



## Update on Seasonal Influenza Vaccination of Young Children

CSL Biotherapies (CSL) today notes the Chief Medical Officer's statement and updated recommendations regarding influenza vaccination for children under 5.

In late April 2010, CSL became aware of reports of side effects in young children following this season's influenza vaccination. The Chief Medical Officer subsequently advised immunisation providers to stop vaccinating children 5 years and under pending further investigation. At this time, CSL ceased distribution of its paediatric influenza vaccine as a precautionary measure and began urgent investigations with government and regulatory authorities.

Analyses of currently available data show that there has been a significant increase in reports of fever and febrile convulsion in children aged less than 5 years shortly after receiving CSL's 2010 influenza vaccine, compared to previous seasons.

Extensive investigations conducted by the authorities and CSL to date have not established an explanation for the increase in reports of side-effects.

In light of this information, CSL has updated its prescribing information for influenza vaccine and is writing to doctors to inform them of this important update.

As a further precautionary measure, and as part of ongoing investigations by CSL and regulatory authorities, CSL has voluntarily commenced a retrieval program for its remaining 2010 paediatric influenza vaccine from medical clinics and distributors.

CSL supports the Chief Medical Officer's recommendation to not vaccinate healthy children under 5 with seasonal influenza vaccine this year, and that doctors should conduct a careful assessment of the risk and benefits when considering vaccination for children at risk.



# Press Release

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“CSL has more than 40 years experience in manufacturing and testing influenza vaccine and the safety profile of our influenza vaccine has been well established. The reports we have seen this season in children under 5 are unexpected and not consistent with our experience using previous seasons’ vaccines,” said Dr Darryl Maher, CSL Medical and Research Director.

“The actions taken by CSL reflect the utmost importance we place on patient safety and the quality of our products. We will continue to work with authorities to find an explanation for the increase in reports of side effects associated with our vaccine,” said Dr Maher.

“If any members of the public have any questions about being vaccinated, they should consult with their doctor,” concluded Dr Maher.

**For more information about CSL Limited, visit [www.csl.com.au](http://www.csl.com.au)**

**For more information about the Chief Medical Officer’s announcement, visit: [www.health.gov.au](http://www.health.gov.au).**

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