Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2012-2013, 30 & 31 May and 1 June 2012

Question: E12-422

OUTCOME 1: Population Health

Topic: CSL contamination

Type of Question: Hansard Page 53, 31 May 2012

Number of pages: 1

Senator: Senator Fierravanti-Wells

Question:

Was there something written other than what TGA distributed? That is what I was talking about in terms of a written notification that has gone out there?

Answer:

On 8 and 9 March 2012 the Department of Health and Ageing's National Incident Room (NIR) provided the notification (set out at Attachment 1) to countries to which Commonwealth Serum Laboratories (CSL) had exported albumin. These countries were China (Hong Kong), Indonesia, Malaysia, New Zealand, and Sri Lanka. The notification was provided to National Focal Points in these countries under the World Health Organization's (WHO) International Health Regulations. The NIR also provided this advice to health authorities in Taiwan, which is not a member of the WHO.

On 10 March 2012 the NIR followed up its earlier notification with further advice (set out at Attachment 2) that the Therapeutic Goods Administration (TGA) had started to authorise the release of batches of albumin. The NIR noted that further releases of batches would be published on TGA's website and recommended that health authorities check the TGA website regularly.

Attachment 1

Sent 8 and 9 March

Australian National Focal Point (NIR Ref #809)

The following information is provided to you by the Australian National Focal Point (NFP).

Background

On 8 March 2012 the National Incident Room was advised that CSL had notified TGA and the National Blood Authority of contamination of Albumin products with ethylene glycol. The contamination occurred accidentally and was discovered on 25 January 2012. CSL have been testing batches of the product produced from November 2011, and have found low levels of ethylene glycol prepared since 4 December. At this stage it is unknown how far back contamination may have occurred, therefore CSL is undertaking further testing. Albumin has a shelf life of four years, therefore all products in this range will need to be tested.

TGA is not satisfied with the safety of the product. Even though the risks are low the recipients of the product are likely to be critical care patients. Therefore, it has been agreed that advice will be distributed to hospitals (public and private) and appropriate stakeholders, advising:

- to be aware of the situation;
- to cease use of current stocks of Albumin;
- use new stocks as soon as they arrive (produced after 25 January 2012); and
- during this interim period, where patients may need Albumin, the attending medical practitioner should undertake an appropriate clinical risk assessment.

DoHA Management Authority/Actions

The NIR will continue to monitor the event and provide updates if new information is received. An AHPC emergency teleconference was held at 1500 AEDT on 8 March 2012 to discuss the issue and appropriate actions. A fact sheet, consisting of a statement regarding the quarantine of Albumin and appropriate clinical information is attached below. TGA has updated their website to contain information about the Alubmin contamination at http://www.tga.gov.au/safety/alerts-medicine-human-albumin-120308.htm

The Australian NFP is providing this information to you under Article 44 of the International Health Regulation (IHR2005) - Collaboration and Assistance.

Please direct any enquiries regarding this matter to the Australian NFP at this e-mail address: health.ops@health.gov.au

Please note: The information contained in this document may include personal information and is supplied in accordance with the *International Health Regulations 2005 (IHR)*. A record may be made of this information, or the information may be used or disclosed only for the purposes of assessing and managing a public health risk in accordance with and subject to the requirements of Article 45 of the IHR.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Subject: Quarantining of CSL Human Albumin (4% and 20%)

The Therapeutic Goods Administration (TGA) has taken steps today to quarantine CSL Human Albumin solutions from further use while an assessment is undertaken of the safety of these products. All hospitals and other relevant medical organisations are being advised of this action.

CSL Biotherapies notified the TGA on 7 March 2012 that some batches of human albumin solutions manufactured prior to 25 January 2012 have been contaminated with ethylene glycol as a consequence of an equipment failure. CSL is continuing to conduct further testing to quantify the levels of contamination and the extent of the batches affected but, as a precaution, TGA has put arrangements in place to quarantine stocks held by hospitals, the Australian Red Cross Blood Service (the Blood Service) and CSL from further use or issue until safety implications have been fully assessed.

