

Chief Health Officer Alert

09 July 2014

Status: Resolved

Update: Suspected contamination of “Provive” Propofol

Status: Resolved

Date issued: 09 July 2014, update to alert issued 12 May 2014

Issued by: Dr Rosemary Lester, 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 [12 May, 2014 for Suspected contamination of “Provive” Propofol](#).
- The Therapeutic Goods Administration (TGA) has advised that all sizes and batches of Provive and Sandoz Propofol 1% products are **no longer under a precautionary supply restriction**.
- While the investigations into the possible causes of eight reported cases of *Ralstonia species* are continuing, based on current information, TGA is satisfied that the contents of propofol 1% emulsion for injection vials from batches previously identified in relation to this issue are not contaminated.

What is the issue?

Ralstonia species are a rare group of infections that have been linked in the past to contamination of medical therapeutic agents. Concern was raised when this organism was identified in three patients in South Australia who had procedures in April 2014. The only common exposure was the administration of Provive propofol. Across Australia, a further five cases were identified in patients who had received propofol in the month prior to the detection of *Ralstonia species* in blood culture samples.

The TGA has conducted a detailed review of the manufacturers' processes for propofol 1% emulsion and have tested samples from 25 batches of propofol 1% emulsion for sterility and bacterial endotoxins. No deviations from approved manufacturing processes were found and all tested samples passed the criteria for sterility and bacterial endotoxins.

As a result, the TGA has advised health professionals, hospitals and health facilities that all sizes and batches of the AFT-distributed Provive and Sandoz Propofol 1% products are no longer under a precautionary supply restriction.

More information

For further information, including extensive detail on testing undertaken, please see the [TGA Update](#).

Yours sincerely



Dr Rosemary Lester
Chief Health Officer

Authorised by the Victorian Government, Melbourne.