called background rate for narcolepsy, i.e. the number of cases that would normally be expected to be diagnosed.

The Committee will be working with experts from across the EU to assess this possible safety concern and any impact on the benefit risk balance of Pandemrix. The Committee will consider at its September 2010 meeting the need for any provisional measures pending completion of the evaluation.

The Agency is also liaising with the European Centre for Disease Prevention and Control (ECDC), international regulatory partners and the World Health Organization (WHO).

The European Medicines Agency will provide updates as new information becomes available.



Notes

1. On 24 August 2010, Finland's National Institute for Health and Welfare recommended that vaccination with Pandemrix be discontinued until the suspected link with narcolepsy is thoroughly evaluated.
2. Pandemrix has been authorised in the European Union since September 2009. The vaccine was extensively used during the 2009 (H1N1) pandemic, with at least 30.8 million Europeans vaccinated.
3. More information about Pandemrix is available [here](#).
4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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