



Update of the EMA European Pharmacovigilance Report

24 May 2010

European Pharmacovigilance Report from the European Medicines Agency (EMA) -18th Edition

On the 20th May 2010, the European medicines Agency (EMA) published the 18th edition of its European Pharmacovigilance Report. These reports are issued at fortnightly intervals and summarise the adverse drug reactions reported after the use of the three centrally authorised 2009 influenza A(H1N1) pandemic vaccines Celvapan, Focetria and Pandemrix - and the antiviral oseltamivir (Tamiflu). Another vaccine Arepanrix is centrally licensed but is not marketed in Europe. As usual the reports also provides estimate of how many doses of vaccines and antivirals have been distributed and given in Europe and other available information on the benefits and risks of vaccines and antivirals. The report bases the analysis on a minimum of 37.6 million people vaccinated with the three vaccines in Europe: around 0.56 million people with Celvapan, around 6.5million with Focetria and 30.6 million with Pandemrix. The company producing Tamiflu estimates that at least 22.7 million people in Europe received oseltamivir during the pandemic period 1 May 2009 to 31 March 2010. The report is on instances of suspected reactions that were observed after the medicines were administered. This does not mean that these reactions were caused by the vaccines or medicine since they could be a symptom of another illness or be associated with another product taken by the patient. As with previous reports in the series this report concludes that the vast majority of the adverse reactions that had been reported as of 09 May 2010 are considered to be non-serious. Thus in EMA's opinion the benefit-risk balance of the centrally authorised pandemic vaccines and antivirals for the current 2009 influenza A(H1N1) pandemic continues to be positive.