CSL has advised the TGA that the levels of contamination which have been detected are very low and that, based on projections of the highest possible amounts administered and available toxicological data, adverse clinical effects appear unlikely to occur. CSL has also advised the TGA that a review of adverse event reporting has shown no evidence of a safety signal associated with the use of the product. Any toxicity due to ethylene glycol would occur acutely and delayed effects beyond 72 hours would not be expected.

As a result of this action by TGA, supplies of albumin may be limited in the immediate future. Clinicians should carefully consider the clinical need for albumin usage, as well as any alternative therapy that could be substituted, such as the use of alternative volume expanders.

The Blood Service will shortly be advising hospitals and laboratories regarding the resupply of CSL Human Albumin products, and the Department of Health and Ageing and the Blood Service have issued advice to treating clinicians regarding this product.

Over coming days, the TGA will be conducting further assessment of data provided by CSL, and will be conducting audits of CSL's manufacturing and quality assurance processes.

8 March 2012

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Clinical Advice on Ethylene Glycol from the Department of Health and Ageing in consultation with the Australian Red Cross Blood Service

What is ethylene glycol?

- Ethylene glycol is an alcohol generally used as a coolant, mixed with water and other solutions.
- It is metabolised by the same enzyme pathway used to metabolise ethanol and other alcohols, using alcohol dehydrogenase and aldehyde dehydrogenase in the liver. It is metabolised to Glycolic acid and Oxalic acid which, along with unmetabolised ethylene glycol (around 20% of a dose) is excreted by the kidneys.

How is it toxic?

- There are three main toxic effects of ethylene glycol:
  1. CNS effects similar to ethanol;
  2. A high anion gap metabolic acidosis; and
  3. Formation of oxalic acid crystals, which can damage kidneys and other tissues and adsorb calcium ions. It can lead to acute renal failure.

How do I recognise ethylene glycol toxicity?

- Poisoning should be considered when a patient has received IV albumin in the last 72 hours and either
  - Develops an unexplained high anion gap metabolic acidosis;
  - Has symptoms consistent with alcohol intoxication but does not have an expected level of ethanol in their blood; or
  - Develops acute renal failure without an alternative explanation.
- If you are concerned regarding a possible episode of poisoning, check if your laboratory is able to measure ethylene glycol levels from a blood sample.

How can ethylene glycol toxicity be treated?

- IV or oral ethanol can be used to block the metabolism of ethylene glycol. Check with your local Intensive Care Unit or Poisons Information Centre for specific advice on the appropriate dose.

What is the risk of patients previously treated with albumin?

- Toxicity due to ethylene glycol occurs acutely and delayed effects beyond 72 hours would not be expected. For this reason patients who received albumin more than 3 days ago and are well do not require investigations to be performed and can be reassured.

What do I do until new stocks of Albumex arrive?

- Clinicians should carefully consider the clinical need for albumin usage during this period, as well as any alternative therapy that could be substituted, such as the use of alternative volume expanders.
- The highest risk would be anticipated in those patients requiring the largest volumes of albumin.
- The Blood Service is also increasing the manufacture of Clinical Fresh Frozen Plasma to meet any extra demand.

8 March 2012

Attachment 2

Sent 11 March 2012

Australian NFP update - Quarantining of Human Albumin (NIR Ref #809)

Background
The NFP of Australia was advised by our Therapeutic Goods Administration of contamination of Albumin products with ethylene glycol. An e-mail was sent on 09 March 2012 to alert you to the possibility that some blood products supplied to your country may be contaminated.

Update
The TGA has started to authorise the release of batches of Albumex™ that after testing have results that indicate the batch is safe to remove from quarantine and therefore safe to use.

The TGA website about the Alubmin contamination can be found at http://www.tga.gov.au/safety/alerts-medicine-human-albumin-120308.htm Relevant links to information updates can be found from this page (see Related Information in the call out box to the right).

The information on released batches is at http://www.tga.gov.au/safety/alerts-medicine-human-albumin-120311.htm

It is anticipated that further releases of batches will be likewise published, hence it is recommended that you check this website regularly.

The Australian NFP is providing this information to you under Article 44 of the International Health Regulation (IHR2005) - Collaboration and Assistance.

Please direct any enquiries regarding this matter to the Australian NFP at this e-mail address: health.ops@health.gov.au

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