Safety Notice 014/19

4 October 2019

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Heads of Departments
- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing and Midwifery

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer, MoH
- Chief Pharmacist Unit, MoH
- Clinical Excellence Commission

Clinical Excellence Commission

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Email:
CEC-MedicationSafety@health.nsw.gov.au

Internet Website:
http://www.health.nsw.gov.au/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Review date

October 2020

Ranitidine – Product Recall

The Therapeutic Goods Administration (TGA) have issued Urgent Medicine Recalls for ranitidine products. The recalls are due to contamination of ranitidine products with N-Nitrosodimethylamine (NDMA). This is a global anomaly that affects several brands and products.

The recall notices provide instruction to quarantine all impacted stock (a complete list of recalled products is available from TGA website), and contact the wholesaler to arrange return of stock and credit.

NDMA is a known environmental contaminant found in water and foods, including meats, dairy products and vegetables. Long-term exposure to NDMA (over years), can increase an individual's risk of developing cancer.

The additional risk posed by NDMA from ranitidine, at the levels identified to date, is considered to be very low. The actual health risks depend on dose and will vary from person to person. The risks from short-term use of ranitidine are expected to be extremely low.

Background

Ranitidine is marketed in Australia under the brand name Zantac® and various generic brands. It is commonly used to treat heartburn and peptic ulcer disease. Ranitidine is also used less frequently for off-label indications, such as chronic spontaneous urticaria, bowel obstruction in palliative care, and as a premedication prior to the administration of paclitaxel in oncology.

Suggested actions by Local Health Districts/Networks

1. Distribute this notice to all relevant staff and all clinical departments.
2. Remove and quarantine all impacted ranitidine products from clinical areas and pharmacy shelves.
3. Patients that are prescribed ranitidine must have their therapy reviewed by a medical officer. Consider alternative therapy (e.g. alternate H2 receptor antagonist, proton pump inhibitors or no pharmacological treatment).
4. Reserve stock of unaffected ranitidine products (e.g. Ranitidine Sandoz injection) for indications where ranitidine remains the clinically preferred treatment over alternative agents (e.g. bowel obstruction in palliative care).
5. Where there is no suitable alternative product to ranitidine, and where benefit of use outweighs potential risk, obtain patient consent and use quarantined ranitidine products until new stock is available.
6. Ensure a system is in place to document actions taken.
7. Report any incidents associated with use of ranitidine into the Incident Information Management System (IIMS) and to the TGA.
8. Confirm receipt of this notice to CEC-MedicationSafety@health.nsw.gov.au by close of business Tuesday 8 October 2019