Australian Government

Department of Health and Ageing

Submission to the

Senate Community Affairs References Committee

Inquiry into the Regulatory Standards for the Approval of Medical Devices

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(a)

Introduction

1. This is a Departmental submission to the Senate Inquiry into the Regulatory Standards for the Approval of Medical Devices. It covers both the regulatory role of the Therapeutic Goods Administration (TGA) and the reimbursement processes managed by the Medical Benefits Division (MBD). *Note a Glossary is available at the end of this document

A. The role of the regulator

2. The TGA is a division of the Australian Government Department of Health and Ageing (the Department). The TGA's overall purpose is to protect public health and safety by regulating therapeutic goods that are supplied in, or exported from, Australia. Therapeutic goods include medicines, medical devices, and biological products.
3. The TGA also aims to ensure that the Australian community has access, within a reasonable timeframe, to new therapeutic goods.
4. Any product for which therapeutic claims are made (unless exempt) must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia.
5. The TGA may evaluate therapeutic goods before they are approved for general supply, and monitors all therapeutic goods once they are on the market.
6. The TGA has a team of manufacturing inspectors that audit manufacturing facilities in Australia and around the world to ensure that products supplied in Australia are of consistently high quality.
7. The TGA works with consumers, health professionals, industry and its international regulatory counterparts in order to effectively regulate increasingly complex products resulting from rapid scientific developments.

B. Australian medical devices legislation

8. The TGA administers the following legislation in order to regulate medical devices:
    - the *Therapeutic Goods Act 1989* (the Act)
    - the *Therapeutic Goods Regulations 1990*
    - the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)
    - The *Therapeutic Goods (Charges) Act 1990*
9. This legislation provides a framework for a risk management approach that allows the Australian community to have timely access to medical devices which have appropriate levels of safety, perform as intended and are of high quality.
10. The Australian medical device legislation is based on the regulatory system recommended by the Global Harmonisation Task Force (GHTF) and is aligned with the European Union (EU) medical device framework.

11. The regulation of medical devices in Australia includes the following elements:

    (a) A classification system for medical devices based on different levels of potential risk to the patient.
    (b) Manufacturers are required to demonstrate compliance with a set of internationally agreed 'Essential Principles' for the quality, safety and performance of the medical devices.
    (c) A requirement that manufacturers implement and maintain a suitable quality management system (QMS) for the design, production, release and post market monitoring of medical devices.
    (d) A requirement that medical devices be included in the ARTG unless they are exempt.
    (e) Medical devices available on the market are subject to monitoring by the TGA. This monitoring includes a comprehensive incident reporting scheme.

12. For a more detailed description of the TGA's regulatory activities for medical devices including access to unapproved and exempt medical devices, please refer to Attachment 2.

C. International context

13. The TGA's participation in international fora helps ensure Australia aligns its regulatory frameworks and standards with international standards and the regulatory practices of other comparable countries' regulators. This assists consumers, patients and practitioners to access therapeutic goods in a timely manner and avoids unnecessary regulatory duplication, burden and cost on the manufacturers of therapeutic goods.

14. For example, TGA has negotiated agreements with other international regulators ranging from the recognition and acceptance of regulatory decisions on specific products to sharing information about regulatory processes, such as what pre-market assessments occur before a product is able to be supplied. These agreements have assisted the TGA in providing timely access to medical devices and maximised regulatory efficiencies.

15. The TGA has agreements in place with regulators from each of the following jurisdictions to facilitate information sharing on regulatory practices and to enhance regulatory cooperation:

    - Canada;
    - European Union (EU);
    - Singapore;
    - Switzerland; and
    - The United States of America (USA).

16. The TGA is also a founding member of the GHTF, a group of representatives from medical device regulatory authorities and the regulated industry. The GHTF is comprised of representatives from five founding members: the EU, the USA, Canada, Australia and Japan. The GHTF has for 18 years worked on the development of a regulatory model and supporting documents to underpin globally harmonised regulation of medical device technologies.

17. The purpose of the GHTF has been to encourage convergence in regulatory practices related to ensuring the safety, effectiveness / performance and quality of medical devices, promoting technological innovation and facilitating international trade. This was primarily achieved through the publication and dissemination of harmonised documents on basic regulatory practices. These documents provide a model for the regulation of medical devices that can then

be adopted by national regulatory authorities.

18. The GHTF in its current form is to be disbanded and a new regulatory forum will replace it to better reflect the changing global requirements of regulators of medical devices in 2011 and beyond. Australia will be taking an active role in the development of the revised regulatory forum.

D. The Australian medical device industry

19. Medical devices supplied in Australia range from bandages that are put on minor cuts and bruises, to high risk products such as pacemakers that are implanted in the body. Other examples of medical devices include:

- orthopaedic joint implants, such as hip, knee and shoulder joint replacements;
- blood pressure monitors;
- urinary catheters;
- blood bags;
- condoms;
- device disinfectants, such as autoclaves and disinfectant solutions;
- lubricating eyedrops;
- medical imaging equipment, such as x-ray film, MRI machines, and imaging software;
- dental products, such as drills and fillings; and
- syringes and needles.

20. The Australian medical device industry is comprised of a diverse range of manufacturers and suppliers, from small family operated businesses to large multi-national companies. The Australian medical device industry:

- includes over 450 medical technology companies in Australia;
- employs over 17,500 people;
- is mainly located in NSW (54%), followed by VIC (24%), QLD (11%) and WA (7%);
- has a total annual revenue in the order of $7.6 billion; and
- is estimated to represent 2.61% of the global medical device market (all figures obtained from the Medical Technology Association of Australia (MTAA) website on 1 July 2011 <http://www.mtaa.org.au/pages/page3.asp>).

21. As at 1 July 2011 there were approximately 36,000 entries for medical devices on the ARTG. As a single entry on the ARTG may cover multiple ‘kinds’ of medical devices, that have the same basic characteristics, this represents around 1 million distinct devices. Most (around 90%) of the medical devices supplied in Australia are manufactured overseas.

22. In the 2010-11 financial year, the TGA received approximately 6,000 new applications (approximately 50% were for Class I medical devices) to include medical devices in the ARTG.

E. Australian regulatory costs

23. In December 2002, the Australian Government adopted a formal cost recovery policy to improve the consistency, transparency and accountability of its cost recovery arrangements and promote the efficient allocation of resources. The underlying principle of the policy is that

entities should set charges to recover all the costs of products or services where it is efficient and effective to do so, where the beneficiaries are a narrow and identifiable group and where charging is consistent with Australian Government policy objectives. Cost recovery policy is administered by the Department of Finance and Deregulation and outlined in the *Australian Government Cost Recovery Guidelines* (Cost Recovery Guidelines).

24. The policy applies to all *Financial Management and Accountability Act 1997* (FMA Act) agencies and to relevant *Commonwealth Authorities and Companies Act 1997 (CAC Act) bodies that have been notifi*ed. In line with the policy, individual portfolio ministers are ultimately responsible for ensuring entities' implementation and compliance with the Cost Recovery Guidelines.

25. The TGA recovers the full cost of its regulatory activities within the scope of the Act through fees and charges for services provided to product sponsors and manufacturers. Fees and charges are prescribed in regulations made under the Act and the *Therapeutic Goods (Charges) Act 1990*.

