



Australian Government
Department of Health and Ageing

CHIEF MEDICAL OFFICER

Professor Jim Bishop AO
MD MMed MBBS FRACP FRCPA
Commonwealth Chief Medical Officer

MEDIA STATEMENT

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SEASONAL FLU VACCINE REMAINS SUSPENDED FOR YOUNG CHILDREN WITHOUT RISK FACTORS

After consideration of the results to date of a comprehensive investigation into the safety of the seasonal flu vaccine for young children, I have advised, that as a precaution, the suspension of seasonal flu vaccination should continue for healthy children under five years of age.

Since the first reports of a higher than usual occurrence of fever with convulsions in young children following seasonal flu vaccination in WA in April, investigations nationally have confirmed that a small number of children aged under five across the country have experienced fever with convulsions in the 24 hours after vaccination with the 2010 seasonal influenza vaccine. These reactions have been associated mainly with Fluvax, manufactured by CSL.

The investigation conducted by the Therapeutic Goods Administration (TGA), in association with the Australian Technical Advisory Group on Immunisation (ATAGI) and the National Centre for Immunisation Research and Surveillance has identified no apparent clinical, biological or epidemiological factors that would explain the higher than expected observed rates of fever with convulsions. Laboratory testing of the vaccine by the TGA and an audit of the CSL manufacturing plant have also revealed no abnormalities to explain this event. However this investigation is continuing.

Nevertheless, to date, epidemiological analyses point to a rate of febrile convulsions in children aged under five years following 2010 seasonal influenza vaccination of about 9 per 1000 children vaccinated, while the expected rate would be less than 1 per 1000.

While I am recommending that healthy children aged under five years not be vaccinated with seasonal flu vaccine this year, where a child aged under five has

medical risk factors that would cause serious health effects for the child if they got the flu, parents should discuss with their doctor whether, on clinical evaluation of the risks and benefits, a seasonal flu vaccination would be the best option.

Doctors should note that, while a higher rate of febrile convulsions has been identified using Fluvax, insufficient doses of this season's Inluvac and Vaxigrip vaccines have been used in children in this age group to accurately determine the rates for these vaccines. In addition, as the cause of the increase in febrile convulsions is not yet known, caution should be exercised.

In addition, the alternative for both healthy children and those with risk factors is the swine flu vaccine, Panvax, which has been shown to be safe and effective in young children and is freely available.

Influenza itself often causes fever in young children which can lead to convulsions and flu vaccine can also produce these side effects but there is a clear signal that the rate of fever with convulsions is higher with this year's vaccine across all jurisdictions.

The investigation found that, while there are some cases of fever with convulsions associated with the swine flu vaccine, these were in line with the expected rate of side effects for a flu vaccine based on the swine flu vaccine clinical trials and experience with seasonal flu vaccines in previous years, both in Australia and internationally.

The TGA will continue to work with overseas Regulators and the US CDC in Atlanta to ascertain the scientific reason for this phenomenon.

More information is available on the Immunise Australia Hotline at 1800 671 811.

Media contact: Kay McNiece, 0412 132 585

Summary of Review Report attached:

INVESTIGATION INTO FEBRILE CONVULSIONS IN YOUNG CHILDREN AFTER SEASONAL INFLUENZA VACCINATION

INTERIM FINDINGS AND RECOMMENDATIONS 1 June 2010

On 23 April 2010, the use of seasonal influenza vaccine in children aged 5 years and under was temporarily suspended in Australia, pending an investigation into the causes of an apparent increase in febrile convulsions after seasonal influenza vaccination in Western Australia (WA).

The investigation is being undertaken by the Therapeutic Goods Administration (TGA) and the Australian Technical Advisory Group on Immunisation (ATAGI) in collaboration with the National Centre for Immunisation Research and Surveillance (NCIRS) and state and territory health authorities. This Fact Sheet provides interim results from the investigation, which is ongoing.

The investigation has included extensive laboratory testing of the seasonal influenza vaccine, review of the clinical case notes of all the cases of febrile convulsions reported from WA, review of adverse events following seasonal and pandemic influenza vaccines reported from all states and territories, review of clinical trial data, liaison with international regulators, consultation with expert advisers and an epidemiological analysis of the adverse events.

The investigation has confirmed a higher rate of fever and febrile convulsions in children under the age of 5 years following 2010 seasonal influenza vaccine than in previous years. The number of cases is higher in WA as more children have been vaccinated in that state than elsewhere, but there is a similar increase in the rate of febrile convulsions across all jurisdictions.

Convulsions occur following fever due to any cause (most commonly an infection) in 2 to 3 in every 100 children by the age of 5 years. From previous studies, the expected rate of convulsions associated with fever within 24 hours of seasonal influenza vaccine in children under 5 years of age is less than one per 1,000 doses.

Almost all the febrile convulsions related to the 2010 seasonal influenza vaccine have occurred following Fluvax[®] or Fluvax[®] Junior. The rate of febrile convulsions with these vaccines is estimated to be up to 9 in 1,000 doses. The rate for Panvax[®] is within expected limits at less than 1 in 1000 doses. The rate for Influvac[®] appears similar to Panvax[®], but is less certain as the number of doses of Influvac[®] used in this age group has been relatively low. There has been insufficient use of Vaxigrip[®] in young children this season in Australia, to determine a rate for that vaccine. To assist in the assessment of these two vaccines, the TGA is seeking information from other Southern Hemisphere countries which have used them this year.

No biological, clinical or epidemiological factors have been identified to explain these higher than expected rates of febrile convulsions. Vaccine testing has shown no abnormalities. Further vaccine testing is planned and will occur in collaboration with the US Centers for Disease Control and Prevention in Atlanta.

The TGA considers that, overall, the balance of benefits and risks of Fluvax[®] and Fluvax[®] Junior continues to be positive but has required a new warning to be inserted in the product information for these vaccines to alert clinicians to the increased rate of high fever and febrile convulsions with their use in children under 5 years of age.

The Chief Medical Officer has advised that the suspension of the use of all 2010 seasonal influenza vaccines should continue for routine vaccination of otherwise healthy in children under 5 years of age until further notice. Vaccination with Panvax[®] against pandemic H1N1 influenza, which is anticipated to be the predominant strain of influenza this winter, is a reasonable alternative in this age group.

Children aged under 5 years with predisposing medical conditions are between 2 to 6 times more likely to be hospitalised following an influenza infection compared with healthy children. Where a child has medical risk factors, vaccination with Panvax[®] may be given. For broader protection, vaccination with or one of the 2010 seasonal vaccines, with a preference for Inluvac[®] or Vaxigrip[®] (where available), may be considered. Immunisation providers should use clinical judgement to evaluate the risks and benefits for the individual child and agree the best clinical management with the parents. Despite the documented increase, febrile convulsions after influenza vaccination continue to be uncommon events, but parents should be made aware of the possibility and the child should be monitored for fever. Paracetamol and physical methods can be used to reduce fever.

Seasonal influenza vaccine for those aged 5 years and over can continue to be recommended as safe and effective, especially those in high risk populations¹ such as those with underlying medical conditions, Indigenous populations, those aged 65 years and over and pregnant women.

¹ See pages 190 to 192 in the *Australian Immunisation Handbook 9th Edition*, accessible via the Immunise Australia website at <http://www.immunise.health.gov.au/>.