NSW HEALTH

Safety Alert 007/09

6 NOV 2009

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations
- Chief Pharmacists

For response by:

- Directors of Clinical Governance

We recommend you also inform:

- Directors of Anaesthesia & Surgery
- Directors of Emergency Medicine
- Directors of Intensive Care
- Pharmacists
- Directors of Medical Services
- Directors of Nursing and Midwifery
- Medical staff
- Nurses and Midwives

Deadline for completion of action

6 November 2009

Clinical Safety, Quality and Governance Branch

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RECALL OF Cefazolin Sandoz BATCH AH 5067

Background

Sandoz have advised of a voluntary recall of Cefazolin Sandoz 1gram vials Batch No AH 5067 following reports of anaphylaxis associated with this batch.

Cefazolin is an antibiotic commonly used in antibiotic prophylaxis during surgery and for other infections.

Specific Incident

During the last 11 days there have been eight anaphylactic or severe allergic reactions (one fatal) experienced by patients following administration of intravenous Cefazolin. The incidents appear to be related to Batch No AH 5067.

The company, TGA and ADRAC have been notified. The TGA have advised they will be issuing a recall shortly.

Mandatory actions for Area Health Services

Area Health Services are to

1. withdraw Cefazolin Sandoz Batch No AH 5067 from use;
2. seek replacement stock noting this drug is used in hospital, outpatient and community settings;
3. ensure that sufficient stock of alternate batches or comparable antibiotics are available for use so that clinical care is not compromised;
4. report any serious allergic reactions to the Chief Pharmacist on call 0401 712 050 and
5. ensure that all staff are reminded of the need for appropriate recognition and management of patients with anaphylaxis or severe allergic reactions.

Further advice

Further advice is being sought from the manufacturer, the TGA and ADRAC.

Action required by Area Health Services

1. Withdraw all Cefazolin Sandoz Batch AH 5067 (expiry 05/12) pending return to supplier.
2. Report any suspected serious allergic reactions immediately to the Chief Pharmacist on Mob 0401 712 050.
3. Verify withdrawal of the Cefalozin Sandoz batch and any other actions by close of business, Monday 9 November 2009.