



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Press release

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# European Medicines Agency reviews further data on narcolepsy and possible association with Pandemrix

## Causal relationship not established; further study results awaited

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has reviewed further data from Finland on the suspected link between narcolepsy in children and adolescents and Pandemrix. The Committee concluded that the new evidence added to the concern arising from case reports in Finland and Sweden, but that the data were still insufficient to establish a causal relationship between Pandemrix and narcolepsy. Further analyses and study results are awaited to clarify the observations in Finland.

In addition to the data from Finland, research is ongoing in Sweden where there has also been an unexpected number of narcolepsy reports following vaccination with Pandemrix. However, other non-Nordic countries have not seen similar increased rates of reporting of narcolepsy. Additionally in Canada, where there has been substantial use of this type of vaccine, there has been no evidence of an increase in reports of narcolepsy. Therefore, at present definitive conclusions cannot be drawn and no changes to the recommendations for use of Pandemrix are proposed.

The Committee reviewed the preliminary results of the Finnish study, an epidemiological study that compared the incidence of narcolepsy in people aged 4 to 19 years vaccinated with Pandemrix between 1 January 2009 and 31 December 2010 with the incidence of narcolepsy in unvaccinated people of the same age. The study, conducted by the Finnish National Institute for Health and Welfare (THL), suggested a nine-fold increase in risk of narcolepsy in the vaccinated population studied (an increase from approximately 1 to 9 cases per 100,000 vaccinees), although the occurrence of narcolepsy was still very rare even with this apparent increase.

The Committee concluded that the THL study was well-designed, although it remains possible that unmeasured effects and biases could potentially have contributed to the observed increased risk. One possible explanation for the results is that Pandemrix may have interacted with an unknown local environmental and/or genetic factor in contributing to an increased risk of narcolepsy among those aged 4 to 19 years in Finland.



In order to conclude this review the CHMP considers it important to gather more data from the use of Pandemrix and related vaccines in a variety of countries to further assess this concern, and thereby understand the nature of any relationship between vaccination and narcolepsy. A variety of research efforts are now ongoing, including an epidemiological study of narcolepsy and pandemic vaccines conducted by the European Centre for Disease Control and Prevention (ECDC) through a network of research and public health institutions (VAESCO) in nine European Union Member States. The final results of this study are expected by the end of June 2011.

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

## Notes

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1. This press release, together with all related documents, is available on the Agency's website.
2. 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. Narcolepsy occurs naturally at a rate of around 1 case per 100,000 people every year.
3. Pandemrix, an (H1N1) v influenza vaccine, has been authorised since September 2009 and was used during the 2009 H1N1 influenza pandemic in at least 30.8 million Europeans.
4. The H1N1 influenza strain continues to be the predominant strain in this winter season.
5. The review of Pandemrix and the occurrence of cases of narcolepsy was initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004, on 27 August 2010, following an increased number of reports on narcolepsy in Finland and Sweden. Related press releases dated 27 August 2010 and 23 September 2011 are available on the Agency's website.
6. More information about Pandemrix can be found in the European public assessment report available on the Agency's website.
7. The interim report from the Finnish National Institute for Health and Welfare study can be found on its website: <http://www.thl.fi/thl-client/pdfs/dce182fb-651e-48a1-b018-3f774d6d1875>
8. More information about the network of research, public health institutions and regulatory agencies VAESCO, funded by the European Centre for Disease Control and Prevention, can be found on its website: <http://vaesco.net/internet/en/index.html>
9. More information on the work of the European Medicines Agency can be found on its website: [www.ema.europa.eu](http://www.ema.europa.eu)

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