

28th March 2011

Re: Possible association between use of Pandemrix and onset of narcolepsy

Dear Doctor,

I am sure you are aware of reports from Finland and more recently from Sweden regarding a possible association between the use of Pandemrix and the onset of narcolepsy in young people.

In early January I advised you that Pandemrix was only recommended if you had a shortage of seasonal flu vaccine. As additional stocks of seasonal flu vaccine were delivered to all sites that requested them from the end of January there has been no requirement to use Pandemrix in any age group.

Arrangements will be made over the coming weeks to collect stocks of Pandemrix from all general practice and other sites.

Please find additional information regarding Pandemrix and narcolepsy overleaf.

Yours sincerely



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Additional information

- Narcolepsy is a disabling chronic neurological disorder characterised by recurrent episodes of excessive daytime sleepiness. Cataplexy (episodic muscle weakness), sleep paralysis, and hypnagogic hallucinations often accompany narcolepsy. Symptoms usually develop gradually. A multi-factorial aetiology has been suggested for narcolepsy, involving a genetic predisposition in combination with environmental risk factors. Researchers have proposed an autoimmune mechanism as a trigger for the selective loss of hypothalamic orexin/hypocretin-producing neurons involved in REM-sleep regulation.
- The increase in cases of narcolepsy in young people in Finland and Sweden has not been noted in all countries using Pandemrix.
- No increase has been seen in the United Kingdom who also used Pandemrix.
- In the Netherlands an increase has been noted in one age group (20-59 years), an age group not targeted for use of pandemic vaccine in the Netherlands.
- The European Centre for Disease Control is undertaking a Vaccine Adverse Events Surveillance and Communications (VAESCO) EU study in 9 European countries. This VAESCO study is examining risk factors such as pandemic flu vaccine, wild type influenza infection and other vaccines administered before/ after pandemic influenza vaccine. The results of this study are expected in June/July 2011.
- The European Medicines Agency has stated that no definitive conclusions can be drawn until further studies are completed and has therefore not recommended any changes to the marketing authorisation for Pandemrix
- In Ireland, the Irish Medicines Board is investigating a number of reports of suspected cases of narcolepsy in those who have received Pandemrix. Two cases of narcolepsy have been confirmed but a causal association with vaccine has not been established. Investigations are ongoing into a number of recently reported suspected cases. The Health Protection Surveillance Centre will now work with The Irish Medicines Board to examine data available on narcolepsy in Ireland.

In summary, there has been conflicting data emerging in relation to narcolepsy and the situation is as yet unclear.