

QSM/MC/IEA.124

08 October 2009

Information Exchange System**Alert No. 124****A/H1N1 vaccination safety: new safety surveillance tool available**

In preparing for a possible (H1N1) swine flu pandemic, regulatory authorities have licensed pandemic vaccines in Australia, China and the United States of America, soon to be followed by Japan and several countries in Europe. Donations of pandemic vaccines for use in developing countries have been announced by the United States of America, in concert with Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland and the United Kingdom. Similar support from additional countries is anticipated. WHO will be coordinating the distribution of these donated vaccines (1).

Because the pandemic virus is new, both non-clinical and clinical trials are being conducted to gain essential information on immune response and safety. Outcomes of trials completed to date suggest that pandemic vaccines are as safe as seasonal influenza vaccines.

Side effects are expected to be similar to those observed with seasonal influenza vaccines. In almost all vaccine recipients, these symptoms are mild, self-limited and last 1-2 days.

However, even very large clinical trials will not be able to identify possible rare events that can occur when pandemic vaccines are administered to many millions of people. WHO advises all countries administering pandemic vaccines to conduct intensive monitoring for safety and to report adverse events. Many countries already have systems for monitoring vaccine safety in place. International sharing of data from such post-marketing surveillance will be vital in guiding risk-benefit assessments and determining whether changes in vaccination policies are needed.

The WHO Collaborating Centre for International Drug Monitoring, the Uppsala Monitoring Centre (UMC) has developed a new software tool, PaniFlow®, for reporting adverse events following immunization (AEFI) (2). WHO will offer this tool free to countries, particularly emerging and developing countries that do not as yet have a good AEFI reporting system in place, to assist with the reporting of AEFIs in these countries following immunizations with the pandemic vaccines.

PaniFlow®, which is a web-based data management software, allows vaccination programme staff to record all adverse events as they occur, from any location with an internet connection. Using this tool, cumulative data will be immediately available locally, nationally, and to the WHO Global Individual Case Safety Report database (VigiBase®) at the UMC, in Sweden, where international patterns of events will be analysed and widely communicated by UMC experts. The software has search and analysis tools which permit issues and problems to be examined in all relevant parameters – including patient age and gender, type of adverse event, details of vaccine and antiviral drugs administered.

Individual countries can very quickly detect potential safety problems in their own populations and take remedial action if causality is established. At UMC, the global picture can be rapidly reviewed and the international community alerted when problems are suspected or confirmed.

PaniFlow® is based on VigiFlow®, which is the programme used throughout the world by many members of the WHO Programme for International Drug Monitoring for managing and reporting adverse drug reactions (ADRs). It is based on the software originally developed jointly by the Swiss national drug regulatory authority, Swissmedic, and UMC for use in Switzerland. Both programmes are uniquely designed to meet the needs of health-care personnel and serve the interests of patient safety.

The first countries being offered free use of PaniFlow® by UMC are: Croatia, Lithuania, Morocco, Serbia, Sierra Leone, Togo and Turkey. They are all countries which have a track-record of reporting AEFIs and are familiar with using VigiFlow®. In addition WHO will select countries that will be allocated vaccines which have been donated by a number of well-developed countries and by vaccine manufactures. Countries not invited may contact UMC to discuss the possibility of joining the group or obtaining and using PaniFlow® for a modest fee.

References:

1. Pandemic influenza vaccines: current status. Pandemic (H1N1) briefing note 11. WHO, 2009.
2. A/H1N1 vaccination safety: new safety surveillance tool available. The Uppsala Monitoring Centre, 5 October 2009 (www.who-umc.org)