

COMMUNIQUE FOR ALL QUEENSLAND GPs (#2) PANDEMIC (H1N1) 2009 VACCINATION PROGRAM 24 September 2009

The new pandemic (H1N1) 2009 vaccine, Panvax® H1N1, was registered for use in people aged 10 years and older by the Therapeutic Goods Administration (TGA) on Friday 18 September 2009.

Program start date

The Federal Minister for Health and Ageing, Nicola Roxon, has announced a recommended national start date for vaccination with pandemic (H1N1) 2009 vaccine of **Wednesday 30 September 2009**. Most of the 783 GPs who have indicated that they wish to participate in the program will receive vaccine in time to begin vaccination on 30 September. However, due to the short time for distribution of vaccine following TGA release of the vaccine, some providers may not have vaccine in time for the commencement date. GPs who requested vaccine after 21 September will receive vaccine in the second round of deliveries.

Clinical trial results

Interim data from CSL's clinical trial of Panvax® H1N1 in adults has been published in the New England Journal of Medicine and is available at <http://h1n1.nejm.org/>. A single 15µg dose (0.5ml) produced a robust immune response in 97% of participants, indicating that only a single vaccine dose is required. Solicited adverse events were similar to those seen in studies of seasonal influenza vaccine. The most common adverse events were injection site tenderness, headache and injection site pain.

Adverse event surveillance

Pandemic influenza vaccines are not regarded by regulatory authorities as entirely "new" vaccines, as they are manufactured using the same process as for seasonal influenza vaccines. The safety profile of seasonal influenza vaccines has been well established over the last 40 years and is the basis for assuming safety for Panvax® H1N1 vaccine. Nevertheless, it is critical to monitor serious adverse events following immunisation with this vaccine. Any serious adverse event that could be associated with vaccination should be reported to Queensland Health in the usual way by completing an adverse event reporting form at http://www.health.qld.gov.au/ph/documents/cdb/adverse_event_immun.pdf. Please contact your local Population Health Unit to if you have any concerns or questions regarding a possible serious adverse event following vaccination with Panvax® H1N1.

The use of multi-dose vials

The Australian Technical Advisory Group on Immunisation (ATAGI) has endorsed *Guidelines for the administration of pandemic (H1N1) influenza vaccine from multi-dose vials*, which will be distributed with vaccine and are on the health emergency website listed below. Please note that a new drawing up needle should be used for each new dose being drawn up from the vial, unless the whole vial is being drawn up. Where there will therefore be multiple penetrations of the vial stopper, please use a 21G needle or smaller, as the stopper integrity with multiple penetrations has not been demonstrated for needles larger than 21G.

Indemnity

The Australian Government has indicated that all medical indemnity insurer organisations have confirmed that they will insure their members if they are involved in the pandemic (H1N1) vaccination program.

Comprehensive information about the Panvax® H1N1 vaccine and vaccination program for health professionals is available at the health emergency website: www.healthemergency.gov.au

Updates and other relevant information can be found on the **Queensland Health Pandemic Vaccination website**: <http://www.health.qld.gov.au/swineflu/html/vacc.asp>.

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