26. The policy of recovering the TGA costs from industry was established in the 1997-98 Budget under *Phased Increase in Industry Contribution for the Regulation of Therapeutic Goods*.

27. In performing its activities, under the legislation, the TGA is required to recover its costs from the various industries that it regulates. The TGA achieves this primarily through application fees (for new ARTG entries), assessment fees, and annual charges for each ARTG entry.

28. The TGA is very conscious of the costs associated with its regulatory responsibilities and is continually seeking to contain those costs through improvements in both efficiency and effectiveness of its processes and services.

29. Each year the TGA consults representatives of the four major industries, including the medical device industry, on the TGA's schedule of fees and charges for the forthcoming financial year. The fees can be found at < http://www.tga.gov.au/about/fees-110701.htm>.

30. The TGA's annual revenue from the medical device sector in the 2010-11 financial year was approximately $23.7 million (around 20% of TGA's total revenue).

F. Regulatory balance

31. The medical device industry characterises itself as highly innovative and competitive, resulting in a relatively short product life cycle with many medical devices undergoing constant development and improvement based on feedback from medical professionals and advances in technology (refer to < http://www.mtaa.org.au/pages/page3.asp>).

32. Medical devices are becoming increasingly complex, and can incorporate other therapeutic goods such as medicines and biological materials.

33. Consumers and health professionals expect medical devices to be regulated to ensure an adequate level of safety and performance and that the latest therapeutic technologies will be available in a timely manner.

34. The TGA seeks to apply a risk-based regulatory system that imposes sufficient regulatory controls, without imposing expensive and unnecessary requirements on manufacturers, that might limit patients' access to effective therapeutic products.

G. Reprocessing of single-use devices

35. In 2001, the Australian Health Ministers' Advisory Council (AHMAC) agreed that, if reprocessing of single-use devices was to occur in Australia, it would be regulated as a manufacturing activity by TGA to the same requirements as the original manufacturer.

36. Under current therapeutic goods legislation, reprocessed single-use medical devices are treated as new distinct medical devices, with the new manufacturer (the reprocessor) responsible for ensuring the reprocessed single-use devices are of acceptable safety, and perform as intended.

37. The TGA conformity assessment approval process requires a review of the information provided by the manufacturer to ensure that:

    - the manufacturer employs a QMS suitable for the class of device being manufactured, and
    - the manufacturer holds adequate evidence to demonstrate the safety and performance of the reprocessed devices.

38. Manufacturers assessed as meeting these regulatory requirements would be issued with a conformity assessment certificate, enabling the reprocessed medical devices to be included on the ARTG.

39. To date, the TGA has not issued a conformity assessment certificate to any manufacturer of reprocessed single-use medical devices.

H. Subsidising medical devices

MBD is a division of the Australian Government Department of Health and Ageing with management responsibility for policies and programs related to private health insurance and the Medicare Benefits Schedule.

Private Health Insurance

40. The Australian Government supports the provision of prostheses in the private health sector through private health insurance arrangements. A number of policies and incentives encourage and support individuals and families to purchase private health insurance. On the incentives side, this includes the private health insurance rebate, the Medicare levy surcharge and Lifetime Health Cover. On the policy side this includes community rating, risk equalisation, and the Prostheses List (PL), which sets out devices which private health insurers are obliged to cover, and the minimum benefits which must apply.

41. The private health insurance rebate involves the Government paying a proportion of the cost of a private health insurance policy. More than half of the Australian population has private health insurance.

42. The Government's support is directed to clinically and cost effective prostheses. As such, the Prostheses List plays a dual role as part of Commonwealth Health Technology Assessment (HTA) processes and as part of the regulation of private health insurance in Australia.

Overview of the Prostheses List

43. Under the *Private Health Insurance Act 2007*, private health insurers are required to pay benefits for a range of prostheses listed on the PL that are provided as part of an episode of

hospital treatment, or hospital substitute treatment, for which a patient has cover and for which a Medicare benefit is payable for the associated professional service.

44. Between 1999 and 2002, the growth of the cost of prostheses significantly increased the benefits paid by private health insurers. In April 2003, the Government introduced a package of reforms to private health insurance that included new arrangements for listing products on the PL that provide for an evidence-based assessment of products and a centralised benefit negotiation process. These reforms have been subject to reviews, such as the Doyle Report (2007) and the Review of Health Technology Assessment in Australia (HTA Review) (2009) and have been revised over time.

45. Benefits paid by health insurers for prostheses in the 12 months to March 2011 were $1.3 billion, 10.6% of the total benefits paid by health insurers of $12.7 billion (of which the Government contributed $4.9 billion through the private health insurance rebate).

46. The Minister for Health and Ageing, or her delegate, makes decisions on the prostheses that should be listed and the benefits payable for them, based on advice from the Prostheses List Advisory Committee (PLAC). In making recommendations, the PLAC considers advice from Clinical Advisory Groups (CAGs) and members of the Panel of Clinical Experts (PoCE). CAGs have been established for hip, knee, cardiac, cardiothoracic, ophthalmic, spinal, urogenital, vascular and specialist orthopaedic prostheses. The PoCE assesses applications to list products that do not fit into these categories. These include ear, nose and throat, plastic and reconstructive, neurosurgery, and general miscellaneous prostheses.

47. Criteria for recommending that a prosthesis be listed include that the product must be included on the ARTG; the product must be provided to a person as part of an episode of hospital or hospital-substitute treatment; and a Medicare benefit must be payable in respect of the professional service associated with the provision of the product. The full criteria are at Attachment 3.

48. The cost of assessing and listing prostheses are recovered from the sponsors of these devices, and include:

    - application fees - $600
    - initial listing fees - $200
    - ongoing listing fees - $200

49. The PL contains prostheses and human tissue items and sets the minimum benefit for each to be paid by private health insurers. There are currently 9,645 products on the PL – 9,379 in Part A (Prostheses) and 266 in Part B (human tissue prostheses). The types of devices listed on the PL include:

    - cardiac pacemakers and defibrillators;
    - cardiac stents;
    - intraocular lenses;
    - orthopaedic joint implants;
    - mesh;
    - spinal implants; and

- human tissue products such as human heart valves, corneas, bones (part and whole) and muscle tissue.

Further information on device types and numbers on Part A of the PL is at Attachment 5. The PL is created twice per year in February and August.

Clinical Assessment

50. Prostheses on the PL need to be clinically effective and products with similar clinical effectiveness need to have similar benefits.

51. The CAGs and PoCE allocate prostheses into groups of similar products according to the feature and characteristics that define their clinical effectiveness and advise the PLAC on the relative clinical effectiveness of each product proposed for listing.

52. In assessing a product, clinicians consider how effectively it achieves, or is likely to achieve, the treatment outcomes for the clinical indication the product is designed to treat.

Benefits

53. Insurers are required to pay a minimum benefit for a prosthesis included on the PL and a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

54. Determination of the prosthesis benefit is based on clinical effectiveness of the prosthesis compared with other listed prostheses providing similar clinical outcomes for comparable clinical circumstances.

I. Health Technology Assessment Review progress

55. In February 2010, the Minister for Health and Ageing and the Minister for Finance and Deregulation released the report of the HTA Review. The Government accepted 13 of the 16 recommendations aimed at setting new directions for HTA in Australia to support better health care for all Australians, and to reduce unnecessary regulatory burdens on the sector while providing timely access to new and improved technologies and treatment modalities.

