POST PROCEDURAL ADVERSE EVENTS WITH PROPOFOL

Background

In May 2015 the Therapeutic Goods Administration (TGA) advised of reports of adverse event clusters potentially linked to specific batches of Provive® brand propofol. During May and June further reports were received relating to numerous batches across different brands.

The TGA requested hospitals take a precautionary approach to quarantine certain batches during the investigation process. Implicated batches of Provive® propofol were investigated with regard to sterility, endotoxin and chemical testing.

Due to the absence of any detectable product quality issues, that these adverse events were already recognised for propofol, and the low number of reports relative to volume of product used, the TGA closed the investigation on 25 June 2015.

Approved product information states that "during the recovery phase, vomiting, headache and shivering occurred in about 2% of the patients, with nausea occurring more frequently."

Current Issue

During August and September 2015 clusters of similar events linked to propofol use have been reported in Western Australian hospitals. These have occurred in oncology and general paediatric use, and in adults undertaking endoscopic procedures. They appear to relate to the products and batches below:

- Provive MCT/LCT 1% 200mg/20ml: A041347, A041343
- Provive MCT/LCT 1% 500mg/50ml: A041160, A040633

Patients have experienced post procedural pyrexia and rigors. All episodes appear to have resolved spontaneously.

Details of the events have been forwarded and hospitals are working with TGA ongoing. No recall of this product has been issued.

Recommended Actions

It is recommended that clinical staff, hospitals and health services:

- note that some post procedural reactions are recognised adverse events of propofol,
- ensure patients are monitored accordingly post procedure,
- appropriately identify and treat adverse events, as necessary,
- report adverse events to the TGA through usual mechanisms (seek pharmacy advice),
- escalate adverse events related to propofol that are more severe or more numerous than expected for further investigation by the hospital,
- individually assess product and stockholding preferences in light of the reported adverse events and hospital needs.

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