

Urgent recall of pneumovax batch number N3336

25 March 2011

Please distribute this information to all GPs and general practice nurses

Key points

1. Do not use batch number N3336 Pneumovax.
2. Please quarantine any stock of this batch currently held in your vaccine fridge. CSL will collect this stock.
3. 23vPPV continues to be available for ordering from the State Vaccine Centre, and orders will be met using a different batch.

Dear Provider,

Please see the attached letter from Merck Sharpe and Dohme regarding the urgent recall of batch N3336 of the 23-valent pneumococcal polysaccharide vaccine.

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>

Yours sincerely



Dr Jeremy McAnulty
Director Centre for Health Protection
25 March 2011

MSD

Merck Sharp & Dohme (Australia) Pty Limited
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25 March 2011

URGENT MEDICINE RECALL

Dear Immunisation Provider,

RE: PNEUMOVAX® 23 Injection (pneumococcal vaccine polyvalent, MSD) 0.5mL Vial (AUST R 10507; CSL code 0786100110 pack vials); Batch No. N3336; Expire 22 June 2011

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 discussion with the TGA, NSW Health and ACT Health, MSD advises, as a precautionary measure, that **Pneumovax 23 batch number N3336 should not be administered and should be returned as described below. Please note that this does not impact other batches of Pneumovax 23 vaccine.** Alternative supplies of Pneumovax 23 are available through your State/Territory Health Department to continue the implementation of the National Immunisation Program for those patients who are 65 years and over.

Background

Following receipt of these adverse event reports, MSD immediately initiated an investigation into our manufacturing and, to date, our initial investigation has not revealed any adverse quality issues related to this batch. Further investigation is currently ongoing.

MSD advises that you immediately quarantine all stock of Pneumovax 23 vaccine batch number N3336 and confirm the exact quantities of this batch you hold on the attached Facsimile Reply Form. This will enable arrangements to be made for this batch of Pneumovax 23 vaccine to be returned. Even if you have no stock of this batch, please complete the Facsimile Reply Form as we require this information for reconciliation purposes.

Please contact CSL Medical Information on 1800 642 865 for any queries.

Nothing is more important to MSD than the quality and safety of the vaccines and medicines that we produce and supply. MSD sincerely apologises for any inconvenience.

Yours sincerely,

A handwritten signature in blue ink that reads 'M. Hammond'.

MARK HAMMOND
Quality Operations Manager

Facsimile Reply Form - NSW

To: MSD
Attention: Customer Services Supervisor
Facsimile Number: 1 800 333 013

Contact Person: _____
Phone number: _____
From: _____
Address: _____

Subject: PNEUMOVAX 23 VACCINES – BATCH NUMBER N3336

We confirm that:

We have stock which is the subject of this letter? YES / NO (circle appropriate response)

If yes, the quantity of stock currently on hand is: _____ (No. of single vials)

CSL will be in contact with you to arrange the collection of this batch.

Any other relevant details:

We agree to quarantine this stock pending collection.

Signature: _____

Date: _____