56. The Department is responsible for implementing recommendations from the HTA Review that have been accepted by Government. Implementation commenced in 2010 and continues throughout 2011 through a phased, iterative approach to allow stakeholder feedback and to ensure that 'business as usual' HTA activities are not disrupted.

57. A number of the agreed HTA Review recommendations have already been fully implemented and have, in accordance with Recommendation 3, been guided by the vision, goal, objectives and principles articulated in the HTA Review.

58. This submission provides a brief overview of the implementation of Recommendations 1, 2, 3, 4-7, 9 and more detail on the implementation of Recommendations 8, 10-15 as these are of most relevance to the terms of reference for this Inquiry.

Recommendation 1 – Evaluation within three years of the Government response to this review

59. This final recommendation remains to be implemented, as it is an evaluation of the impact of the changes to Commonwealth HTA processes arising from the HTA Review. This evaluation is expected to be completed during 2012-13.

Recommendation 2 – Rigorous consideration of evidence be consistently applied across all Commonwealth HTA processes to ensure sustainability of the Australian Government's health financing arrangements; and

Recommendation 3 – That the Commonwealth HTA system be guided by the vision, goal, objectives and principles articulated in this (HTA Review) Report.

60. The Department has conducted an audit on the assessment processes of individual HTA committees and, following analysis, has identified common themes. An action plan has been developed to address and incorporate these themes and includes a vision, goal, objectives and key HTA principles, which have been converted into measurable characteristics. This work will be progressed in the second half of 2011.

Recommendation 4 – A central HTA website

61. The central Australian Government HTA website (see <www.health.gov.au/hta>) was launched on 15 September 2010. This website enables effective communication of relevant information to stakeholders and improves access to policy and guidance for all Commonwealth HTA processes. It also provides links to all Commonwealth HTA websites.

Recommendation 5 – Improve procedural fairness and consistency

62. Procedural fairness and consistency are being implemented through the development of standard templates and documents that address a range of administrative issues including secretariat operating procedures and management of conflicts of interest.

Recommendation 6 –Establish a single entry point

63. The HTA Access Point (HTAAP) commenced operation on 15 September 2010. The HTAAP provides a single entry point for potential applicants seeking reimbursement of co-dependent technologies under the Medicare Benefits Schedule, Pharmaceutical Benefits Scheme and/or Prostheses List. The HTAAP streamlines the assessment and appraisal processes by coordinating responses from different advisory committees as required.

Recommendation 7- That applicants have the option of applying to different HTA processes concurrently

64. Each Commonwealth HTA process accepts co-dependent applications concurrently, and following the implementation of Recommendation 6, the HTAAP coordinates and monitors co-dependent technology applications.

Recommendation 8

65. That the TGA, in the context of international harmonisation:

    (a) continue its role as the independent national regulator solely responsible for assessing the safety, quality and efficacy of therapeutic goods for entry on the ARTG and marketing in Australia;

    (b) respond to the issues raised in consultations regarding third party conformity assessment by July 2010, with a view to implementing changes agreed by government by 2011;

(c) increase the rigour of regulatory assessment of higher risk medical devices by 2011, to ensure an appropriate level of evidential review is undertaken to ensure safety, quality and efficacy of these devices prior to entry on the ARTG and to provide a sound evidence basis for Commonwealth HTA processes; and

(d) develop protocols by July 2010 for sharing information with other HTA agencies through the SEP (subject to commercial-in-confidence constraints) on the outcomes of its safety assessments.

66. The TGA has developed a number of proposed reforms designed to increase pre-market assessment and the capacity for post-market monitoring of medical devices and consulted broadly through a Discussion Paper released in October 2010 (refer to website at < http://www.tga.gov.au/pdf/consult/consult-devices-reforms-101130.pdf>).

67. Progressing these reforms is being balanced against the need for consultation and analysis of feedback.

Recommendation 9 - MSAC strengthen and streamline its operations and improve the flexibility of its regulatory processes

68. MSAC has undertaken extensive policy analysis and re-design to streamline its operations and restructure the committee, with new governance arrangements and processes having commenced from 1 January 2011. This will reduce assessment timeframes and simplify processes for both the applicant and the committee.

Recommendations 10-12

69. Government agreed to implement Recommendations 10-12 of the HTA Review which were:

Recommendation 10:

That in order to reduce regulatory costs:

(a) *the terms of reference for the Prostheses and Devices Committee (PDC) and its subcommittees be revised by July 2010 so that it is clear that its assessments of prostheses only consider clinical effectiveness (including comparative safety); and*

(b) that channels of communication between the TGA and the PDC should be formalised to ensure that any concerns the PDC encounters regarding the intrinsic safety of prostheses are immediately referred to the TGA and dealt with appropriately.

70. Recommendation 10 has been implemented. The terms of reference for the PDC (now PLAC) were amended so that assessments of prostheses only consider clinical effectiveness. A protocol for PLAC feedback to the TGA has been developed that establishes a formal process for providing information to the TGA and for the TGA to respond to this information. These are at Attachment 5.

Recommendation 11:

That the PDC be restructured by July 2010 to ensure that its membership is balanced and:

(a) includes individuals with expertise in current clinical practice, health policy and health economics;

(b) includes representation from health consumers, health service providers, and the health insurance and health technology industries; and

(c) has an independent chair.

71. Recommendation 11 has been implemented. On 4 October 2010, the Minister for Health and Ageing approved the restructure of the PDC (now PLAC) and made appointments. The committee consists of experts including clinicians, health economists, health service providers, health insurers, health policy advisors, health technology industry representatives, a health consumer, and an independent chair.

Recommendation 12:

That the arrangements for the PL be changed by 2011, with appropriate consultation, to:

(a) accept applications on a continuous basis, but still make the Prostheses List every six months;

(b) establish and maintain groups of products with similar clinical effectiveness;

(c) abolish the negotiation of benefits for individual listed products, establish and maintain a single (benchmark) benefit for the products included in each group, with sponsors being required to accept this benefit in order to be listed;

(d) abolish the negotiation, setting or publication of maximum benefits, to eliminate the potential for gap payments for patients who have PHI; and

(e) permit the establishment of new product groups (or sub-groups) where a sponsor establishes clear superiority of their product compared to those in an existing group.

72. Recommendation 12(a) has been implemented. Applications for new listings and amendments to the PL have been accepted on a continuous basis since August 2010, with the PL still being published every six months. Recommendations 12(b)-(e) are being implemented in two tranches. The August 2011 PL will include the first, and the February 2012 PL will include the second tranche of product groups.

73. This work is being guided by the HTA Consultative Committee (HTA CC) which includes membership of the Department, private health insurers, Consumers Health Forum, sponsors/suppliers, private hospitals, Australian Medical Association and any further clinical expertise that is required. This committee has met three times and has a further two meetings scheduled for 2011. Progress is being balanced with time for consultation and analysis of feedback from all sponsors.

Recommendation 13 (inter-related with Recommendations 14-15)

74. Recommendations 13-15 of the HTA Review have not yet been accepted by the Government and are subject to further consideration due to the costs involved in their implementation. The recommendations are as follows:

Recommendation 13:

That, in order to improve the contribution of post-market surveillance to patient safety, the TGA take steps to increase the rate of reporting of adverse events, including by health service providers and consumers.

Recommendation 14:

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 processes, DoHA 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.

