



Withdrawal of Panvax Junior

26 August 2010

Stability testing by the Therapeutic Goods Administration (TGA) of the pandemic influenza vaccine for children, Panvax H1N1 Junior, has shown a decline in potency of the product which is supplied in 0.25 ml pre-filled syringes. The potency of the vaccine is tested to ensure that it continues to produce an effective immunological response. If the potency of the vaccine were to decline further it would no longer be possible to be confident that this would be the case.

The TGA has informed the manufacturer, CSL, that its registered 12 month shelf life can no longer be supported and the shelf life has been reduced to 6 months. As a result existing stocks of Panvax Jr should now be considered expired.

The decline in potency appears to be the result of particular characteristics of the H1N1 virus itself. Similar declines in potency have been identified internationally by other regulators and have led to reductions in shelf life for other brands of H1N1 monovalent vaccine.

The safety of the vaccine is not affected.

In Australia, the decline in potency is specific to the Panvax Junior vaccine which is supplied in 0.25 mL pre-filled syringes.

Panvax in multidose vials is not affected by the decline in potency, nor are the trivalent seasonal influenza vaccines all of which include an H1N1 component.

To ensure the vaccine is no longer administered, CSL is retrieving all stock from immunisation providers and vaccine distribution points. CSL will contact all immunisation providers to advise them of this issue and the retrieval process.

The Australian Technical Advisory Group on Immunisation (ATAGI) has developed detailed advice on the implications of the withdrawal of Panvax Jr for children 6 months to 3 years of age. ATAGI has advised that revaccination of children who have already received two doses of Panvax Junior is not necessary, as the potency of the vaccine administered to date is considered adequate to induce an immune response. If a child aged 6 months to < 3years of age is due to receive a second dose of H1N1 containing vaccine, this can be provided by using the age appropriate dose (0.25ml) obtained from a Panvax multi-dose vial. Alternatively, the 2010 seasonal influenza vaccines (Vaxigrip and Influvac) are also suitable for use.

ATAGI's full advice is available on [Health Emergency](http://www.healthemergency.gov.au)
<<http://www.healthemergency.gov.au>> and [Immunise Australia Program](http://immunise.health.gov.au)
<<http://immunise.health.gov.au>>.