# Additional comments by Government Senators

1.1 An issue highlighted by both this inquiry and the inquiry into medical devices is the need for greater clarity of the role of the TGA and the role of the Chief Medical Officer (CMO) in high risk implantable medical device recalls.

1.2 While the TGA, through the recall process, has responsibility for informing sponsors that the medical device is no longer on the ARTG and therefore unable to be used in Australia, it is less clear who, if anyone, has responsibility for providing general clinical advice to the population of patients who continue to have their high risk medical devices implanted.

1.3 Nothing can, nor should, replace the clinical advice provided directly to individual patients by their treating health professional; however it is clear from evidence that there was an expectation from consumers that either the TGA or the CMO would provide general clinical advice.

1.4 In the case of the PIP recall the convening of an expert clinical group (albeit two years after the recall) by the CMO to develop such general advice and monitor any change in evidence emerging from the work of the TGA, would appear to be an appropriate model.

1.5 Government Senators suggest that the more routine use of such a model in the case of high risk medical device recalls be explored by DoHA and the CMO and that a clear set of protocols be developed.

**Senator Claire Moore** **Senator Carol Brown**