Recommendation 15:

That registers for high-risk implantable medical devices and/or procedures be established, with:

(a) key stakeholders such as clinicians, health consumers and industry to participate in governance of and contribution to registries;

(b) establishment of mechanisms to apply data from the register to future HTA;

(c) the feasibility, benefits and methodologies for data linkage to be explored in a pilot project in regard to a particular device identified by the high-risk implantable devices register;

(d) consideration of how developments in e-health and data linkage could improve the efficiency of the post-market surveillance of medical technology more generally; and

(e) the development of criteria, the identification of opportunities and the consideration of strategies for improvements in public investment in medical devices.

75. Feedback from stakeholders as part of the HTA Review identified that there was room for further improvement in post market surveillance and in the ongoing monitoring of devices. This includes ensuring there is a continuing process of performance assessment over the 'life-cycle' of a device.

76. Medical device registers traditionally monitor high risk implantable items. A small number of Australian clinical quality registries receive support from government and private sponsors, including the National Joint Replacement Registry (NJRR).

77. The NJRR collects data on joint replacements undertaken across Australia and a high percentage of orthopaedic surgeons submit data to the NJRR. The NJRR is a flagship example of a high quality evidence base that is successfully driving change to improve clinical practice and patient outcomes, and achieve more efficient health spending.

78. Every time the NJRR identifies a prosthesis that is underperforming, the use of that device falls considerably. Since its commencement, surgical revision rates for joint prostheses have declined significantly. The NJRR also informs the TGA of all underperforming prostheses, and the TGA investigates the identified devices through its Orthopaedic Expert Working Group (OWEG).

79. The NJRR publishes its research through its Annual Report. This report is available free of charge to download from its website <http://www.dmac.adelaide.edu.au/aoanjrr/>.

80. Some issues bearing on the establishment and ongoing management of registries include:

- adequacy and reliability of funding – funding needs to cover infrastructure/core costs, data collection, analysis and reporting, operational requirements and the ability to support growth and innovation;
- agreement on the funding obligation - amongst beneficiaries of the data and information produced by the registry;
- definition of role and role clarity - the extent to which different stakeholders can access data and information and engage in registry governance and operations;
- the elements of central registry functions - data management, quality control, reporting and governance;
- the elements of peripheral registry functions - data collection and patient follow up which occur at a hospital level and rely upon the engagement and support of health service providers; and
- requirements for information technology and other infrastructure to support registry operations and governance.

81. In addition, numerous clinical data collections being maintained in Australian hospitals consume considerable resources but do not necessarily facilitate access to complete and reliable information that can be used to understand and advance quality of care.

82. Thorough post market surveillance requires that a device's billing code (under the Prostheses List) can be linked to the product's catalogue number (designated by the sponsor for each individual item). A billing code is a reference code allocated to a listed prosthesis. The billing code facilitates hospital invoicing procedures and the payment of benefits by insurers. A billing code may be allocated to a single piece product, a 'kit', a 'system' or 'set' or a pack that contains different sizes of otherwise identical items. Work is underway within the department to collect catalogue numbers, linked to these billing codes, which will allow for the identification of each specific product. This will help to ensure that the correct product is being supplied and implanted.

83. This process is supported by the Medical Technology Association of Australia, which recently expressed support for its members to supply the relevant information to link catalogue numbers with billing codes and also to provide the NJRR with this data. It is anticipated that the catalogue numbers for the majority of orthopaedic billing codes will be received by the NJRR by the end of this year. The department will work with the NJRR to refine the data collection and it is anticipated that this will be accessible by the February 2012 Prostheses List.

84. The finalisation of recommendation 12b-e of the HTA Review, combined with the continued refinement of data available through the NJRR, will increasingly assist the department to ensure that devices on the Prostheses List are safe, effective and cost effective. This will also allow devices identified as being 'ineffective' to be easily identified and managed accordingly.

85. The TGA has been progressing internal post market mechanisms to improve its post market surveillance. The TGA:

    - recently wrote to stakeholder groups reiterating reporting requirements for adverse event reporting;
    - has been seeking specialist college input to assist with interpretation of signals and in dissemination of safety related information;

- has been exploring sources of information about devices such as from private health insurers;
- has been exploring sourcing data from other registries where available;
- currently hosts the GHTF National Competent Authority Report (NCAR) database which allows reports of adverse events to be exchanged between GHTF members.

86. The TGA is also exploring mechanisms to streamline its processes with HTA committees and is currently participating in a project with the MSAC and the PLAC to review the decision points for HTA processes.

J. Role of expert advisory committees

87. The TGA operates under a complex legislative environment which requires advice from clinical and technical experts. The medical devices area of the TGA relies on three Committees to assist it with its pre and post market functions:

- the Advisory Committee on Medical Devices (ACMD) which is a statutory committee;
- the Medical Devices Incident Review Committee (MDIRC); and
- the OEWG.

ACMD

88. The ACMD provides independent medical and scientific advice to the Minister for Health and Ageing and the TGA on safety, quality and performance of medical devices supplied in Australia including issues relating to premarket conformity assessment and post market monitoring.

89. Members of the ACMD are appointed by the Minister for Health and Ageing and up to 32 members may be appointed with appropriate expertise, which includes: (a) medical or surgical expertise in of the following fields: gastroenterology; vascular; orthopaedics; neurology; cardiology; plastic and reconstructive surgery; respiratory medicine; obstetrics or gynaecology; pathology; anaesthetics; ophthalmology; dentistry; ear nose and throat; renal; (b) manufacture of medical devices; (c) consumer issues; (d) biomedical engineering; (e) biomaterials; and (f) clinical medicine.

90. The Chairperson of the ACMD is Professor Guy Ludbrook (Professor of Anaesthesia, Royal Adelaide Hospital, Head of Acute Care Medicine, University of Adelaide, and Co-Director, Pain and Anaesthesia Research Clinic) who has recognised and respected expertise in anaesthesia, health care delivery and clinical research. There are a further 18 members, their names and specialties can be found at < http://www.tga.gov.au/about/committees-acmd.htm>.

MDIRC

91. MDIRC is established as a sub-committee of the ACMD. The major function of MDIRC is to advise the TGA and the ACMD on matters relating to the safety performance of medical devices supplied in Australia. It does this by reviewing reports received by the TGA through its medical device Incident Reporting and Investigation Scheme.

OEWG

92. The OEWG is established as a sub-committee of the ACMD. This group consists of orthopaedic surgeons with expertise in joint replacement surgery. It has a crucial role to play in

advising the TGA on appropriate actions to take in the regulation of orthopaedic devices. It is called upon to review available clinical data and other relevant information and provide advice to the TGA on whether an early revision (replacement) rate for orthopaedic devices is acceptable for the identified implant of concern.

93. To date the OEWG has been called on nine times and considered 76 orthopaedic implants that appear to have higher than expected revision rates. Of these, the OEWG have recommended no further action or ongoing monitoring in 50 joint replacements.

94. Of the remaining 26 joint replacements, 15 have been removed from the market, four are under consideration following the OEWG's last meeting in November 2010, and seven remain on the market after consideration by the TGA of further evidence provided by the manufacturer. These seven joint replacements remain the subject of active ongoing monitoring by the TGA.

