Australia: Provive and Sandoz Propofol 1% Emulsion for Injection - All Sizes and All Batches

Health professionals, hospitals and health facilities are advised that batches of a widely used intravenous anaesthetic drug, propofol, may include some vials that have been contaminated with the bacteria *Ralstonia pickettii*.

There have been reports of patients having developed sepsis following administration of 1% propofol injection.

In consultation with the TGA, the Australian distributor of Provive MCT-LCT 1% (propofol 1%) emulsion for injection in 20 ml vials (ARTG 162318), AFT Pharmaceuticals, has quarantined two batches due to potential contamination with *Ralstonia pickettii*. The affected batch numbers are:

- A030906 (expiry date 08/15)
- A030907 (expiry date 08/15).

At this time, no batches of any of the drugs listed below are subject to a recall.

As a precautionary measure, health professionals are advised, where possible, to avoid use of all sizes and all batches of the AFT-distributed Provive and Sandoz Propofol 1% products as listed below pending further investigation into this issue:

ARTG	ARTG Label
118940	Claris Lifesciences Australia Pty Ltd PROVIVE 1% propofol 1000mg/100mL emulsion for injection vial (distributed by AFT)
118938	Claris Lifesciences Australia Pty Ltd PROVIVE 1% propofol 200mg/20mL emulsion for injection vial (distributed by AFT)
162319	PROVIVE MCT-LCT 1% propofol 500mg/50mL emulsion for injection vial (distributed by AFT)
118939	Claris Lifesciences Australia Pty Ltd PROVIVE 1% propofol 500mg/50mL emulsion for injection vial (distributed by AFT)
162320	PROVIVE MCT-LCT 1% propofol 1000mg/100mL emulsion for injection vial (distributed by AFT)
162318	PROVIVE MCT-LCT 1% propofol 200mg/20mL emulsion for injection vial (distributed by AFT)
148870	PROPOFOL SANDOZ propofol 200mg/20mL emulsion for injection vial
148872	PROPOFOL SANDOZ propofol 1000mg/100mL emulsion for injection vial

148871	PROPOFOL SANDOZ propofol 500mg/50mL emulsion for injection vial

Ralstonia pickettii are Gram-negative bacteria. It may take several days for a blood culture to become positive and may be difficult for a laboratory to identify. Possible initial identifications include *Stenotrophomonas*, *Burkholderia* and *Pseudomonas* species of bacteria.

Please refer to the following website of TGA for details:
http://www.tga.gov.au/safety/alerts-medicine-provive-mct-lct-140502.htm

In Hong Kong, there are 6 registered products containing propofol and they are all prescription medicines. Amongst these products, 2 products are manufactured by Claris Lifesciences Ltd, namely Provive IV Infusion 1% (HK-56205) and Spiva Intravenous Infusion 1% (HK-58947) and they are registered by certificate holder Unico & Co. The certificate holder has confirmed the above 2 products are not marketed in Hong Kong. The PROPOFOL SANDOZ propofol injections in TGA's announcement are not registered in Hong Kong.

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