



# Safety Alert 006/10

**10 Dec 2010**

## RECALL OF Sitaxentan (Thelin)

**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

**For response by:**

- Directors of Clinical Governance

**We recommend you also inform:**

- Directors of Neonate Emergency Transfer Services
- Directors of Anaesthesia & Surgery
- Directors of Biomedical Engineering
- Directors of Emergency Medicine
- Directors of Intensive Care
- Directors of Neonatal Intensive Care
- Directors of Paediatric intensive Care
- Directors of Medical Services
- Directors of Specialty Training Units
- Directors of Nursing and Midwifery
- Medical staff
- Nurses and Midwives

**Deadline for completion of action****13 Dec 2010****Clinical Safety, Quality and Governance Branch**

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Intranet Website

<http://internal.health.nsw.gov.au/quality/sabs/>

### Background

The TGA have advised that Pfizer have decided to do a world-wide suspension of Sitaxentan (Thelin), following two reported deaths overseas.

Sitaxentan (Thelin) is used for arterial pulmonary hypertension in patients with New York Heart Association/World Health Organisation functional class III symptoms to improve exercise ability. TGA has advised that there are twenty specialist prescribers for this medicine with around 200 relevant patients Australia wide.

The TGA have advised that specialist prescribers have been advised to talk to their patients and review treatment to transition to alternative drug therapy.

### Specific Incident

Advice from the TGA of reports of two associated deaths overseas.

### Mandatory actions for Area Health Services

Area Health Services are to:

1. identify any patients currently prescribed Sitaxentan (Thelin) and seek advice from their medical specialist regarding transition to alternative drug therapy and
2. ensure that sufficient stock of the alternate drug therapy is obtained so that clinical care is not compromised.

### Further advice

TGA have advised that a recall notice is being prepared and is expected to be distributed early next week allowing time for physicians to contact patients. TGA also advise that sponsors of alternate drug therapies have confirmed available supplies.

For advice from the Company contact Jeannie Wells on 0407 285861

### Action required by Area Health Services

1. Identify any patients currently prescribed Sitaxentan (Thelin) and seek advice from their medical specialist regarding transition to alternative drug therapy and
2. Ensure that sufficient stock of the alternate drug therapy is obtained so that clinical care is not compromised.
3. Verify withdrawal of the Sitaxentan (Thelin) and any other actions by close of business, Monday 13 December 2010.