

Chapter 5

Conclusion and recommendations

5.1 This inquiry addresses the regulation of medical devices in Australia. This is a complex and evolving area of regulation. The inquiry examined the role of the TGA in regulating the quality of devices in Australia, including the processes in place to ensure that single use and remanufactured products continue to meet Australian standards. It also examined issues related to subsidies for medical devices.

5.2 More importantly, the inquiry focused on the consumer experience of those approximately 5500 Australians who have received DePuy metal on metal hip replacements, including total hip replacements and hip resurfacing systems. Many of the consumers who received the DePuy metal on metal hip devices subsequently needed one or more revision surgeries. They also reported serious and systemic health problems extending beyond initial complications with the device.

5.3 In association with these concerns, the committee scrutinised the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices; and the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and action taken once the devices are identified. The committee found that, in practice, these processes should be improved.

5.4 The committee was shocked by the intolerable, and unacceptable, experiences of patients who received the DePuy hip and hip resurfacing system. These very personal experiences serve to underline the need for improved pre-market clinical testing and post-market surveillance systems for medical devices, as well as improved timeliness and decisiveness when acting upon the information that is available.

5.5 These experiences brought home to the committee that the TGA could have done more in response to the concerns with the device and that Johnson & Johnson Medical did not serve patients well.

5.6 This inquiry is being conducted in parallel with the Government's implementation of the recommendations of the HTA Review, and consideration of the recommendations of the TGA Transparency Review. Many of the recommendations of these reviews are material to the considerations of the inquiry.

5.7 The committee notes the regulatory balance that the TGA attempts to achieve between ensuring safety of medical devices and the encouragement of new technologies that may provide benefit to patients. It also noted the balance the TGA seeks to strike in allocation of resources to pre-market assessment and post-market surveillance of medical devices.

5.8 The committee heard evidence about the TGA's approach to global harmonisation, and its efforts in concluding a range of bilateral agreements. The committee received evidence regarding the leading role that the TGA has played in

the Global Harmonisation Task Force (GHTF) for medical devices. The committee commends the ongoing work of the TGA in seeking to raise the standard of regulation of medical devices in the international arena.

Pre-market assessment

5.9 The committee received a range of evidence regarding the adequacy of the TGA's approach to pre-market assessment of medical devices. In particular, the committee examined the current approach to assessing clinical evidence prior to listing on the ARTG.

5.10 The committee notes that the HTA Review recommended increasing the rigour of regulatory assessment of higher risk medical devices, and that the TGA has subsequently carried out consultations on proposals designed to address this matter. The TGA announced its intention to implement a proposal to reclassify joint replacement devices included in the ARTG from Class IIb to Class III through an amendment to the Therapeutic Goods (Medical Devices) Regulations 2002 with a two year transition period commencing from 1 July 2012. However, the TGA has announced that it will conduct further consultation on a proposal to increase the level of assessment of Class III devices.

5.11 While the committee commends the TGA for reclassifying joint replacement devices from Class IIb to Class III, it is also of the view that a higher level of assessment of Class III medical devices is required. The committee is mindful of statements by some submitters that there is a material difference in carrying out clinical trials on pharmaceuticals and medical devices due to the extra complications of a device being inserted in a patient's body.

5.12 However, the committee is concerned that an emphasis on post-market surveillance may mean that medical devices are, in a sense, being trialled unofficially, without the protections associated with registered clinical trials. The committee believes that Recommendation 8c of the HTA Review should be implemented in order to increase the rigour of regulatory assessment of higher-risk medical devices. An appropriate level of evidential review should be undertaken over an adequate period of time. The committee is also of the view that the requirements of the clinical evidence should be defined. The committee notes the AOA's recommendation for a minimum of two year's clinical evidence.

5.13 The committee also received evidence about the increasing number of medical devices, in a wide variety of combinations, entering the Australian market. The committee was not entirely convinced by the argument from DoHA that this represents better consumer and practitioner choice. Such an approach will make assessing the available clinical evidence more onerous and resource intensive. A larger number of devices also makes assessment of post-market surveillance data more complex, with a possibly longer lead time before problems become apparent.

5.14 The committee was disturbed by evidence from the AOA that its research indicates that many prosthetic devices entering the market actually perform worse than, or no better than, those that are currently available.

5.15 The committee was persuaded by the AOA that the development of a publicly available list of approved devices on the ARTG is vital. Currently, it is difficult for anyone to work out what has been approved as the TGA only publishes limited information about what is available on the ARTG.

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.

5.20 The committee heard evidence about current TGA consideration of third party conformity assessment, in relation to global harmonisation of regulatory frameworks for medical devices. On the one hand, the committee heard that accepting clinical evidence from overseas, in particular where there is a very high degree of regulatory alignment, would reduce the time and costs associated with regulatory compliance and listing of a device, without compromising patient safety. On the other hand, the committee heard of the potential for mistakes made in other jurisdictions to be replicated in the Australian context through this mechanism, with one submitter raising concerns about such a system being 'a race to the bottom'.

5.21 The committee was sympathetic to the concerns of Australian medical device manufacturers that they are subjected to a more onerous regulatory regime than overseas manufacturers. Similarly, the committee acknowledges the concerns raised by medical device manufacturers about the increasing timeframes for the TGA to carry out conformity assessments.

5.22 The committee notes that the HTA Review, and a number of consultations by the TGA, examined the issue of third party conformity assessment. The TGA recently circulated proposals in relation to this matter for comment, and has now decided to undertake further consultations on a series of amended proposals. The committee recognises this is a complex issue and urges the TGA to consult as widely as possible with all stakeholders in their continuing consideration of this matter.

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.

5.24 The committee received conflicting evidence from submitters in relation to whether remanufactured devices are safe. While Stryker South Pacific argued that their remanufacturing processes were sufficiently rigorous to ensure patient safety, other submitters raised concerns about the potential health effects of remanufactured single-use devices including risks of contamination, material degradation and mechanical failure of medical devices. The committee also received evidence that the remanufacturing of single-use medical devices raises issues related to tracking of those medical devices, as well as issues of informed patient consent.

5.25 The committee is mindful of the argument that remanufacturing medical devices may, in part, address the growing environmental impact of the disposal of hospital waste, and the financial burden on hospitals of only using devices once. However, the committee heard that as yet there is no adequate evidence on whether an assessment of the entire reprocessing cycle would yield such apparently positive environmental results.

5.26 The positions of submitters fell fairly neatly into medical device manufacturers who stand to gain from continuing to market single-use devices; and those who stand to gain if they are approved to carry out validated remanufacturing by the TGA, at some point in the future.

5.27 The committee notes that a prudent approach was taken by the Australian Health Ministers Advisory Council in 2001 when it decided that, if reprocessing of single-use devices was to occur in Australia, it should be regulated to the same requirements as the original manufacture. A similarly prudent approach by the TGA has, to date, seen no conformity assessment certificate issued to any manufacturer of reprocessed single-use medical devices.

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.

Post-market surveillance

5.29 The committee notes that Recommendations 13, 14 and 15 of the HTA Review go to 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.

5.30 Similarly, Recommendations 15–21 of the TGA Transparency Review go to substantially improving the way that the TGA communicates with stakeholders in relation to post-market monitoring and compliance, and the way that it manages adverse events. Recommendations 1–14 of the TGA Review are also pertinent as they address the need for improved communication and information provision by the TGA for the benefit of, and with greater involvement by, stakeholders.

5.31 The committee is of the view that consideration should be given to attaching a flag or an indicator to the billing code of devices subject to an alert or recall. Additionally, this would allow an adjustment to benefits paid, based on industry feedback regarding the device's performance. This would be facilitated by the simultaneous allocation of ARTG numbers, Private Health Insurance prostheses listing, and allocation of billing codes, catalogue numbers and Medicare Benefits Schedule (MBS) item numbers for each device.

5.32 The committee received evidence about the need for improved adverse event reporting. It is clear that doctors, rather than manufacturers, are the front line for consumers reporting problems with their medical devices. Yet, the system is currently limited by the lack of mandatory adverse event reporting by doctors. Similarly, it is evident that there is a lack of awareness among consumers about the possibility of, and the mechanism for, reporting adverse events to the TGA.

5.33 Information received by the committee that many prosthetic devices approved for use in Australia are performing worse than those already available highlighted the need for evidence-based decision making of the type anticipated by Recommendation 14 of the HTA Review.

5.34 The committee received considerable amounts of evidence about the important work that the NJRR does in monitoring joint replacement revisions, and identifying those medical devices or procedures with a statistically higher rate of revision. Information received about the way that this monitoring and identification

role will be enhanced through participation in the newly established International Consortium of Orthopaedic Registries (ICOR) is encouraging.

5.35 The committee found the evidence that establishing other clinical registries for high-risk devices and procedures, modelled on the NJRR, would make a critical contribution to improving post-market surveillance in Australia compelling. The committee noted, however, that establishing quality clinical registries is a costly undertaking, and registries should be prioritised according to identified health needs.

5.36 The committee notes that Recommendations 13, 14 and 15 of the HTA Review have not been accepted by Government due to cost considerations and that the TGA Transparency Review is still under consideration.

5.37 While the financial implications of implementing the HTA recommendations are not insignificant, the committee considers that it is a worthwhile investment in the future health of all Australians. The committee is of the view that such an investment stands to reduce health costs over the longer term by reducing the need for costly interventions, as HTA decisions are increasingly evidence based.

