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Press Office

Press release

European Medicines Agency recommends interim measures for Pandemrix

Updated prescribing advice highlights preliminary results from epidemiological studies on narcolepsy; further research needed

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended that the product information for Pandemrix should be amended to advise prescribers to take into account preliminary results from epidemiological studies on Pandemrix and narcolepsy, and to perform an individual benefit-risk assessment when considering the use of Pandemrix in children and adolescents. This is an interim measure pending the outcome of the European review, expected to conclude in July 2011.

The CHMP reviewed all available data, including new findings from Sweden and France on the suspected link between narcolepsy in children and adolescents and Pandemrix. The CHMP concluded that, following the earlier results of an epidemiological study from Finland, the new evidence strengthened the signal in children and adolescents, but that the data had methodological limitations. The relationship between Pandemrix and narcolepsy is still under investigation.

Preliminary results of the Swedish registry study from October 2009 to December 2010 on Pandemrix vaccination and the risk of narcolepsy indicates a four-fold increase of cases of narcolepsy in children and adolescents (below 20 years of age) who received Pandemrix compared with unvaccinated people of the same age. The additional risk corresponds to an additional 3-4 narcolepsy cases per 100,000 vaccinated subjects. These results are broadly in line with the study results from Finland indicating an association between Pandemrix and narcolepsy in children and adolescents. The study did not identify any increased risk in adults. The CHMP concluded that the study was well conducted, although it has inherent limitations.

An analysis of narcolepsy reports in France provides some further evidence.

The lack of a clear increase in reports of narcolepsy following Pandemrix in other EU and non-EU countries may point towards the influence of other unknown factors affecting the trend seen in some countries. Also, there is currently no clearly identified biological plausibility for an association between

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Pandemrix and narcolepsy, and further non-clinical studies, especially in the juvenile setting, are needed.

The CHMP considers it important to gather more data on the use of Pandemrix and related vaccines in a variety of countries to further assess this concern. A variety of research efforts are now ongoing. These include an epidemiological study of narcolepsy and pandemic vaccines conducted by the European Centre for Disease Prevention and Control (ECDC) through a network of research and public health institutions (VAESCO) in nine European Union Member States, and an epidemiological study conducted by Glaxo Smith Kline (the marketing authorisation holder of Pandemrix) in Canada. Preliminary results of the VAESCO study and of the Canadian study are expected by July 2011.

The CHMP is working with experts from across the EU to assess the possible safety concern and any impact on the benefit-risk balance of Pandemrix. The CHMP plans to hold an expert meeting with participation of international experts, the World Health Organization (WHO) and ECDC.

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

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The exact wording to be included in the Pandemrix product information reads as follows:

   "Preliminary reports form epidemiological studies in two countries (Sweden and Finland) have indicated a 4-9-fold risk increase of narcolepsy in vaccinated as compared with unvaccinated children/adolescents, corresponding to an absolute risk increase of about three to four additional cases in 100 000 vaccinated subjects. This risk increase has not been found in adults (older than 20 years). Similar epidemiological studies have not yet been conducted in other countries.

   The relationship between Pandemrix and narcolepsy is still under investigation.

   When considering the use of Pandemrix in children and adolescents, an individual benefit risk assessment should be performed taking this information into account."
3. 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.
4. 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.
5. The H1N1 influenza strain continues to be the predominant strain in this season.
6. 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, 23 September 2011 and 18 February 2011 are available on the Agency's website.
7. More information about Pandemrix can be found in the European public assessment report available on the Agency's website.
8. The report from the Swedish registry study can be found on the website of the Swedish Medicines Agency (MPA): http://www.lakemedelsverket.se/english/All-news/NYHETER-2011/A-Swedish-

registry-based-cohort-study-provides-strengthened-evidence-of-an-association-between-vaccination-with-Pandemrix-and-narcolepsy-in-children-and-adolescents-/.

9. The report from the French observed expected study can be found on the website of the French Medicines Agency: http://www.afssaps.fr/Infos-de-securite/Communiques-Points-presse/Vaccins-pandemiques-grippe-A-H1N1-et-narcolepsie-Actualisation-des-donnees-Communique

10. More information about the network of research, public-health institutions and regulatory agencies VAESCO, funded by the European Centre for Disease Prevention and Control, can be found on its website: http://vaesco.net/internet/en/index.html

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

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