Safety Alert 007/11

5 December 2011

CAELYX® pegylated liposomal doxorubicin 20mg and 50mg

Distributed to:

- Chief Executives
- Directors of Clinical Governance

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Pharmacy
- NUM of local chemotherapy units.

For response by:

- Directors of Clinical Governance

We recommend you also inform:

- Pharmacists
- Nurses
- Medical staff

Deadline for completion of action

7 December 2011 4pm

Clinical Safety Quality and Governance Branch
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On 2 December 2011 the Ministry was advised by the Therapeutic Goods Administration that Janssen-Cilag Pty Ltd (the drug sponsor) had identified deficiencies in sterility assurance at the contract drug manufacturer's site in November 2011.

The drug sponsor advised that the benefit/risk for CAELYX® can only be considered positive for absolutely essential use, to meet the clinical needs of patients already part-way through a course of treatment. Following consultation with the Therapeutic Goods Administration Janssen-Cilag Pty Ltd has recommended:

1. **Existing CAELYX® stocks should only be used to complete treatment that has been initiated.**
2. **No new patients should be initiated on CAELYX®, until further notice.**

Today the Ministry has been advised of two, and possibly three, patients who are showing symptoms and signs of sepsis, which may be related to the administration of CAELYX®.

Local Health District/Networks should

- Advise all departments that administer chemotherapy, hospital pharmacies and drug and therapeutic committees.
- Review patients that have been treated with CAELYX® to determine if they have experienced any adverse effects that could be related to sepsis, especially around the time they received CAELYX®.
- Report any case of sepsis, or suspected sepsis (such as acute pyrexia) which could be linked to contamination of CAELYX® to the Advisory Committee on the Safety of Medicines (ACSOM).

Treatment Alternatives (advice from drug sponsor and TGA)

- Treatment decisions should be made on an individual patient basis after thorough discussion of the options between the patient and attending physician.
- Non-liposomal and non-pegylated forms of doxorubicin have not demonstrated bioequivalence to CAELYX®. As a reminder, CAELYX® cannot be substituted on mg-per-mg basis with doxorubicin HCl. These alternatives should only be used where the benefit outweighs the risks for individual patients.
- Non-anthracycline alternatives may be considered, if the benefits outweigh the risks.

Further Information

Action required by Local Health Districts/Networks:

1. Ensure that this Safety Alert is distributed to all relevant stakeholders.
2. Review patients treated with CAELYX® for possible adverse effects.
3. Local Health Districts/Network to provide response to the Ministry by Wednesday, 7 December 2011, 4pm.