Glossary

Australian Register of Therapeutic Goods (ARTG): is the register of information about therapeutic goods for human use that may be imported, supplied in or exported from Australia. All medical devices, including Class I, must be included in the ARTG before supply in Australia. There are limited exceptions to this requirement specified in the legislation.

Application audit assessments: The Act enables the Regulations to prescribe certain kinds of applications that are to be selected for audit. These kinds of applications must be selected for audit by the Secretary. However, the Secretary may also select for auditing any other application.[1] The TGA has established two levels of application audit, Level 1 and Level 2:

Level 1: The TGA will consider:
(a) the original or correctly notarised copy of the manufacturer's Australian Declaration of Conformity;
(b) Copy of the latest and current conformity assessment evidence for the medical device; and
(c) Information about the device, including copies of the:

(i) Label;
(ii) Instructions for use;
(iii) Advertising material such as brochures, web pages and advertisements.

Level 2: The TGA will consider all of the documentation considered in a Level 1 audit. In addition, the TGA will consider:
(a) the risk management report;
(b) the clinical evaluation report;
(c) efficacy and performance data for medical devices that disinfect including those that sterilise other medical devices.

Conformity assessment: is the name given to the processes that are used to demonstrate that a device and manufacturing process meet specified requirements. In Australia this means that the manufacturer must be able to demonstrate that both the medical device and the manufacturing processes used to make the device conform to the requirements of the therapeutic goods legislation.

Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with the Essential Principles. It provides objective evidence of the safety, performance, benefits and risks for a specified medical device and also enables regulatory bodies to ensure that products placed on the market conform to the applicable regulatory requirements.

The conformity assessment procedures allow risk based pre-market assessment for devices. All manufacturers of all medical devices are required to meet manufacturing standards and all manufacturers, except those manufacturing the lowest risk devices, are audited and are required to have their systems certified. The level of assessment is commensurate with the level and nature of

[1] See section 41FH of the Act.

the risks posed by the device to the patient, ranging from manufacturer self-assessment for low risk devices through to full TGA assessment with respect to high-risk devices.

Conformity assessment certificate: A certificate to demonstrate that the conformity assessment procedure has been assessed.

Essential Principles: provide the measures for safety and performance and are set out in the Regulations. For a medical device to be supplied in Australia, it must be demonstrated that the relevant Essential Principles have been met.

The Essential Principles are:

General principles that apply to all devices

1. Medical devices not to compromise health and safety
2. Design and construction of medical devices to conform to safety principles
3. Medical devices to be suitable for intended purpose
4. Long term safety
5. Medical devices not to be adversely affected by transport or storage
6. Benefits of medical devices to outweigh any side effects

Principles about design and construction that apply depending on the kind of device

7. Chemical, physical and biological properties
8. Infection and microbial contamination
9. Construction and environmental properties
10. Protection against radiation
12. Medical devices connected to or equipped with an energy source
13. Information to be provided with medical devices.
14. Clinical evidence

Additional essential principle for IVDs only

15. Principles applying to IVD medical devices only (this includes 7 principles relating specifically to the safety and performance of IVD medical devices).

IVD: A medical device is an in vitro diagnostic medical device (IVD) if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with other diagnostic goods for in vitro use. It must be intended by the manufacturer to be used in vitro for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures. The definition of an IVD does not encompass products that are intended for general laboratory use that are not manufactured, sold or presented for use specifically as an IVD.

Kind of medical device: single entry in the ARTG may cover a range of products that are of the same kind rather than individual devices. At present, medical devices (with the exception of Class III and Active Implantable Devices (AIMDs) and Class 4 IVDs and Class 4 in-house IVDs) are included as a group on the ARTG under a single entry if they: have the same sponsor; have the same manufacturer; have the same medical device classification; have the same nomenclature system code (GMDN) code.

Manufacturer: of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.[2]

Manufacturer's evidence: the conformity assessment evidence that demonstrates that a manufacturer has appropriate manufacturing processes to make the devices. Once the manufacturer's evidence is accepted by the TGA the sponsor can make an application to include their device on the ARTG. Acceptable manufacturer's evidence for most medical devices includes equivalent conformity assessment certification issued under the provisions of the European Medical Devices Directives, commonly referred to as CE certificates.

Medical device: is:
(a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;
ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
iii. investigation, replacement or modification of the anatomy or of a physiological process;
iv. control of conception;

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

(aa) any instrument, apparatus, appliance, material or other article specified under subsection (2A); or

(ab) any instrument, apparatus, appliance, material or other article that is included in a class of instruments, apparatus, appliances, materials or other articles specified under subsection (2B); or

(b) an accessory to an instrument, apparatus, appliance, material or other article covered by paragraph (a), (aa) or (ab).[3]

Medical device classifications: Medical devices are classified by the manufacturer according to the intended purpose of the medical device and the degree of risk involved for the patient and user. The device classifications are determined using a set of rules contained in the Regulations that take into account the degree of invasiveness in the human body, the duration and location of use and whether the device relies on a source of energy other than the body or gravity. There are two sets of classification rules; one based on the above and the other based on whether an IVD medical device.

Medical devices (other than IVD medical devices):

CLASS	RISK	EXAMPLES
Class I	Low risk	Surgical retractors, tongue depressors

[2] Refer to section 41BG of the Act for remainder of definition.
[3] Refer to section 41BD of the Act for remainder of definition.

Class IIa	Low-medium risk	Hypodermic needles, suction unit
Class IIb	Medium-high risk	Lung ventilator, bong fixation plate
Class III	High risk	Heart valves
AIMD (Active Implantable Medical Devices)		Implantable defibrillator

IVD medical devices:

CLASS	**RISK**	**EXAMPLES**
Class 1 IVD	No public health risk or low personal risk	Enzyme immunoassay analyser. Ready to use microbiological culture media.
Class 2 IVD	Low public health risk or moderate personal risk	Pregnancy self-testing kit. Liver function tests.
Class 3 IVD	Moderate public health risk or high personal risk	Test to detect the presence or exposure to a sexually transmitted agent such as C. trachomatis or N. gonorrhoea. System for self-monitoring of blood glucose.
Class 4 IVD	High public health risk	Assay intended for the clinical diagnosis of infection by HIV 1 & 2. Assay intended for screening blood donations for Hepatitis C virus.

Notified bodies: A "Notified Body" (NB) is a European Conformity Assessment Body (CAB) which performs conformity assessments of manufacturers and medical devices.

Notified Bodies are designated to perform this function by their local Competent Authority (or Designating Authority), which is usually a government agency responsible for assessing and monitoring Notified Bodies in their own country. For example, the Medical and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) is responsible for designating UK Notified Bodies.

Notified Bodies issue certificates to manufacturers under the European legislation:

- Medical Device Directive (MDD) 93/42/EEC, and
- Active Implantable Medical Device Directive (AIMDD) 90/385/EEC.

Some Notified Bodies are also designated under the Aust-EU Mutual Recognition Agreement (MRA) to issue certification to Australian legislative requirements.

Notified Bodies are usually for-profit commercial organisations, and may have regional offices outside of Europe.

There are currently 76 Notified Bodies designated under the European Medical Devices Directive (MDD).

Only 19 of the 76 Notified Bodies are also designated under the European Active Implantable Medical Devices Directive (AIMDD).

Only 12 (including TGA) of the 76 Notified Bodies are designated to issue certificates under the Aust-EU MRA.

