PHARMAC has a particular interest in the implications of an Early Warning System for medical devices because PHARMAC will, from July 2015, be responsible for deciding which medical devices are able to be purchased for use in DHB hospitals. This will extend to full management of a fixed budget for medical device expenditure on behalf of DHBs from July 2017.

PHARMAC submits two key points in relation to the proposed Early Warning System:

1. PHARMAC would like to see a process established whereby PHARMAC is consulted early in any situation where the safety of a medical device is raised – either in New Zealand or in Australia. This would ensure that possible safety issues and the implications of any monitoring, alert communication or recall are able to be discussed fully and openly before a notification is issued to the public or the health sector (e.g., so that PHARMAC could provide advice on the implications of a recall, including needing to source an alternative supplier or product).

2. Australia has an Advisory Committee on the Safety of Medical Devices (ACSMD), which is one of the mechanisms by which an early warning process can be initiated. While New Zealand has a medicines-focussed advisory committee, it does not have does not have an equivalent for devices. PHARMAC would want to be involved in any discussions Medsafe might have around plans to establish an equivalent to ACSMD, or if any of the existing medicines committees (MARC, MCC and MAAC) or CARM were to have their roles expanded to include medical devices.

PHARMAC would like to make a few notes regarding the glossary:

- The entry for PHARMAC should include reference to our role in respect to medical devices as from July 2015 – e.g., 'From July 2015, PHARMAC will be responsible for deciding which medical devices are able to be purchased by DHBs for use in public hospitals.'
- The entry for 'Adverse event' might need to be amended to reflect that a care-giver can include a health professional delivering care, as well as a care-giver who works in a disability support context.

Lastly, the appendix (page 22 onwards) appears to be about proposed content for the TGA's website, not Medsafe's. In due course, PHARMAC would like the opportunity to review Medsafe's website context.