Global Advisory Committee on Vaccine Safety

Statement on narcolepsy and vaccination

8 February 2011

Since August 2010, following widespread use of vaccines against influenza (H1N1) 2009, cases of narcolepsy, especially in children and adolescents, have been reported from at least 12 countries. Narcolepsy is a rare sleep disorder that causes a person to fall asleep suddenly and unexpectedly. The rates reported from Sweden, Finland and Iceland have been notably higher than those from other countries. The National Institute for Health and Welfare of Finland issued a preliminary statement on 1 February 2011 following an investigation into the cases in Finland. A systematic retrospective registry-based review was conducted of all new narcolepsy cases diagnosed during 2006-2010 and cases in 2009-2010, born in 1990 or later, were reviewed using newly developed Brighton collaboration criteria for the disease. During 2009-2010 they found a higher risk of narcolepsy among those aged 4-19 years old who had received the vaccination against influenza (H1N1) 2009 compared with those who had not been vaccinated. The only pandemic vaccine used in Finland was Pandemrix, an adjuvanted influenza (H1N1) 2009 monovalent vaccine manufactured by GlaxoSmithKline. Pandemrix vaccine was used in 47 countries worldwide during the 2009-2010 season. Studies are ongoing to determine if the apparent increased risk of narcolepsy reported in Sweden is higher in vaccinated persons.

The National Institute in Finland (on the advice of the Finnish National Narcolepsy Task Force) has concluded that the risk of developing narcolepsy among those vaccinated aged between 4 and 19 years is about nine times greater than those unvaccinated in the same age group, corresponding to a risk of about 1 case of narcolepsy per 12,000 vaccinated in this age group. The increased risk has not been seen in younger or older age groups. Narcolepsy is a condition that has a strong genetic linkage, being almost uniquely seen in persons who have the (HLA) DQB1*0602 genotype. Of the cases of narcolepsy tested so far in Finland (n=22), diagnosed during 2009-2010, all have that genotype. The National Institute considers it probable that the Pandemrix vaccine was a contributing factor to this observed increase, and has called for further investigation of other co-factors that may be associated with the increased risk. They consider it most likely that the Pandemrix vaccine increased the risk of narcolepsy in a joint effect in those genetically disposed with some other, still unknown, genetic and/or environmental factor. The final report from the Finnish National Narcolepsy Task Force is expected by 31 August 2011.
WHO's Global Advisory Committee on Vaccine Safety (GACVS) reviewed this data by telephone conference on 4 February 2011. GACVS agrees that further investigation is warranted concerning narcolepsy and vaccination against influenza (H1N1) 2009 with Pandemrix and other pandemic H1N1 vaccines. An increased risk of narcolepsy has not been observed in association with the use of any vaccines whether against influenza or other diseases in the past. Even at this stage, it does not appear that narcolepsy following vaccination against pandemic influenza is a general worldwide phenomenon and this complicates interpretation of the findings in Finland. In collaboration with a number of European Union member states, the European Centre for Disease Prevention and Control (ECDC) is currently conducting epidemiological studies of narcolepsy and pandemic influenza vaccines. The findings from these studies and others, including further investigations in Finland, may help clarify the determinants of any increased risk of narcolepsy which currently appears to be restricted to the months following vaccination and by age group and country.

GACVS will continue to monitor the situation closely and updates will be provided as further information becomes available and is assessed.

Statement from the National Institute for Health and Welfare of Finland of 1 February 2011