The TGA is considered a Notified Body for the purposes of issuing European certificates to Australian/New Zealand manufacturers under the provisions of the Aust-EU MRA.

Quality Management System (QMS): The International Standards Organisation (ISO) describes a quality management system as a set of interrelated or interacting processes and interfaces, whose purpose is to achieve defined objectives, within the constraints of established policy. The system is to direct and control a group of people and facilities, with an arrangement of responsibilities, authorities and relationships. Such controls and arrangements are necessary to ensure that the outputs of the system have a set of predetermined inherent and distinguishing features that fulfil a need or expectation that is stated generally, implied or obligatory.

Sponsor: in relation to therapeutic goods, means:

(a) a person who exports, or arranges the exportation of, the goods from Australia; or
(b) a person who imports, or arranges the importation of, the goods into Australia; or
(c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who:
(d) exports, imports or manufactures the goods; or
(e) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.[4]

[4] Section 7 of the Act.

Attachment 1 - Terms of Reference

The regulatory standards for the approval of medical devices in Australia, with particular attention to devices with high revision rates, and in undertaking the inquiry the committee consider:

(a) the role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;

(b) the cost effectiveness of subsidised devices;

(c) the effectiveness and accuracy of the billing code and prostheses list;

(d) the processes in place to ensure that approved products continue to meet Australian standards;

(e) the safety standards and approval processes for devices that are remanufactured for multiple use;

(f) the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices;

(g) the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified;

(h) the effectiveness of the implemented recommendations of the Health Technology Assessment; and

(i) any other related matter.

Attachment 2 - Regulation of Medical Devices in Australia

Introduction

1. Medical devices are regulated by the Therapeutic Goods Administration (TGA) under Chapter 4 of the *Therapeutic Goods Act 1989* (the Act). The purpose of the requirements of the Act relating to medical devices is to ensure the safety and satisfactory performance of those devices.

2. There are two key types of requirements that apply to medical devices:

   (a) all medical devices must comply with requirements of quality, safety and performance prescribed in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations). These requirements are referred to as the Essential Principles; and
   (b) the manufacturer of the medical device must demonstrate that the product complies with the Essential Principles by applying appropriate conformity assessment procedures (see Glossary).

3. The Act gives the Secretary various powers in relation to the regulation of medical devices, including powers to:

   (a) issue conformity assessment certificates to manufacturers of a medical device;
   (b) suspend or revoke conformity assessment certificates in particular circumstances;
   (c) include a medical device in the Australian Register of Therapeutic Goods (ARTG);
   (d) suspend or cancel entries of devices from the ARTG;
   (e) obtain information about medical devices; and
   (f) require the recovery (recall) of medical devices, or to inform the public about medical devices, where the devices do not comply with the requirements of the legislation.

Pre-market review by the TGA before inclusion in the ARTG

4. The levels of pre-marketing assessment of medical devices can be summarised as follows:

Class I medical devices and Class 1 In Vitro Diagnostics (IVDs) (see Glossary under ‘medical device classification’ and ‘IVD’)

   (a) Most Class I medical devices validly lodged under the TGA’s electronic lodgement system will result in an automatic entry to the ARTG. There is no assessment of the application. However, applicants must certify as to a range of matters in relation to the device. Some Class 1 IVD medical devices are required to be selected for audit (this does not apply to Class I sterile or measuring medical devices). Where a Class 1 IVD medical device is not required to be selected for audit, it will receive the same level of pre-market assessment as a Class I medical device. The automatic entry process is monitored by a random selection process, under which 10% of applications are selected for review at the post-market stage. There is also provision for targeted review, triggered by the use of “restricted words” in the “intended purpose” field of the application form, or for other reasons where the TGA considers there is reason for review.

Class I measuring, Class I sterile, Class IIa, Class IIb medical devices and Class 2 and 3 IVD devices (see Glossary under 'medical device classification' and 'IVD')

(b) Before making an application to include a Class I measuring, Class I sterile, Class IIa or IIb medical device or Class 2 or 3 IVD devices, the Manufacturer's Evidence (see Glossary) must have been accepted by the TGA. The details of the device application will be compared with the details on the Manufacturer's Evidence, to ensure that the device is appropriately covered by conformity assessment certification, and an administrative review of details of the application will be conducted, such as appropriate classification and intended purpose. No further assessment is conducted unless it is an application that is required to be audited under the Regulations or the application is selected for a non-mandatory application audit (see Glossary).

Class III and Active Implantable Medical Devices (AIMD) (see Glossary under 'medical device classification' and 'IVD')

(c) Applications for Class III and AIMD devices are subject to acceptance of Manufacturer's Evidence. They will generally undergo a Level 2 application audit assessment (see Glossary).

Class 4 IVDs and other medical devices that require a TGA conformity assessment certificate (see Glossary under 'medical device classification' and 'IVD')

(d) Applications for these types of devices are subject to acceptance of Manufacturer's Evidence. As the manufacturer must have conformity assessment certificates issued by the TGA, no further assessment is required at the stage of application for ARTG entry.

Conformity Assessment

5. Conformity assessment is the name given to the processes that are used to demonstrate that a device and manufacturing process meet specified requirements. In Australia this means that the manufacturer must be able to demonstrate that both the medical device and the manufacturing processes used to make the device conform to the requirements of the therapeutic goods legislation.

6. Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with the Essential Principles. It provides objective evidence of the safety, performance, benefits and risks for a specified medical device and also enables regulatory bodies to ensure that products placed on the market conform to the applicable regulatory requirements.

7. The conformity assessment procedures allow risk based pre-market assessment for devices. All manufacturers of all medical devices are required to meet manufacturing standards and all manufacturers, except those manufacturing the lowest risk devices, are audited and are required to have their systems certified. The level of assessment is commensurate with the level and nature of the risks posed by the device to the patient, ranging from manufacturer self-assessment for low risk devices through to full TGA assessment with respect to high-risk devices.

8. There are different conformity assessment procedures that a manufacturer can choose to follow to demonstrate that they have met the Essential Principles for a particular medical device. The classification of a medical device determines the conformity assessment procedures a manufacturer can choose to ensure that the device is adequately assessed. Higher classification devices must undergo more stringent conformity assessment procedures than lower classification devices.

9. An outline of the different stages of conformity assessment and who is responsible for each stage is as follows:

Stage 1:

10. The manufacturer is responsible for:

- Demonstrating that they have met the Essential Principles for a particular kind of device. This involves assessment of:
    - the technical documentation for the design of the kind of device;
    - the manufacturing process used to manufacture that kind of device;
    - the risk analysis relating to that kind of device;
    - the clinical evidence to support that kind of device; and
    - ongoing monitoring and vigilance procedures that will be in place once the kind of device is available for supply.

Stage 2:

11. The regulatory body (which may be the TGA or, in some circumstances in relation to devices manufactured outside Australia, may be an overseas regulatory body) is responsible for issuing conformity assessment evidence in the form of a certificate.

12. This demonstrates that the manufacturer has been assessed and has the appropriate systems in place to manufacture the particular kind of device. This assessment (which will vary depending on the conformity assessment procedures selected by the manufacturer) includes:

- confirming that the conformity assessment procedures are appropriate for the classification of that kind of device and that they have been applied correctly;
- systematic examination of the documentation provided and the procedures undertaken by the manufacturer; and
- may include an on-site audit of the manufacturing premises.

