



18 April 2011

Distributed to:

- Chief Operating Officers (Clinical Support)
- Chief Executives
- Directors of Clinical Governance

Action required by:

- LHN Chief Executives
- Directors of Clinical Governance
- Directors of Pharmacy

For response by:

- Directors of Clinical Governance

We recommend you also inform:

- Drug and Therapeutic Committees
- Directors of Nursing
- Pharmacists
- Relevant Nurses
- Relevant Medical staff
- Community Health Centres

Deadline for completion of action

20 April 2011

Clinical Safety Quality & Governance Branch

NSW Department of Health
Tel. 02 9391 9200
Fax. 02 9391 9556

Email
quality@doh.health.nsw.gov.au

Safety Alert available at
<http://internal.health.nsw.gov.au/quality/sabs/>

Safety Alert 003/11

PNEUMOVAX ®23 Injection Advice against Revaccination

Background

Pneumovax ®23 is used to prevent life threatening bacterial infections and is known to be associated with a high rate of local injection site reactions. These can include severe injection site reactions such as cellulitis and abscess formation. 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.

The TGA is working with the Australian Technical Advisory Group on Immunisation (ATAGI) and States and Territories to collect and analyse adverse event data. A previous Safety Alert SA002/11 related to use of a particular batch number was issued on 25 March 2011. Until this analysis is complete it is recommended that **patients are not revaccinated with Pneumovax ®23 regardless of batch number.**

Additional Information

Further information about Pneumovax ®23 is available in the Product Information and Consumer Medicines Information for Pneumovax ®23 on the TGA website at <https://www.ebs.tga.gov.au>.

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

Immunisation providers are encouraged to report any adverse events following immunisation directly to their local Public Health Unit, for contacts see <http://www.health.nsw.gov.au/public-health/phus/phus.html>

Mandatory actions for Local Health Networks

Local Health Networks are to:

- Distribute this Safety Alert to all relevant staff.
- Ensure Health practitioners do **NOT** administer a second dose of Pneumovax ®23 to patients who have previously received a dose of Pneumovax ®23 until a review of the matter is completed by the TGA.
- Advise consumers not to seek revaccination with Pneumovax ®23 if they have previously received this vaccine.
- Advise any consumer who believes they may have suffered an adverse reaction to Pneumovax ®23 to see their medical practitioner for review.

Action required by Local Health Networks

1. Verify receipt of this Safety Alert and actions taken by Networks by close of business Wednesday 20 April 2011.
2. Review any local protocols to ensure Health practitioners do **NOT to administer Pneumovax ®23** to patients who have previously received a dose of **Pneumovax ®23** until a review of the matter is completed by the TGA.