

**From:**  
**To:** [Community Affairs Committee \(SEN\)](#)  
**Subject:** Access to Cancer Medicines - Additional Info  
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To The Secretary  
Senate Community Affairs Committee

Dear Sir/ Madam

At a recent public event hosted by Rare cancers Australia in Parliament House I made the following points in relation to access to medicines for rare cancer patients in Australia

- Currently, before a medicine can be widely used throughout the cancer community it must be registered with the TGA. Application for registration can only be made by the sponsoring pharmaceutical company. In many cases commercial realities dictate that it is not a priority of the relevant company to proceed with an application for those rare indications (cancers) where patient populations are very small.
- The development of cancer medicines in recent times has substantially focused on targeting particular cancer mechanisms that mean that the medicine is potentially applicable across a range of indications both common and rare.
- The potential outcome is that today we have medicines registered with the TGA for one indication meaning they are deemed safe and for that indication also efficacious. However their utilisation for other indications is prevented simply by the lack of application for registration.
- It is our strong view that under the circumstance where a medicine is already registered in Australia for one indication that clinicians and/or patient groups ought to be able to apply to the TGA to extend the registration to additional indications where reasonable evidence of efficacy exists.
- Such a system would then allow these applicants to progress to applying to list the medicine on the PBS for the relevant indication.

Our registration and reimbursement processes need to acknowledge that rare indications are at a significant disadvantage in achieving fair and reasonable access to affordable medicines. This predicament is compounded by the inherent commercial realities of multi-national pharmaceutical companies. A flexible "affirmative action" process is urgently needed.

Yours Faithfully

Richard Vines  
Director

