



Company Statement

August 26, 2010

Shelf Life Reduction of Panvax[®] Junior

Ongoing monitoring by both CSL and the TGA of CSL's Panvax[®] Junior vaccine has shown a decline in its potency and as a result a 12 month shelf life can no longer be supported. Panvax[®] Junior is the paediatric presentation of CSL's 2009 H1N1 (pandemic) influenza vaccine, which is supplied in a single 0.25ml pre-filled syringe.

This situation is not unique. Regulators and manufacturers in other countries have identified similar trends in their single-dose monovalent H1N1 vaccines. The decline in potency is specific to the 2009 monovalent (single strain) H1N1 vaccine when presented in small volumes, such as Panvax[®] Junior. Panvax[®] (and other manufacturers' H1N1 vaccines) in multi-dose vials are not affected, nor are trivalent seasonal influenza vaccines that contain the H1N1 strain.

Based on this information and following consultation with the TGA, a decision has been made to limit the shelf life of Panvax[®] Junior to 6 months and as a result, all remaining doses are now to be considered expired. CSL has written to immunisation providers to inform them of this decision and will be conducting a retrieval program for all remaining doses of Panvax[®] Junior.

Importantly, no unexpected safety or efficacy concerns have been identified with administration of Panvax[®] Junior. Panvax[®] Junior has been available for children aged 3 years and under since 9th December 2009.

Advice regarding influenza vaccinations for children is available at www.immunise.health.gov.au.

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