



EUROPEAN MEDICINES AGENCY
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Press Office

Press release

European Medicines Agency updates on the review of Pandemrix and reports of narcolepsy

Available evidence does not confirm a link; more research needed

The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has reviewed all available data on the suspected link between narcolepsy and Pandemrix. The Committee concluded that the available evidence was insufficient to determine whether there is any link between Pandemrix and reports of narcolepsy, and that further studies were necessary to fully understand this issue.

The Committee agreed that at present the benefit-risk balance for Pandemrix continues to be positive, and that while the review is still ongoing there was no need for Europe-wide restrictions on use.

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.

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.

As per 17 September 2010, there are 81 reports from healthcare professionals suggestive of narcolepsy, all collected through spontaneous reporting systems. Of these, 34 reports come from Sweden, 30 from Finland, 10 from France, 6 from Norway and 1 from Portugal. In addition, there are a further 13 consumer reports from Sweden and 2 from Norway. The age range of patients is between 4 and 52 years.

The ongoing review is complex and will take some three to six months to complete. The Agency is working with experts from across the European Union to carefully scrutinise all available reports. Owing to a potential overlap of narcolepsy symptoms with several other neurological and psychiatric disorders, diagnosis is very often not confirmed until several years after symptom onset.

The number of reports of narcolepsy that occurred in children in some countries seems to be higher than expected in comparison with data from previous years. However, there are many uncertainties in



the available information that need to be clarified. These include a possibility that earlier diagnoses of narcolepsy have contributed to this apparent increase. Also, the influenza pandemic itself may have contributed to a change in the rates of narcolepsy. These factors need to be assessed before firm conclusions can be drawn.

The ongoing review will require new observational (epidemiological) research in order to reach any firm conclusions on whether there is a link between Pandemrix and narcolepsy.

The Agency is in contact with its international regulatory partners (in the United States of America, Canada and Australia), to compare the available data with information from outside Europe. In addition, an investigation in collaboration with the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO) is in progress. ECDC has presented a plan for an epidemiological study of narcolepsy and pandemic vaccines to be conducted by a network of research and public health institutions (VAESCO) in several EU Member States. The study protocol is currently being evaluated by the EMA.

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

Notes

1. 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. See here for the [press release](#).
2. More information about Pandemrix can be found in the [European Public Assessment Report \(EPAR\)](#).
3. More information about the network of research and public health institutions VAESCO can be found on their website: <http://vaesco.net/internet/en/index.html>
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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