Update: Suspected contamination of “Provive” Propofol

Status: Active

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Issued by: Dr Michael Ackland, Deputy Chief Health Officer, Victoria

Issued to: Medical and dental practitioners, including Anaesthetists, Emergency Physicians, Intensivists, Infectious diseases physicians, pathology laboratories, retrieval units and paramedics. All Hospitals and Day Procedure Centres, pharmacists.

Key messages

- This is an update to the CHO Alert dated 2 May, 2014 for Suspected contamination of “Provive” Propofol.
- A number of people across Australia have developed septicaemia due to *Ralstonia species* with a common link of having been administered Provive propofol in April 2014.
- Further investigations are being undertaken by the Therapeutic Goods Administration (TGA) to determine the cause of sepsis and the strength of evidence linking propofol products with reported cases.
- The TGA recommendation to quarantine the two suspect batches of propofol **remains**. At this time, no batches of any of the drugs listed below are subject to a recall.
- Hospitals should quarantine stock of Provive and Sandoz propofol products and continue to seek alternatives to Provive and Sandoz propofol products until further notice.
- Maintain a high index of suspicion in all febrile patients following intravenous sedation or anaesthesia.
- Report any potential cases of sepsis following administration of Provive propofol to the TGA and the Department of Health.

What is the issue?

Ralstonia pickettii is a rare infection. It is a gram negative organism that has been linked in the past to contamination of medical therapeutic agents.

Concern was raised when this organism was identified in three South Australian patients who had procedures in April 2014. The only common exposure was the administration of Provive propofol during their procedures.

Five cases of septicaemia due to *Ralstonia species* where Provive propofol was also administered were subsequently identified in Queensland (4) and Victoria (1). Additional cases of septicaemia due to *Ralstonia species* have also been identified where there was no link to propofol administration.

The TGA is working with State and Territory health departments to gather further information regarding the reported cases of sepsis and to identify the specific organism(s) suspected of causing the infection.

In particular, the TGA is investigating the strength of the evidence linking these propofol products with the reported cases of sepsis.

As part of these investigations, the TGA is testing samples of the suspect batches for microbial quality. This testing includes performing sterility and bacterial endotoxin tests on the products. Results from the sterility testing will not be available for 2-3 weeks due to the prolonged incubation period for this test and the nature of the product.

The TGA is also carefully examining the manufacturing site data to identify relevant information.

Who is at risk?

All patients undergoing anaesthesia or sedation involving the suspected batches of propofol are potentially at risk.

Symptoms

Affected persons have developed rapid onset of fever and signs of septicaemia following medical procedures involving the suspected batches of propofol. Some have required admission to intensive care.

Prevention/treatment

Medical practitioners should avoid using the following batches of propofol: **Provive MCT-LCT 1% 20 ml vials, batches A030906 Exp. 08/15, and A030907 Exp. 08/15** because of the potential risk of septicaemia.

As a precaution it is recommended that all practitioners avoid using all Provive propofol products. Because the same manufacturer and supplier are used by Sandoz, clinicians should also avoid the use of Sandoz propofol products. Hospitals should seek alternatives to these brands.

Sandoz and Provive propofol products should only be used where there is no suitable alternative and consideration is given to the benefit relative to the risk to the patient.

Hospitals and other treatment facilities should check their stocks of propofol for the identified products and quarantine these immediately.

Maintain a high index of suspicion in all febrile patients following intravenous sedation or anaesthesia.

For any suspected case, consider the following actions:

- take blood cultures
- check whether there was an exposure to a product of concern
- seek advice from an Infectious Diseases physician.

If you become aware of any potential cases of sepsis following administration of Provive propofol:

- contact the TGA at adr.reports@tga.gov.au or on 1800 044 114
- notify to the department's Communicable Disease Prevention and Control section on 1300 651 160.

More information

For further information please see the TGA website on www.tga.gov.au

Contacts

Contact the Communicable Disease Prevention and Control section at the Department of Health on 1300 651 160.

Yours sincerely

Dr Michael Ackland
Deputy Chief Health Officer

Authorised by the Victorian Government, Melbourne.