# Appendix 4

## List of Recommendations made in the Senate Community Affairs References Committee report into *The Regulatory Standards for the Approval of Medical Devices in Australia*

**Recommendation 1**

**5.16 The committee recommends that the Therapeutic Goods Administration make a list of the devices on the Australian Register of Therapeutic Goods publicly available.**

**Recommendation 2**

**5.17 The committee recommends that the Department of Health and Ageing fully implement Recommendation 8c of the Health Technology Assessment Review regarding the need for increased rigour of regulatory assessment of higher-risk medical devices.**

**Recommendation 3**

**5.18 The committee recommends that the level of assessment of Class III medical devices be increased.**

**Recommendation 4**

**5.19 The committee recommends that the Therapeutic Goods Administration investigate whether allowing an increasing number of medical devices onto the Australian market actually improves clinical outcomes; and whether a more judicious approach could improve pre-market assessment and post-market surveillance of higher risk medical devices, for the ultimate benefit of patients.**

**Recommendation 5**

**5.23 The committee recommends that the Therapeutic Goods Administration continue to consult widely with stakeholders, including consumer health organisations, on the amended proposals related to third party conformity assessment; and weigh carefully considerations of the advantages of streamlined international regulatory frameworks and patient safety.**

**Recommendation 6**

**5.28 The committee recommends that the Therapeutic Goods Administration continue its prudent approach to the regulation of reprocessed single-use medical devices, with due consideration for issues of informed patient consent and the**

**need for suitable mechanisms to enable tracing of remanufactured medical devices in the case of adverse events.**

**Recommendation 7**

**5.39 The committee recommends that the Department of Health and Ageing implements Recommendations 13, 14, and 15 of the Health Technology Assessment Review in a timely manner. These recommendations address the need for improved post-market surveillance by increasing the rate of reporting of adverse events, including by health service providers and consumers; facilitating the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions; and establishing further clinical registers for high risk implantable devices and procedures.**

**Recommendation 8**

**5.40 The committee recommends that the Therapeutic Goods Administration put in place mechanisms to educate and encourage doctors to report adverse incidents associated with the use of medical devices. The committee further recommends that the Department of Health and Ageing introduce mandatory reporting for health practitioners to the Therapeutic Goods Administration on relevant issues, in certain circumstances including problems with medical devices.**

**Recommendation 9**

**5.41 The committee recommends that the Government implements the Recommendations of the Therapeutic Goods Administration Transparency Review in a timely manner.**

**Recommendation 10**

**5.42 The committee recommends that the Therapeutic Goods Administration consider simultaneously allocating or aligning the great variety of codes used to identify medical devices, in order to facilitate more efficient regulation and more rapid identification of devices when problems occur.**

**Recommendation 11**

**5.43 The committee recommends that the Department of Health and Ageing consider a mechanism for flagging billing codes in order to identify devices subject to an alert or recall; as well as a consequent adjustment to benefits paid, based on industry feedback as to the performance of the device.**

**Recommendation 12**

**5.46 The committee recommends that the Therapeutic Goods Administration consider whether custom made dental devices are adequately regulated; and whether the approach used in the United Kingdom of requiring a statement of**

**manufacture to be provided to patients, and retained by the dental practitioner, has merit.**

**Recommendation 13**

**5.47 The committee recommends that the Therapeutic Good Administration carry out an investigation to ascertain whether importation of medical devices via the internet is adequately regulated.**

**Recommendation 14**

**5.52 The committee recommends that the Therapeutic Goods Administration, in consultation with the National Joint Replacement Registry, investigate ways in which information provided by the National Joint Replacement Registry can be used and responded to in a more timely way for the benefit of patients, and to inform future evidence based decision making on the listing of prostheses on the Australian Register of Therapeutic Goods.**

**Recommendation 15**

**5.57 The committee recommends that the Department of Health and Ageing prepare, as a matter of priority, a comprehensive communications strategy to inform medical practitioners, patients and the general public about the issues associated with De Puy hip and hip resurfacing devices as well as options for treatment, obtaining further information, and reporting adverse outcomes. The committee further recommends that such a strategy be implemented as a standard process for any future adverse event reporting.**

**Recommendation 16**

**5.58 The committee recommends that the Department of Health and Ageing, as a matter of urgency, consider the best way of establishing a process for monitoring the levels of cobalt, chromium, and other toxic metals; and any possible health effects, in all patients who have received metal-on-metal hip replacements.**

**Recommendation 17**

**5.59 The committee recommends that the Government consider the best mechanism for initiating and advancing research on the health effects of cobalt, chromium, and other toxic metals, on the human body. The committee also recommends that consideration be given to ensuring adequate funding for that research is made available.**

**Recommendation 18**

**5.64 The committee recommends that the Department of Health and Ageing undertake further work to address the issue of inducements paid by pharmaceutical companies and medical device manufacturers to doctors and**

**teaching hospitals, in line with the Physician Payment Sunshine provisions of the Patient Protection and Affordable Care Act of 2009 in the United States. The definition of inducements should include a commercial interest in a company or device; any cash payments or discounts offered to medical practitioners; and any other gifts provided to medical practitioners.**