Safety Alert 001/12

8 March 2012

Distributed to:

- Chief Executives
- Directors of Clinical Governance

Action required by:

- Chief Executives
- Directors of Clinical Governance

For response by:

- Directors of Clinical Governance

We recommend you also inform: (eg's)

- Directors of Anaesthesia & Surgery
- Directors of Emergency Medicine
- Directors of Intensive Care
- Directors of Neonatal Intensive Care
- Directors of Paediatric intensive Care
- Directors of Medical Services
- Medical staff

Deadline for completion of action

9 March 2012

Expert Reference Group

- Advice from TGA

Clinical Excellence Commission

Tel. 02 9269 5500
Fax. 02 926905599

Email:
quality@cec.health.nsw.gov.au

Internet Website:
http://www.health.nsw.gov.au/quality/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Product Recall CSL Human Albumin

Background

The Therapeutic Goods Administration (TGA) has informed NSW Ministry of Health that current stocks of CSL Human Albumin (4% and 20%) may be contaminated with Ethylene Glycol. CSL and the TGA are arranging quarantining of Albumin.

Toxic levels of Ethylene Glycol can cause metabolic acidosis and renal failure.

It is unclear which batches of Albumin may be contaminated.

Further testing of batches will occur to see which batches will need to be returned to the supplier.

Mandatory actions for Local Health Districts/Networks

- Albumin is not to be used on patients unless clinically essential.See attached advice from TGA.
- All stocks of Albumin are to be quarantined and withdrawn from routine use until further notice.

References

- Advice from the TGA

Further information will be forwarded when available

Action required by Local Health Districts /Networks

1. Ensure all stocks of Albumex are quarantined and withdrawn from clinical use.
2. Report to CEC by 9 March 2012 when action complete