



Therapeutic Goods Administration public consultation on the Management and Communication of Medicines Shortages in Australia

The Clinical Oncology Society of Australia and Cancer Council recognise the importance of identifying, managing and communicating medicines shortages. This requires an efficient assessment of the impact and risk of a pending shortage on the current users, as well as any flow on effect to the supply of potential medicine substitute or alternative, and the population yet to be diagnosed who would ordinarily be prescribed the registered medicine. Keeping patient needs at the centre of this topic is critical, as well as the communication to practitioners, both medical and pharmacy, to support decision making in the ongoing care and treatment of their patients. We thank the Department for acknowledging this issue and the introduction of mandatory notification of medicines shortages and public reporting of those with high or extreme impact on patients.

Cancer is a complex condition and its management may require the use of multiple treatments to control the disease and any side effects. Additionally, cancer may not be the patient's only health condition, therefore the interaction of multiple medicines is an important consideration. Continuity of access to safe and effective medicines is not only critically important in reducing the progression of cancer, but also in the management of the patient's psychosocial welfare.

COSA and Cancer Council take this opportunity to highlight the following points for consideration by the Department in the context of cancer and cancer medicines.

Cancer therapies on the Medicines Watch List

The Medicines Watch List included in the document omits cytotoxic or targeted anticancer therapy. In addition, there is no clarity about the process of assigning agents to the list, and whether this list was developed with expert input. The World Health Organisation publishes an Essential Medicines Listⁱ, and an Essential Medicines for Cancerⁱⁱ list which we refer the Department to consider. We would support the inclusion of registered oncology therapies on the Medicines Watch List.

The number of cancer medicine related shortages over the last few years emphasises the importance of communication and planning. Examples of where the shortage of cancer agents could have or did lead to a significant disruption to patient care, include vinblastine, dacarbazine, etoposide phosphate, mitomycin, doxorubicin, to name a few. Implications of shortages often go beyond a simple change in therapy that may be possible in other disciplines and may involve the use of regimes where data is less robust or older, or impact on other services such as radiotherapy, if combined modality treatment is involved.

On review of the published Medicines Watch List, our pharmacy colleagues noted that calcium folinate is listed as an antidote, presumably for the treatment of methotrexate toxicity, however the list does not include methotrexate itself. Other important supportive care therapies used in cancer care should be included on the list such as filgrastim, mesna, glucarpidase and bone strengthening agents such as zoledronic acid (a good example of a recent shortage of a drug which is listed on the World Health Organisation Essential Medicines List). The process to listing medicines on the Medicines Watch List must include both the supportive medication and the actual therapy.

Additionally, we recommend the Department consider the inclusion of specialist input across disciplines to advise on which medicines are listed on the Medicines Watch List.

Public notification

In addition to announcing shortages on the website, and notification sent to relevant professional colleges, it would be beneficial if the new system allowed practitioners to opt-in to receive an email notification from the Department as soon as a medicine shortage with a high or extreme impact of patients is announced. This will assist the practitioner in the early identification of other options for their patients, and in the management of:

- Patient anxiety and apprehension of the use of a different medicine, especially for patients who are responding positively to current treatment;
- Potential changes in side effects experienced by the patient on a new medicine;
- Identification of potential interactions between the different medicine and any other medicines the patient is taking for cancer or other conditions;
- Additional costs associated with using the different medicine. Although outside the TGA's remit, any increased cost to the patient can be a significant barrier to the ability to continue treatment. Costs could be associated with the different medicine not being listed on the Pharmaceutical Benefits Scheme, direct cost of managing additional side effects or the indirect costs of additional side effects such as increased tiredness requiring more time off work.

Both organisations would welcome involvement in future discussions or consultations on the issue of medicine shortages.

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ⁱWorld Health Organization. Model List of Essential Medicines (20th edition). March 2017 (amended August 2017)

http://www.who.int/medicines/publications/essentialmedicines/20th_EML2017_FINAL_amendedAug2017.pdf?ua=1

ⁱⁱRobertson J, Barr R, Shulman LN, Forte GB & Magrini N. *Essential medicines for cancer: WHO recommendations and national priorities*. Volume 94, Number 10, October 2016, 735-742. Bulletin of the World Health Organization. <http://www.who.int/bulletin/volumes/94/10/BLT-15-163998-table-T1.html>