



**Australian Government**  
**Department of Health and Ageing**

**CHIEF MEDICAL OFFICER**

Dear Immunisation Provider

Children under 5 years of age can now be vaccinated against influenza using Vaxigrip® or Influvac® seasonal influenza vaccine.

I am writing to provide information on the progress of the investigations into the increase in the numbers of young children experiencing fever and febrile convulsions after seasonal influenza vaccination. The epidemiological investigations both in Australia and internationally have confirmed the increase in the rate of febrile convulsions in children less than 5 years of age in the 24 hours after vaccination with the 2010 seasonal trivalent influenza vaccine (TIV). Despite extensive investigation by the Therapeutic Goods Administration (TGA) a cause for this increase has not yet been identified however additional, more sensitive tests are on-going.

The increase in rates of febrile convulsions has been documented for the 2010 Fluvax® and Fluvax® Junior. Investigations from New Zealand where Vaxigrip® has been widely used during the 2010 influenza season did not demonstrate any increase in rates of febrile convulsions. Analysis of Australian data for Influvac® also does not demonstrate any increase in rates of febrile convulsions.

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 less than 5 years of age.

As a result of these investigations, we recommend that children from 6 months to less than 5 years of age may be vaccinated with Vaxigrip® and Influvac® following a discussion of the risks and benefits of these vaccines with parents and guardians. This includes both children at risk of medical complications of influenza and healthy children. Vaccination of children in this age group with Fluvax® and Fluvax® Junior is not recommended due to the identified increase risk of febrile convulsions.

Children less than 5 years of age with predisposing medical conditions are between 2 to 6 times more likely to be hospitalised following an influenza infection compared with healthy children.

Despite the reassuring epidemiological evidence of no increased rate of febrile convulsions with Vaxigrip® and Inluvac®, febrile convulsions after influenza vaccination can occur although this is an uncommon event. 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.

Recommendations for the use of seasonal influenza vaccine including Fluvax® in children 5 years and older and in adults has not changed. The recommendation to avoid Fluvax® is limited to children aged 6 months to less than 5 years of age.

Further information about the investigation findings are provided in the enclosed Fact Sheet. Copies of this letter, the Fact Sheet, Australian Technical Advisory Group on Immunisation (ATAGI) advice for clinicians on the 2010 trivalent influenza vaccine for healthy children aged 6 months to less than 5 years and a recent media release are posted on the Immunise Australia website at [www.immunise.health.gov.au](http://www.immunise.health.gov.au). Additional information can be accessed on the same website or by phoning the Immunise Australia Call Centre on 1800 671 811.



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