Recommendations

Recommendation 1

2.9 The committee recommends that there be rigorous systems put in place to ensure that medical practitioners provide consumers with all the information needed to allow them to give fully informed consent.

Recommendation 2

2.24 The committee recommends that the TGA review all cases where sponsors have not met their obligations in relation to their listing on the Australian Register of Therapeutic Goods to ensure that these cases do not pose any health risk to the Australian public, and that important data has not been missed.

Recommendation 3

2.25 The committee recommends that the Department of Health and Ageing include as part of their annual report process, information on the TGA's procedures for monitoring requirements placed on Class III medical devices.

Recommendation 4

2.45 The committee recommends that the TGA put in place measures to ensure that when recommendations made by the Advisory Committee on Medical Devices (formally the Medical Devices Evaluation Committee) are not followed, the delegate needs to set out specific and compelling reasons why the decision was taken.

Recommendation 5

3.21 The committee recommends that the Therapeutic Goods Administration include in their updates on PIP breast implants, and as part of any future recalls on other devices or medications, details of the type of evidence they are pursuing in order to further inform the Australian public.

Recommendation 6

3.27 The committee recommends that the TGA publish updates and details of the discussions that have taken place with international regulators.

Recommendation 7

3.44 The committee recommends that the TGA review its processes to ensure that faulty explanted devices are available to the TGA for independent testing.

Recommendation 8

3.54 The committee recommends that the TGA's advice about PIP breast implants include the limitations of the evidence and data to ensure that consumers and medical professionals alike are in receipt of as much information

as possible that will enable them to make informed decisions about any future treatment.

Recommendation 9

3.66 The committee recommends that, in light of the Poly Implant Prothese breast implant recall, the Department of Health and Ageing establish an opt-out Breast Implant Registry as a priority. The design of such a registry should be based on the National Joint Replacement Registry.

Recommendation 10

3.75 The committee recommends that the Australian Government extend the Medicare rebates for MRIs in accordance with the current medical advice.

Recommendation 11

3.87 The committee recommends that the Department of Health and Ageing implement recommendations 13, 14 and 15 of the HTA Review recommendations as soon as possible. The committee notes this recommendation was also made in its 2011 report on regulation of medical devices (recommendation 7).

Recommendation 11

4.15 The committee strongly recommends that professional bodies, particularly the ASPS and ACCS, ensure through formal advice that surgeons are aware of their responsibilities to ensure that they provide an ongoing advisory role to their patients even after medical treatment has concluded.

Recommendation 12

4.29 The committee recommends that the clinical advisory committee established by the Chief Medical Officer should develop advice, based on current evidence regarding breastfeeding and PIP breast implants, as soon as possible, and that this information be included in future Chief Medical Officer reports on this issue.

Recommendation 13

5.13 The committee recommends that the TGA include in their advice that it is unclear whether PIP breast implants rupture more than other silicone breast implants and that further testing and investigation of PIP breast implants will continue to inform this advice.