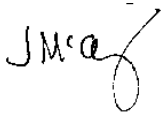


**Pneumovax 23 - Recommendation about Revaccination  
from the Therapeutic Goods Administration**

The TGA is advising health professionals not to administer a second dose of Pneumovax 23 vaccine pending the outcome of a review of an apparent increased rate of injection site reactions following administration of the second dose.

Please see the advice below from TGA for details.

Yours sincerely



Dr Jeremy McAnulty  
**Director Health Protection**  
17 April 2011

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*Information from Therapeutic Goods Administration:*

**Pneumovax 23 - Recommendation about Revaccination**

**The TGA is advising health professionals not to administer a second dose of Pneumovax 23 vaccine pending the outcome of a review of an apparent increased rate of injection site reactions following administration of the second dose.**

Pneumovax 23 vaccination is used to prevent life threatening bacterial infections. It has been included in the National Immunisation Program since 2005 and is recommended for:

- All people age 65 or over,
- Aboriginal and Torres Strait Islander people age 50 and over,
- Tobacco smokers,
- People age 10 and over who are predisposed to invasive pneumococcal disease.

The Immunisation Handbook currently recommends revaccination 5 years after the first dose.

Pneumovax 23 vaccine is known to be associated with a high rate of local injection site reactions which can include severe injection site reactions such as cellulitis and abscess. There is varying evidence from published trials as to whether injection site reactions are more common following revaccination

In the week commencing 21 March 2011, NSW Health notified to TGA an apparent cluster of adverse events related to the use of a single batch (N3336) of Pneumovax 23. Seven patients vaccinated since early March were reported to have severe local site reactions including cellulitis and abscess. The specific batch had only been supplied to NSW Health and ACT Health. Working with the NSW and ACT Health and the vaccine sponsors, TGA effected a recall of the implicated batch on 25 March.

Laboratory analyses of batch N3336 to date have not detected any problem related to vaccine manufacture or handling.

Since notification of the cluster in NSW, TGA has worked with the States and Territories to determine whether this event is confined to a specific vaccine batch or not. Adverse event reports from all States and Territories have been collated and analysed and that work is ongoing.

Preliminary analysis of data received to 14 April for adverse events reported to TGA for Pneumovax 23 vaccine administered since 1 January 2011 demonstrates:

- 178 adverse reactions reported, of which 169 are injection site reactions (ISRs). This compares to 63 adverse reactions reported to end April in 2010 and 34 to end April 2009.
- 57 of 178 adverse reaction reports are from Batch N3336 used in NSW and ACT.
- 82 of the 169 ISRs are severe reactions including cellulitis, extensive swelling from shoulder to elbow and/or abscess.
- There is a preponderance of second dose (revaccination) reactions. Of the 82 severe reactions, 44 are second dose, 22 are first dose and in 15 cases it is unknown at this stage whether it was a first or second dose.

Although Pneumovax23 has been available since 1983, vaccination with Pneumovax23 has increased substantially since it was included in the NIP in January 2005. Consequently the number of people who have received their second dose has increased since 2010/2011.

The Australian Technical Advisory Group on Immunisation (ATAGI) is currently reviewing the place of Pneumovax23 in the National Immunisation Programme.

The TGA is continuing to work with ATAGI and the States and Territories to collect and analyse adverse event data. Until that analysis is completed it is recommended that patients are not revaccinated with Pneumovax 23.

Health professionals and consumers are advised that further information about Pneumovax 23 is available in the Product Information and Consumer Medicines Information for Pneumovax 23 available on TGA's website at <https://www.ebs.tga.gov.au>

This alert is **not** applicable to use of the 7-valent pneumococcal conjugate vaccine Prevenar.

### Recommendations

- Health practitioners are advised not to administer Pneumovax 23 vaccine to patients who have previously received a dose of Pneumovax 23 until completion of a review of this matter by the TGA and ATAGI is completed.
- Consumers are advised not to seek revaccination with Pneumovax 23 if they have previously received this vaccine.
- Any consumer who believes they may have suffered an adverse reaction to Pneumovax 23 is advised to see their medical practitioner for review.

[ENDS]