Stage 3:

13. The manufacturer, once they have obtained the conformity assessment evidence, must then make an Australian Declaration of Conformity that declares that the device complies with:

- the applicable provisions of the Essential Principles;
- the classification rules; and
- an appropriate conformity assessment procedure.

Stage 4:

14. The manufacturer then has ongoing responsibilities to maintain the appropriate records and

procedures required to demonstrate continued compliance with the Essential Principles. They are also responsible to apply for re-certification prior to the expiry of existing conformity assessment evidence.

15. For most devices manufactured outside Australia the TGA accepts the conformity assessment evidence issued by assessment bodies that are considered to have the appropriate authority and expertise. As the Australian and European regulatory requirements are similar, the TGA has determined that certificates issued by European Notified Bodies may be accepted as conformity assessment evidence for the supply of medical devices in Australia. However, the manufacturer must still prepare a Declaration of Conformity to Australian requirements, taking into account any differences in regulatory requirements, or any difference in performance that may result from use in Australia, such as changes in performance due to environmental conditions.

Manufacturers and devices requiring TGA conformity assessment certification

16. In some cases, a conformity assessment certificate must be issued by the TGA before an application to include a kind of medical device in the Register may be made. The types of applications to which this requirement applies are set out in Regulation 4.1 of the Regulations.

Australian manufacturers must have a TGA conformity assessment certificate

17. The Regulations currently provide that any manufacturer who manufactures medical devices, higher than Class I, in Australia must have a conformity assessment certificate issued by the TGA in order to make an application to include a medical device on the Register.

Particular "kinds" of devices that require TGA conformity assessment certificates

18. The Regulations also provide that the following medical devices manufactured outside Australia must have a conformity assessment certificate issued by the TGA:

    - medical devices, other than IVD medical devices, that contain tissues of animal origin that have been rendered non-viable (other than those that are intended to come into contact with intact skin only);
    - medical devices, other than IVD medical devices, that contain tissues, cells or substances of microbial or recombinant origin and are intended for use in or on the human body;
    - medical devices, other than IVD medical devices, incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;
    - medical devices, other than IVD medical devices, that incorporate, or are intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device; and
    - Class 4 IVD medical devices and Class 4 in-house IVD medical devices.

Conformity Assessment by the TGA

19. When considering an application for a conformity assessment certificate, the TGA may carry out an on-site audit of the manufacturer's quality management system (QMS) and a desk-based evaluation of the scientific data generated by that system. The documentation reviewed by the TGA covers engineering and design, risk management, materials and biocompatibility, sterility and viral safety, preclinical and animal studies and clinical evidence.

Clinical evidence requirements

20. All medical devices are required to have clinical evidence to support the safety and performance of the device at the time the device is placed on the market in Australia. The clinical evidence is required to include an appraisal (evaluation) of the available clinical data (including clinical trial data, post market surveillance and clinical experience data) for that device (or similar/equivalent devices) with respect to both performance of the device as intended by the manufacturer and the safety of the device.

21. The clinical evidence and other technical documentation, such as animal and biocompatibility data, must be held by the manufacturer and made available to the TGA if requested.

22. For the majority of low to medium risk devices, the clinical evidence is not reviewed routinely by the TGA – the manufacturer is only required to have signed a declaration that the device conforms with the Essential Principles and that the supporting evidence of compliance, including clinical evidence, can be provided to the TGA if requested. Generally, the TGA will only see the clinical evidence under the following circumstances prescribed in the Regulations:

    (a) for medium to higher risk devices in relation to which the TGA must undertake an application audit, to confirm that the declaration of conformity is valid (these will be subject to a Level 2 audit); and
    (b) for higher risk devices in relation to which the TGA is required to issue a conformity assessment certificate following full review of technical (including clinical) documentation for the device to confirm the device performs as intended, does not pose any undue safety concerns and that the benefits of using the device outweigh the risks; and
    (c) irrespective of the risk level, under the circumstances of a post-market review.

Exempt goods

23. Some medical devices are exempt from requirements of the Act or from the requirement to be included in the ARTG in particular circumstances (see discussion below for ‘Export Only’ and ‘Custom-Made Medical Devices’).

24. This means that medical devices that have not been assessed by the TGA for quality, safety, and performance and included in the ARTG may still be accessed in certain legitimate circumstances via specific exemptions in the therapeutic goods legislation. Such exempt medical devices are also typically referred to as ‘unapproved medical devices’ or ‘unapproved therapeutic goods’.

25. There are four main mechanisms for legally accessing unapproved medical devices not included on the ARTG. These are:

    (a) the Clinical Trial exemptions;
    (b) the Authorised Prescriber Scheme;
    (c) the Special Access Scheme (SAS); and
    (d) personal importation.

Clinical trials in Australia

26. A clinical trial or clinical investigation is an experiment conducted in humans in order to assess the effects, efficacy and/or safety of a medicine, medical device or procedure/intervention.

Clinical trials of medical devices are undertaken to answer questions about their performance and safety. The responsibility for monitoring a clinical trial rests with the: sponsor; institution in which the trial is being conducted; ethics committee; and, the investigator.

27. Clinical trials must be approved by a Human Research Ethics Committee (HREC). The committee must be constituted and operating in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research. With respect to the conduct of a trial at a specific site, approval of the trial is required from a HREC with jurisdiction at that site.

28. It is important to distinguish between clinical trials and use of a device in an individual patient as part of clinical practice. Use of unapproved medical devices in individual patients as part of clinical patient care should be done using the provisions of the Authorised Prescriber or Special Access Scheme and not as a clinical trial.

29. There are two schemes under which clinical trials involving medical devices may be conducted, the Clinical Trial Notification (CTN) Scheme and the Clinical Trial Exemption (CTX) Scheme.

30. These schemes are used for clinical trials involving: any device not included in the ARTG and use of a device in a clinical trial beyond the conditions of its marketing approval.

31. It is a decision of the clinical trial sponsor with respect to which scheme they wish to use. The CTN process involves a notification only to the TGA with a nominal notification fee (no approval or decision is made by the TGA) and the CTX process comprises an assessment by the TGA of summary data and usage guidelines for a proposed clinical development programme, and if approval is granted the subsequent trials must be carried out under the terms of the approval and be notified to the TGA.

The Authorised Prescriber Scheme

32. The TGA is able to grant certain medical practitioners authority to prescribe a specified unapproved medical device or kind of medical device to recipients who have a particular medical condition. The medical practitioner becomes an 'Authorised Prescriber' and can prescribe that product for that condition to individual patients in their immediate care without further approval from the TGA.

33. The authorisation only allows the Authorised Prescriber to supply the device directly to specified patients and not to other practitioners who are not authorised to prescribe/administer the device to patients.

34. The basis for providing the approval is that the authorised medical practitioner has training and expertise appropriate for the condition being treated and the proposed use of the device and that the Authorised Prescriber is able to best determine the needs of the patient and to monitor the outcome of therapy.

35. Authorised Prescribers can supply individual patients with unapproved therapeutic goods under a range of circumstances, such as when devices: were provided initially to patients through a clinical trial while an application for inclusion on the ARTG is being considered; are available overseas but not in Australia; and/or no suitable alternative approved device is available in Australia.

36. Patients who may access unapproved medical devices prescribed by an Authorised Prescriber

are those suffering from an illness or condition that is either: life-threatening, or serious, being generally accepted as not being appropriate to be diagnosed or evaluated and treated safely without consulting a health practitioner.

