

**Please find following statements from NSW Health and the Commonwealth Department of Health and Ageing, regarding seasonal influenza vaccination for children 5 years of age and under.**

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On behalf of NSW Health:

Dear All

As you will have heard in the Media this morning the Commonwealth has asked all immunisation providers to not administer seasonal influenza vaccine to children 5 years of age and under until further notice. The matter is under further investigation.

We provide you with the following information as released to us from the Commonwealth:

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As you would be aware Western Australia has temporarily suspended its seasonal influenza vaccination program for children under 5 following an increase in presentations of children post seasonal influenza vaccination to the emergency department at Princess Margaret Hospital in Perth.

People should continue be vaccinated against seasonal influenza as flu can be a serious disease especially in people who are in high risk categories including people aged 65 years and over; all Aboriginal and Torres Strait Islander people aged 15 years and over and pregnant women for whom the seasonal flu vaccine is being provided free by the Commonwealth government.

However, until it can be established what is causing the rise in adverse events in some children in WA, Australia's Chief Medical Officer is writing to all immunization providers to advise them not to administer season flu vaccine to all children 5 years of age and under until further notice.

The suspension of the vaccination program in children under 5 years at this stage is a precautionary step while the matter is being urgently investigated by jurisdictional and Commonwealth health authorities. Chief Health Officers and immunisation experts will come together at 10am Friday 23 April to discuss the situation.

The Therapeutic Goods Administration (TGA) is investigating the WA data as a matter of urgency to determine whether the adverse reactions reported in WA relate to the vaccine, or whether factors related to the program delivery in WA are involved. The TGA has contacted CSL Ltd to confirm which batches of vaccine were used in WA and is obtaining samples of the vaccine to test in its laboratories to determine if there are any abnormalities in the batches of vaccine used in WA.

The TGA has requested data from WA Health about the adverse events and the vaccine distribution data to see if the rates of side effects are truly higher than expected. The TGA is urgently convening an expert scientific advisory panel to review the information from WA, and is seeking additional information from the manufacturer, CSL Ltd, and from regulatory colleagues internationally.

To date the pattern and rate of adverse reactions reported by WA have not been seen in other states, so the TGA will test batches of the vaccine used in WA for any abnormalities.

The Department of Health and Ageing has sought urgent advice from the Australian Technical Advisory Group on Immunisation, which is currently reviewing the available information on cases and the Department will be seeking its further advice. States and territories have been urged to report any

adverse events related to seasonal influenza urgently to the Therapeutic Goods Administration. States and territories have also been asked to provide details on batch numbers and type of vaccine.

### **Whether there are any implications for swine flu vaccine**

At this stage there do not appear to be implications for the swine flu vaccine Panvax®. It is safe to have the Panvax® H1N1 vaccine, even if you are already immune to the virus, just as it is safe to get a seasonal influenza vaccination if you've already had seasonal flu. The TGA's assessment and the advice of its expert committees is that Panvax® is a safe, effective vaccine for prevention of the H1N1 influenza.

The seasonal influenza vaccine is a trivalent vaccine and includes antigen to three influenza types: influenza A(H1N1), influenza B and Influenza A(H3N2).

### **Swine flu vaccination as alternative to seasonal flu vaccine**

People should have the seasonal influenza vaccine to ensure full protection this season, even if you have already had Panvax®. As Panvax® H1N1 vaccine only protects you against the pandemic (H1N1) 2009 influenza virus. People can still be infected by seasonal influenza viruses circulating in the community. To reduce the risk of influenza during Australia's winter months people should still get the seasonal flu vaccine, particularly if they are in a high risk seasonal flu group.

23<sup>rd</sup> April 2010

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It should be noted that a review of NSW triage text data from Emergency Departments has not picked up a similar trend, nor has data in our notifiable diseases database picked up any notifications for seasonal influenza. However, if your colleagues approach you with reports of severe adverse reactions to either seasonal or pandemic influenza vaccines please encourage them to 1)notify their local public health unit and 2)return a report to the TGA (reporting can be done through <http://www.tga.gov.au/adr/bluecard.htm>).

We hope to stay in touch with further information as investigations progress today.

Kind regards

Jan

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