



25 March 2011

Distributed to:

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

Action required by:

- 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

Deadline for completion of action

28 March 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 002/11

RECALL of PNEUMOVAX ®23 Injection

(pneumococcal polyvalent, MSD 0.5ml Vial AUST R 10507; CSL code 0786100110 pack vials)

Batch No. N3336, expiry date 22 June 2011

Background

Merck Sharp and Dohme (Australia) Pty Limited (a subsidiary of Merck & Co. Inc and known as MSD) has recently been advised of several injection site adverse events, including cellulitis and / or abscess in patients administered with batch number N3336 of Pneumovax ® 23 vaccine.

Following receipt of these adverse event reports, Merck Sharp and Dohme have advised that they have initiated an investigation into the manufacturing of this product, and, to date, the initial investigation has not revealed any adverse quality issues related to batch number N3336. Investigations are still continuing.

Following discussion with the Therapeutic Goods Administration (TGA), NSW Health and ACT Health, Merck Sharp and Dohme advises, as a precautionary measure, that **Pneumovax ®23 batch number N3336 is being voluntarily recalled.**

Please note that this does not impact on other batches of Pneumovax ® 23 vaccine.

Alternative supplies of Pneumovax ® 23 are available for ordering from the State Vaccine Centre. Orders will be met using a different batch to continue the implementation of the National Immunisation Program for those patients who are 65 years and older.

Additional Information

Immunisation providers are encouraged to report any adverse events following immunisation directly to your local Public Health Unit available at <http://www.health.nsw.gov.au/public-health/phus/phus.html>

Mandatory actions for Local Health Networks

Local Health Networks are to:

- Quarantine all stocks of Pneumovax ® 23 vaccine batch number N3336
- Distribute this Safety Alert to all relevant staff.
- Obtain alternative supplies of Pneumovax ® 23 vaccine through NSW Vaccine Centre.

Action required by Area Health Services

1. Immediately quarantine all stocks of Pneumovax ® 23 vaccines batch number N3336 held in your vaccine fridge.
2. Verify withdrawal of above products and any other actions by close of business 28 March 2011