21 July 2011
EMA/CHMP/568830/2011
Press Office

Press release

European Medicines Agency recommends restricting use of Pandemrix

In persons under 20 years of age Pandemrix to be used only in the absence of seasonal trivalent influenza vaccines, following link to very rare cases of narcolepsy in young people. Overall benefit-risk remains positive.

Finalising its review of Pandemrix and narcolepsy the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended that in persons under 20 years of age Pandemrix may only be used if the recommended seasonal trivalent influenza vaccine is not available and if immunisation against H1N1 is still needed (e.g. in persons at risk of the complications of infection). The CHMP confirmed that overall the benefit-risk balance of Pandemrix remains positive.

The review of Pandemrix was initiated to investigate a possible link between Pandemrix vaccination and narcolepsy, following an increased number of reported cases of narcolepsy among children and adolescents in Finland and Sweden. The reported cases of narcolepsy occurred following the H1N1 pandemic vaccination campaign in late 2009 and early 2010. The current review has been conducted in the context of seasonal use.

The CHMP considered all available data on the possible association between Pandemrix and narcolepsy and the impact on the overall benefit-risk balance of Pandemrix. These included the results of epidemiological studies carried out in Finland and Sweden, analysis of safety surveillance data performed in several Member States and case reports from across the EU. They also included the preliminary results of an epidemiological study of narcolepsy and pandemic vaccines in eight EU Member States, coordinated by the European Centre for Disease Prevention and Control (ECDC) through a network of research and public health institutions (VAESCO).

The CHMP also took advice from a specially convened meeting of experts in fields such as paediatric neurology, vaccinology, immunology, sleep disorders, infectious diseases, epidemiology, as well as experts from Health Canada, the World Health Organization (WHO) and the ECDC, to consider the latest available data regarding the possible link between Pandemrix and narcolepsy.

The CHMP considered that the epidemiological studies relating to Pandemrix in Finland and Sweden were well designed and the results show an association between Pandemrix vaccination and narcolepsy

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

in children and adolescents in those countries. The results indicate a six to 13-fold increased risk of narcolepsy with or without cataplexy in vaccinated as compared with unvaccinated children/adolescents, corresponding to about an additional three to seven cases in every 100,000 vaccinated subjects. This risk increase has not been found in adults (older than 20 years). A similar risk has not been confirmed but cannot be ruled out in other countries.

The Committee noted that the vaccine is likely to have interacted with genetic or environmental factors which might raise the risk of narcolepsy, and that other factors may have contributed to the results. There are several initiatives being developed across the EU to further investigate this association.

The CHMP noted that similar epidemiological studies have not been completed in other countries. The preliminary results of the VAESCO study confirmed the signal in Finland. Results are still preliminary and do not allow conclusions in other countries (where vaccination coverage with Pandemrix was lower), but the final results of the VAESCO study are still awaited.

Exposure to specific infectious diseases (including H1N1) at different ages, particularly upper respiratory infections, may have contributed to the observations in the Nordic area. The CHMP considered that it would be helpful if ongoing epidemiological studies seek to address this question.

The CHMP stressed that further research is necessary.

The marketing authorisation holder for Pandemrix, GlaxoSmithKline, is carrying out a retrospective cohort study in Canada, where an equivalent H1N1 vaccine (Arepanrix) was widely used. The company is required to carry out non-clinical and clinical studies in order to further explore the association between Pandemrix vaccination and narcolepsy.

Notes

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 season.
5. The review of Pandemrix and 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 2010 and 18 February 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. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Sabine Haubenreisser

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu