Australian Government Response

to

Senate Community Affairs References Committee

Report on The Regulatory Standards for the Approval of Medical Devices in Australia

August 2012

Government response to recommendations

Recommendation 1
The committee recommends that the Therapeutic Goods Administration make a list of the devices on the Australian Register of Therapeutic Goods publicly available.

Response:

The Australian Government agrees with the recommendation.

The Australian Register of Therapeutic Goods (ARTG) is a publicly searchable data base which includes all medical devices currently approved for supply in Australia. The Therapeutic Goods Administration is currently working to improve the searchability of the ARTG.

Recommendation 2
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.

Response:

The Australian Government agrees with the recommendation.

The Therapeutic Goods Administration has consulted publicly on proposals to increase the rigour of regulatory assessment for higher risk medical devices.

Some reforms will be in place before the end of the calendar year, but the Government notes that timing and approach depends on the completion of the appropriate assessment of any potential regulatory and cost recovery effects, including on patients and the Australian medical device industry.

Recommendation 3
The committee recommends that the level of assessment of Class III medical devices be increased.

Response:

The Australian Government agrees to consult further with affected stakeholders on this recommendation.

The Government recognises that greater regulatory rigour for high risk, Class III medical devices would allow further evidential review prior to market entry for these devices.

International harmonisation is a critical element in medical device regulation. This harmonisation allows access for Australian patients to the best devices available around the world and avoids costly repetition for industry seeking to enter the market. As such, the Government believes that any increase to the level of assessment of Class III medical devices will be best achieved in harmony with international counterpart regulators.

The Therapeutic Goods Administration (TGA) has begun consultation with key stakeholders in Australia in relation to increasing this assessment. Further consultation with the international community may be required to identify the most appropriate approach. The

Government has instructed the TGA to continue this dialogue. It is important to note that any change in pre-market regulation would need to consider the increase in the level of mitigation of risks to patients' safety, as well as the impacts on the Australian medical device industry and on patients' access to medical technologies. The TGA will be required to undertake consultation with domestic stakeholders on any proposed changes to increase assessment, including developing a Regulatory Impact Statement if required.

Recommendation 4
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.

Response:

The Australian Government agrees with the intent of the recommendation, to improve the quality of medical devices available in the Australian market place, by continuing to refine requirements for pre-market assessment and post-market surveillance.

The TGA has no legal power to limit the number of applications made for inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG). Medical devices included in the ARTG are required to comply with standardised criteria for quality, safety and performance under the Therapeutic Goods legislation.

Further responses on pre-market assessment are provided in relation to recommendations 2 and 3. A further response on post-market surveillance is provided in relation to recommendation 7.

Recommendation 5
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.

Response:

The Australian Government agrees with the recommendation.

The TGA will conduct consultation with all stakeholders on the details of any specific proposals to implement third party conformity assessments and will develop a Regulatory Impact Statement, if required.

The Government notes that recent events have raised questions relating to the current framework governing the use of third party conformity assessments bodies overseas.

The European Commission has announced that it will review the current structure for third party conformity assessment in the European Union (EU) with a view to making amendments and the possible introduction of an accreditation process for notified bodies.

The Therapeutic Goods Administration (TGA) will monitor developments in Europe with a view to identifying the most appropriate arrangements for Australia which adequately balance the advantages of streamlined international regulatory frameworks and patient safety.

In order to provide certainty for all stakeholders, the Government commits to expedite its considerations, subject to regulatory developments in the EU.

Recommendation 6
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.

Response:

The Australian Government agrees with the recommendation.

Current approach to regulation
The Australian regulatory framework for medical devices is designed to ensure that the reprocessing of devices that were not originally intended for reprocessing does not compromise the safety and effectiveness of the device. Under these regulatory controls, the reprocessing facility is regulated as a manufacturer, and is required to demonstrate that the reprocessed device is equivalent to the original and will continue to perform without additional risk to the patient.

Informed patient consent
The Medical Board of Australia (MBA) is responsible for all matters relating to the regulation of medical practitioners in Australia. It has produced *Good medical practice: A code of conduct for doctors in Australia* which provides guidance to medical practitioners on a range of matters including issues about informed patient consent.

The Government notes that the National Health and Medical Research Council has published *General Guidelines for Medical Practitioners on Providing Information to Patients (2004)*. These guidelines recommend that doctors provide information to patients about the risks of any interventions, especially those likely to influence patients' decisions.

The Government undertakes to refer the issue of patient consent, in the context of reprocessed single-use medical devices, to the relevant National Boards and the Australian Health Practitioner Regulation Agency (AHPRA).

Tracing of remanufactured medical devices
The Therapeutic Goods Administration (TGA) has established regulatory guidelines for remanufactured medical devices, requiring compliance with the post-market requirements, such as reporting adverse events to the TGA associated with the use of the device, tracking the number of times the device is remanufactured and reused, tracing the device to the batch/serial number of the original device and recording to whom the device was supplied in case of recall or other regulatory action (*Australian regulatory guidelines for medical devices 2007*).

Recommendation 7

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.

Response:

The Australian Government agrees with the recommendation in principle.

Recommendation 13 of the Health Technology Assessment Review (HTA Review) states that in order to improve the contribution of post-market surveillance to patient safety, the Therapeutic Goods Administration (TGA) take steps to increase the rate of reporting of adverse events, including by health service providers. The Government's response to this is set out in the response to recommendation 8 of this inquiry (below).

Recommendation 14 of the HTA Review states that, in order to improve the contribution of post-market surveillance to the sustainability of the health system and the longer term regulatory efficiency of HTA Review processes, the Department of Health and Ageing (the Department) explore options for consideration by Government in 2011 to facilitate the expansion and use of post-market surveillance data to inform safety, effectiveness and reimbursement decisions for devices and procedures.

The Government supports the expanded use of post-market surveillance data from adverse event reporting in assessing the safety and effectiveness of medical devices. As set out in the response to recommendation 8 below, the Government will seek to improve the reporting of adverse events by health practitioners and the general public in order to provide greater data relating to the devices in use in Australia. In addition, the TGA will provide reports of adverse events, as well as any relevant conditions the TGA imposes on a sponsor in order to register their device (including the provision of post-market data), to the TGA's newly established Advisory Committee on Medical Devices (ACMD). The ACMD will use this data as part of its post-market monitoring responsibilities.

The TGA will inform the Prostheses List Advisory Committee, through the Department, when a prosthesis is withdrawn from the ARTG, so that the Government may receive timely advice on any consequent changes to private health insurance reimbursement arrangements for that device.

The Government announced in the 2012-13 Budget that it will remove joint replacement prostheses with evidence of higher than acceptable revision rates from the Prostheses List, so that private health insurers are no longer required to pay benefits for those prosthetics.

Recommendation 15 of the HTA Review is that registers for high risk implantable medical devices and/or procedures be established.

The Government supports the development of clinical registers for high risk implantable medical devices and has to date supported the establishment of the National Joint Replacement Registry.

The Government will continue to work with industry and medical groups to identify the most effective ways to track the use and performance of high risk implantable medical devices, balancing benefits and costs to patients, providers and the wider community.

As part of this process, the Government is also currently considering funding options for the establishment of these registers, including the feasibility of the use of cost recovery from industry through the TGA cost recovery arrangements.

The Government further undertakes to review the communication and reporting links between existing registries/registers, the TGA and the Department.

Recommendation 8
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.

Response:

The Australian Government agrees that adverse event reporting by medical practitioners is a vital component of a comprehensive system of post-market surveillance, and in that context, commits to the following course of action.

The Government has recognised that further work is required to encourage greater reporting of adverse events from therapeutic goods (including medical devices). As announced in *TGA Reforms: A Blueprint for the Future* on 8 December 2011, the Australian Government has agreed to implement recommendations 19 and 20 of the Transparency Review: to more effectively facilitate the recognition and reporting of adverse events by health practitioners and consumers, and promote the adverse event reporting system; and to make the Adverse Events Database available to, and searchable by, the public in a manner that promotes the quality use of therapeutic goods. In this context, the Therapeutic Goods Administration (TGA) will investigate ways to upgrade the value of individual clinician input and subsequent information exchange.

The TGA has included additional information on its website on reporting adverse events and published a brochure outlining ways to report an adverse event. This brochure is being disseminated at conferences and other venues where it will reach healthcare professionals. An online reporting form for adverse event reporting for medical devices was made available on the TGA website from mid-March 2012. The Government also undertakes to draw this recommendation to the attention of medical educators and organisations funded to provide training and support to medical practitioners.

On the matter of mandatory reporting for health practitioners on problems with medical devices, the Government undertakes to raise this matter with the Medical Board of Australia (Board) which is responsible for the regulation of medical practitioners. The Government notes that any changes to standards set by the Board, or to codes and guidelines produced by the Board, are subject to requirements set out in legislation, including consultation and, in the case of changes to registration or accreditation standards, the agreement of the Australian Health Workforce Ministerial Council.

The Department of Health and Ageing (the Department) will work with the states and territories to identify opportunities to coordinate adverse event reporting currently required in the public hospital sector in each jurisdiction. The Department will also work with the Australian Commission on Safety and Quality in Health Care to investigate the Commission's capacity to provide safety oversight of the use of therapeutic devices through the development of standards and indicators.

Recommendation 9
The committee recommends that the Government implements the Recommendations of the Therapeutic Goods Administration Transparency Review in a timely manner.

Response:

The Australian Government agrees with the recommendation.

The Government announced its response to the recommendations of the Therapeutic Goods Administration Transparency Review on 8 December 2011. An implementation plan for the actions agreed in the report *TGA Reforms: a Blueprint for the TGA's Future* became available in July 2012.

Recommendation 10
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
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.

Combined Response:

The Australian Government notes recommendations 10 and 11.

There are practical challenges in simultaneously allocating codes. Catalogue numbers are established by industry internationally, and Australian Register of Therapeutic Goods (ARTG) and Prostheses List billing codes are allocated through consecutive approval steps. Market approval can occur in advance of any decision to reimburse, and many devices are never considered for reimbursement. To delay the allocation of an ARTG number until a billing code for private health insurance purposes was granted, would unduly delay the availability of the product onto the Australian market.

Nevertheless, the Government acknowledges that better integration and alignment of identifiers can assist post-market surveillance and device identification when problems occur. A new database is under development to support Prostheses Listing arrangements which will allow the Department of Health and Ageing (the Department) to link catalogue numbers with billing codes to assist with identification of specific products. This work is scheduled for completion by the end of 2012.

The Department and the Therapeutic Goods Administration (TGA) are also liaising with the National E-Health Transition Authority on scope to link its National Product Catalogue to billing codes and ARTG numbers to assist identification of devices.

In relation to benefit setting, the Department is implementing recommendation 12 (b-e) of the Health Technology Assessment Review in Australia (HTA Review), to refine grouping schemes and develop single group benefits for clinically similar products on the Prostheses List. Once this work is completed, the Department, with advice from its expert and advisory committees, will review benefit setting arrangements into the future.

Recommendation 12
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.

Response:

The Australian Government notes the recommendation.

Custom made dental devices are not required to be included on the Australian Register of Therapeutic Goods. However, there are a number of requirements that must be met.

The therapeutic goods legislation requires that the importers of custom made dental devices hold certain information about the device including information identifying the manufacturer, the device and any special characteristics of the device.

The Australian Government will consult with the Dental Board of Australia on this recommendation, as the governing body with the authority to regulate the dental profession.

Recommendation 13
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.

Response:

The Australia Government agrees with this recommendation.

The Therapeutic Goods Administration (TGA) will continue to work with all stakeholders to examine evidence in relation to the adequacy of existing arrangements for the importation of medical devices.

Under the *Therapeutic Goods Act 1989*, the *Therapeutic Goods Regulations 1990* and the *Therapeutic Goods (Medical Devices) Regulations 2002*, therapeutic goods are required to be approved and included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied unless there is an exemption.

It is illegal to import commercial quantities of therapeutic goods into Australia without the goods being entered onto the ARTG. This applies even if the importer is a healthcare provider. If products are imported for on-sale, including for use within a professional practice, they would need to be appropriately entered onto the ARTG by the importer who would be recognised as the sponsor of the product. The importer would need to meet the appropriate responsibilities of a sponsor as set out in the legislation. Therapeutic goods

imported directly from international websites and not entered in the ARTG may not meet the standards of quality, safety or efficacy prescribed by the therapeutic goods legislation. Registered health practitioners who import directly need to be aware how their sponsor responsibilities interact with their professional responsibilities for registration within their relevant sector.

It is possible for individuals to import therapeutic goods into Australia for their own personal use (www.tga.gov.au/pdf/access-personal-import-guidelines.pdf). Such importation is subject to various conditions and it is the responsibility of individuals wishing to import unapproved therapeutic goods for their own use to ensure they have complied with all relevant Commonwealth and state/or territory laws. If care is not taken, consumers may inadvertently break the law, waste their money, or risk their health.

The potential consequence of the importation of medical devices via the internet is limited as private health insurance and Medicare benefits are only payable for medical devices purchased and used with professional services rendered within Australia. Consumers and health professionals are likely to choose devices for which benefits are payable.

From time to time, in the course of routine surveillance activity, the TGA becomes aware that Australian consumers may have purchased potentially dangerous therapeutic goods from overseas sources via mail-order or the internet. In these cases the TGA will issue a safety alert via its website advising consumers to cease using the goods and to consult a healthcare practitioner if there are any health concerns.

Recommendation 14
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.

Response:

The Australian Government agrees with the recommendation.

Recommendation 15
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.

Response:

The Australian Government agrees with this recommendation in principle.

The communications strategy
In announcing *TGA reforms: a blueprint for TGA's future,* the Government has agreed to implement the recommendations of the Therapeutic Goods Administration (TGA) Transparency Review which will make further information available to medical practitioners and the public where any issues arise associated with therapeutic goods, including adverse outcomes and recalls.

The Government notes that the device sponsors, Johnson & Johnson Medical, working closely with the TGA and the Australian Orthopedic Association (AOA), have put in a place a communications strategy to inform medical practitioners about the issues associated with De Puy hip and hip resurfacing devices.

Information for the general public and patients has also been published on the TGA website: http://www.tga.gov.au/newsroom/btn-dupuy-recall.htm#patients. The Government notes that patients who suspect that they may have side effects related to their hip replacement surgery were advised to contact their surgeon for further clinical review as appropriate. In addition, following recall of the DePuy ASR implant, the TGA worked with DePuy and the AOA to ensure that all Australian orthopaedic surgeons were aware of the recall and appropriate advice was available to be provided to patients.

Communication between health practitioners and patients

The Medical Board of Australia (MBA) is responsible for all matters relating to the regulation of medical practitioners in Australia. It has produced *Good medical practice: A code of conduct for doctors in Australia* which provides guidance to medical practitioners on a range of matters including issues about provision of information to patients.

The Government undertakes to bring to the attention of the MBA and the Australian Health Practitioner Regulation Agency the need to ensure that surgeons are communicating any emerging concerns relating to medical devices to patients in a timely manner, including options for treatment.

Standard processes

The Department has standard procedures in place to respond to health crises and issues management, including development of appropriate communication strategies. These strategies are tailored to the specific situation as each issue is different and the response required can differ significantly.

Nevertheless, the Department and the TGA will undertake to review the efficiency, timeliness and comprehensiveness of standard processes to communicate with consumers and clinicians in the event of major recalls of implantable medical devices that may have public health consequences.

Recommendation 16

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.

Response:

The Australian Government notes the recommendation and will continue to monitor the emergence of evidence on the need for, and most effective approaches to, monitoring effects of metal levels associated with metal-on-metal hip replacements.

The TGA, in consultation with the AOA, has developed advice for healthcare professionals and patients regarding De Puy's ASR metal-on-metal hips. The AOA has notified orthopaedic surgeons of the issues and they have been advised to contact patients implanted with an ASR hip replacement system to arrange assessment and regular follow-up. Surgeons have been advised to follow patients closely, including annual review, for at least five years following surgery.

Currently, the health effects of increased blood metal levels are uncertain. Moreover, the effectiveness of monitoring blood metal levels to identify suspected problems with metal-on-metal hips has not been established, and such results are generally considered in the context of other clinical findings. The type of monitoring should be determined on a case-by-case basis following a detailed consideration of each patient's circumstances by their surgeon. This may involve diagnostic imaging and blood tests as determined by the treating surgeon in consultation with each individual patient. Chromium testing is reimbursed under the Medicare Benefits Schedule.

Recommendation 17
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.

Response:

The Australian Government agrees with this recommendation in principle.

Australia is participating in a world wide study of patients who have received the ASR Hip. This study will be the largest of its kind in determining the relevance, extent and impact of raised metal ion levels, in patients who have had hip surgery using the ASR prostheses.

The Department of Health and Ageing and the Therapeutic Goods Administration are also having ongoing discussions with the Australian Orthopaedic Association National Joint Replacement Registry about ways in which the registry may assist in assessing the outcomes for patients who have received other metal-on-metal hip replacement and any potential for ongoing medical problems.

In addition, as the Government's peak funding body for health and medical research, the National Health and Medical Research Council (NHMRC) invests in research through a variety of funding mechanisms including investigator-initiated research projects and clinical trials, broad programs of research, training awards for scholars and postdoctoral fellows, career research fellowships and special strategic research programs. The majority of these schemes operate according to annual funding rounds and the details of opening and closing dates are available on the NHMRC website.

Investigator-initiated research proposals into the health effects of cobalt, chromium, and other toxic metals on the human body will be considered as part of annual funding rounds. These funding schemes are highly competitive with each application considered on its merits through a rigorous peer review process.

Recommendation 18
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.

Response:

The Australian Government agrees with the recommendation in principle but notes that a legislative framework for ethical conduct of industry in the promotion of therapeutic goods to healthcare professions is not warranted in the Australian context at this time.

The Government is committed to achieving a level playing field in this area. Recognising the need for improvement, the Government established an industry-led working group in 2010 to examine the issues around promotion of therapeutic goods and opportunities to strengthen the current self-regulatory arrangements.

The Government announced its response to the working group's recommendations as part of the *TGA reforms: a blueprint for TGA's future*. In this response the Government gave strong support to industry's initiative to harmonise their codes of conduct to incorporate the high level principles agreed to by the Working Group. Robust and consistent codes of conduct are a powerful first step in strengthening oversight of the relationship between therapeutic goods companies and healthcare professionals.

As part of the 2012-13 Budget, the Government will provide $1.4 million over four years to further assist industry to respond to the Working Group's recommendations. The resources provided through this measure will support stronger self-regulation, better communication and shared systems for complaints reporting.

The Government will work with industry to evaluate the effectiveness of this approach and consider the need to provide further support, or changes to the current self-regulated arrangements if the therapeutic goods industry requires greater encouragement to achieve universal adherence to consistent, high ethical standards. The Government notes that a legislative framework for ethical conduct of industry in the promotion of therapeutic goods to healthcare professionals is not warranted in the Australian context at this time.

In relation to standards for ethical conduct of healthcare professionals, the Australian Government undertakes to bring the recommendation to the notice of the Australian Health Workforce Ministerial Council, and to refer the recommendation to the relevant National Boards and the Australian Health Practitioner Regulation Agency.

The Government has also been working with its partners in the Asia Pacific Economic Cooperation (APEC) to develop and endorse principles to guide business ethics in the medical device and pharmaceutical sectors. These principles clearly set out expectations for companies operating within APEC economies in regard to ethical behaviour and identify activities that are inappropriate influences and inducements.

Amended recommendations

The Australian Government notes the proposed timeframes and additional considerations proposed by Senator Xenophon and has considered and responded to these matters in the main recommendations.