5.38 Similarly, many submitters raised issues related to the provision of, and ease of access to, information available from the TGA. These issues are not new. For this reason the committee believes that the Government should support the recommendations of the TGA Transparency Review.

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.

Custom made dental devices and internet purchasing

5.44 The committee is concerned by evidence that, in Australia, custom made dental devices appear to escape TGA scrutiny, with dental professionals and patients alike unaware that up to 50 per cent of custom made dental prostheses are manufactured overseas, with no validation at the source of manufacture. The committee was also informed that in the United Kingdom patients are offered a statement of manufacture; and practitioners are obliged to retain this statement for the lifetime of the prosthesis. In addition, practitioners must record whether the statement was provided to the patient or not.

5.45 The committee is also concerned that the issue of unregulated importation of dental devices via the internet may indicate a much broader problem of inadequate regulation of other medical devices purchased through the internet.

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.

Identification of high risk prostheses

5.48 The committee received evidence that the NJRR clearly identified the higher than usual revision rates of the DePuy hip resurfacing system in 2007 and the DePuy hip in 2008.

5.49 The committee notes that the TGA convened meetings of the OEWG commencing in 2007, albeit with a substantial gap between June 2008 and December 2009.

5.50 The committee received evidence from Professor Stephen Graves, of the NJRR, that although he is now happy with the current timeliness of the TGA's response to new reports of increased rates of revision from the NJRR, this had not always been the case. Similarly, the minutes of the Orthopaedic Expert Working Group express similar concerns regarding the timeliness of the TGA in responding to information available regarding the high revision rates of the ASR hips. Although the committee notes the reasons for delays offered by the TGA, the failure of the TGA to act in a more timely and decisive manner is regrettable.

5.51 The NJRR provided evidence to the committee that it is not only the DePuy devices that are experiencing higher rates of revision. The committee was informed that there is new information that there are further classes of devices which are now being identified as an issue. This includes the metal-on-metal group as a whole, particularly in conventional hip replacements and large-head metal-on-metal devices. The NJRR has also identified another class which use 'exchangeable necks' which appear to have over twice the risk of revision compared to devices that do not have those exchangeable necks.

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.

Notification and follow up

5.53 The processes used by the TGA for communicating adverse events to patients and medical practitioners have previously been identified as needing substantial improvement. The evidence received by the committee that consumers suffering complications from their DePuy hip and hip resurfacing devices did not receive adequate information from their doctors, despite repeated visits, indicates that something is seriously wrong with the management of adverse event reporting and follow up.

5.54 Many consumers only became aware that their medical device had been withdrawn from the market when they heard about it through the media or through internet searches. Some consumers were provided information about the ASR hip withdrawal by their doctors only when it came time for their annual review. The committee believes that there may be many thousands of Australians who continue to be unaware of these issues. This is clearly unacceptable.

5.55 At a minimum, as noted above at Recommendation 8, the committee recommends the implementation of the TGA Transparency Review Recommendations.

5.56 The committee received substantial evidence from consumers of serious ill health and complications associated with metal toxicity, caused by the leaching of cobalt and chromium ions from the hip replacements into patients' bodies. It appears from evidence received that research or monitoring of this issue is at best nascent. The committee believes that this matter should be considered more urgently by health authorities and professionals. The committee is also of the view that research on the health effects of cobalt and chromium, as well as other metals producing toxicity in the human body; should be made a research priority, with adequate funding provided for the conduct of such research.

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.

Inducements

5.60 The committee received evidence from consumers about their concerns that there may have been inducements paid to doctors or hospitals to favour particular prostheses. The committee also received information about a range of voluntary codes of conduct that regulate such behaviour. The committee notes that Johnson & Johnson Medical have been required to pay high civil penalties in other jurisdictions for illegal conduct related to paying inducements to doctors.

5.61 The committee was interested to hear of legislative developments in the United States under the Physician Payment Sunshine provisions, included in the *Patient Protection and Affordable Care Act* of 2009, requiring disclosure of all payments made to physicians and teaching hospitals by medical manufacturers and pharmaceutical companies. The committee considers that a legislative, rather than voluntary, approach to this matter may have some merit in Australia as well.

5.62 The committee further notes that public disclosure of payments to physicians and teaching hospitals by medical manufacturers and pharmaceutical companies is now the subject of legislation in the United States. The Physician Payment Sunshine provisions were included in the *Patient Protection and Affordable Care Act* of 2009 (H.R. 3590, section 6002) which was signed into law on 23 March 2010, and will come into effect on 1 January 2012. The committee is of the view that this approach is also merited in Australia.

5.63 The committee will continue to monitor the issue of inducements that may be paid to doctors or hospitals.

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.

5.65 In conclusion, the committee would like to thank all witnesses who provided evidence to the committee. In particular the committee extends their thanks to the patient witnesses, many suffering extremely poor health, who gave their time to provide such compelling evidence.

Senator Rachel Siewert
Chair