Safety Notice 014/16

Melphalan powder for intravenous infusion - Disruption to supply

15 December 2016

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:

- Oncology Departments
- Haematology/BMT Departments
- Directors of Medical Services
- Directors of Nursing
- Directors of Pharmacy
- Drugs and Therapeutics Committees

Expert Reference Group

Content reviewed by:

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

Clinical Excellence Commission

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Review date

June 2017

Background

An out of stock notification has been received for melphalan powder for intravenous infusion from the drug sponsor, Aspen. This is the direct result of the ongoing worldwide supply shortage that was first communicated in 2014. The only supply of intravenous melphalan currently marketed in Australia is through Aspen. Some stock is expected week commencing 19 December 2016; however this will not fill all backorders and the supply of future stock is currently unknown.

To ensure ongoing availability for patient care, overseas supply through the Special Access Scheme will need to be accessed.

Supply of 2mg melphalan oral tablets is unaffected.

Intravenous melphalan is a cytotoxic antineoplastic medication used according to specialised treatment protocols, e.g. for multiple myeloma where oral therapy is not appropriate or conditioning treatment before haemopoietic stem cell transplant.

Melphalan is the most widely used chemotherapy agent for preparation of patients for blood marrow transplantation, use of other agents is not proven to have equivalent outcomes.

Further information

For details of supply options for Special Access Scheme (SAS) products Email: contract902@hss.health.nsw.gov.au

Therapeutic Goods Administration: http://apps.tga.gov.au/prod/MSI/Search/Details/melphalan

Suggested actions by Local Health Districts/Networks

1. Distribute this notice to all stakeholders and all clinical departments
2. Assess the current status of intravenous melphalan available in each facility, ensuring all locations of stock are identified.
3. Develop a local plan to manage the supply shortage which should include:
    a. Considering clinical implications of the shortage for patients
    b. Reserving current stock for patients where treatment is time critical or where treatment on intravenous melphalan protocols has already commenced.
    c. Determining expected time of arrival of stock on order and strategies for any delays, ensuring there are available supplies for critical situations.
    d. If required, obtaining and using SAS stock of intravenous melphalan during the temporary shortage. Preference should be given to SAS stock that has been approved by comparable regulators (e.g. FDA or EMA). N.B. SAS stock may take three to four weeks to arrive.
4. Inform clinicians to ensure that the shortage is taken into consideration when planning treatment with intravenous melphalan. Inform patients affected by the shortage of potential delays to their treatment.
5. Inform clinicians, stakeholders and clinical departments when supply of intravenous melphalan is reinstated.
6. Ensure a system is in place to document actions taken.