The Special Access Scheme (SAS)

37. The SAS is a mechanism to provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. Applications are made by registered medical practitioners.

38. The SAS allows individual patients, with the support of their medical practitioner, access to unapproved devices in a range of circumstances, such as when: early access for terminally ill patients to almost any device, including experimental and investigational devices is needed (see Category A); devices were provided initially to patients through a clinical trial while a marketing application is being considered; and/or devices are available overseas but not in Australia.

39. Final responsibility for the use of an unapproved device within an institution always rests with that institution. Medical practitioners working in an institution may also need approval from the institution's Ethics Committee or Drug and Therapeutics Committee prior to using a particular device.

40. There are two categories of patients who may use the SAS:

    (1) Category A patients—medical practitioners can supply unapproved devices to some very seriously ill patients without the approval of the TGA as long as the medical practitioner notifies the TGA within 28 days. Category A patients are defined in the Therapeutic Goods legislation as ‘persons who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment’.

    (2) Category B patients—all other patients. Approval of an application to supply an unapproved device is required from a delegate in the TGA. Approval by the TGA is given on a patient by patient basis to reflect the needs of different patients.

41. The choice of classification of each patient lies with the treating medical practitioner. However, TGA is able to review, seek clarification and request information regarding the classification of patients under Category A.

Personal importation

42. Personal importation occurs when an individual: brings a medical device into Australia on their person or arranges from within Australia for a device to be sent to them from an overseas supplier.

43. The goods must be used by that individual or a member of his/her immediate family and must not be sold or supplied to any other person.

44. Individuals wishing to import unapproved devices for their personal use are advised by the TGA should be aware that in many cases the quality, safety and performance of the device may be unknown and they must therefore be prepared to accept any risks associated with the use of the device. If an individual suffers adverse consequences from using such devices, information about the goods and redress may be difficult to obtain.

45. Where the device is classified as low-medium risk (Class IIa) or higher, the quantity imported

must not exceed the amount required to deliver three months treatment using the device according to a treating medical practitioner's directions. The total quantity imported per year must not exceed 15 months treatment using the device according to a treating medical practitioner's directions. These supply restrictions do not apply to devices used for long-term treatment, such as a hip implant.

46. Individuals may import medical devices without the goods being included in the ARTG where: the goods are either for use by the importer or a member of the importer's immediate family; the goods do not contain a substance that is a prohibited import under the *Customs (Prohibited Imports) Regulations 1956*; the device is not manufactured using tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of bacterial or recombinant origin; and the device either does not incorporate or is not intended to incorporate derivatives of human blood or blood plasma.

Custom-made medical devices

47. Custom-made medical devices are exempt from the normal conformity assessment and registration procedures. A custom-made medical device is a medical device that:

    (a) is made specifically in accordance with a request by a health professional specifying the design characteristics or construction of the medical device; and
    (b) is intended:
        (i) to be used only in relation to a particular individual; or

        (ii) to be used by the health professional to meet special needs arising in the course of his or her practice (as defined in the dictionary of the Regulations).

48. Custom-made medical devices fall under a broad range of categories and risk levels and include devices such as prosthetic limbs and eyes, cranial implants, brachytherapy devices, stent-grafts for treating aortic aneurysms, dental implants and appliances.

49. Custom-made medical manufacturers and sponsors of custom-made devices must comply with special requirements which include: notifying the Secretary of their address and the types of devices they are manufacturing/supplying; performing a special conformity assessment procedure; reporting adverse events and recalls to the Secretary; and where instructions for use are necessary that they also contain an indication that the device has been custom-made.

Export only devices

50. Medical devices that are exported from Australia for non-commercial supply and that do not contain a substance that is prohibited under the *Customs Act 1901*, are exempt from inclusion in the ARTG.

Mutual recognition arrangements

51. The Aust-EU Mutual Recognition Agreement (MRA) is a trade agreement between the Government of Australia and the European Community (EC). The MRA itself covers multiple industry sectors, of which medical devices is just one.

52. The MRA allows the TGA to issue European conformity assessment certificates to Australian manufacturers to supply in Europe, and allows specified European Notified Bodies to issue

Australian conformity assessment certificates to European manufacturers for supply in Australia.

53. Specific types of medical devices are excluded from operation of the MRA:

    (a) radioactive materials that are medical devices;
    (b) devices incorporating tissues of animal origin (with some exceptions); and
    (c) certain devices that were subject to a transitional period (18 months) to allow for "confidence building" of the designation systems to occur. As no confidence building arrangements were entered into, the TGA does not accept EU MRA certificates for the following devices:
    (i) active implantable devices;
    (ii) intra-uterine contraceptive devices;
    (iii) heart valves;
    (iv) intra-ocular lenses;
    (v) intra-ocular visco elastic fluids;
    (vi) powered drug infusion pumps;
    (vii) implantable breast prostheses (except water/saline filled);
    (viii) barrier contraceptives (excluding condoms);
    (ix) instrument grade disinfectants.

54. For all other devices, the MRA requires the TGA to include devices on the ARTG within 5 work days of receiving an application, and without further assessment, if it is supported by a MRA certificate issued by a European Notified Body.

Post-market vigilance

55. The regulatory framework for medical devices includes provision for post market monitoring by the TGA including: checking evidence of conformity; conducting periodic inspections of manufacturer's quality management systems and technical documentation, including documentation held by a sponsor; and imposing specific requirements for manufacturers and sponsors to report, within specified timeframes, adverse incidents involving their medical devices.

56. In support of the TGA's post market monitoring activities, the sponsor (see Glossary) of a medical device has ongoing responsibilities once a device has been included in the ARTG. The Act requires that the sponsor must:

    (a) allow the TGA to enter and inspect its premises;
    (b) deliver samples to the TGA on request;
    (c) have access to information demonstrating compliance with the Essential Principles;
    (d) provide information to the TGA on request;
    (e) ensure that advertising material complies with the TGA requirements;
    (f) report adverse incidents;
    (g) report overseas regulatory action;
    (h) report to the TGA results of investigations undertaken by the manufacturer;
    (i) assist the TGA and manufacturer in investigation of incidents;

(j) maintain distribution records; and
(k) take corrective action (recalls and public notifications) when necessary.

57. Manufacturers also have ongoing obligations in respect of their devices which will vary depending on the conformity assessment procedures that they have chosen. The manufacturer also has specific obligations to:

(a) maintain appropriate records;
(b) allow TGA authorised inspectors to enter its premises and undertake inspections;
(c) cooperate with the TGA in any review to determine whether conformity assessment procedures have been applied to the devices covered by a conformity assessment certificate; and
(d) notifying the TGA of any plan for substantial changes to the quality management systems, the product range covered by those systems or the design of the devices covered by a conformity assessment certificate.

58. Market monitoring by the TGA is a series of activities carried out to ensure the ongoing regulatory compliance and safety of the medical devices supplied to the Australian market.

59. Monitoring activities can include:

(a) reviews of technical and clinical information to ensure that compliance with the Essential Principles is demonstrated;
(b) testing to confirm compliance with the Essential Principles;
(c) inspections of manufacturer's or sponsor's records and documentation;
(d) audits of distribution records;
(e) audits of the traceability of raw materials used in the manufacture of therapeutic goods and tracking of component parts;
(f) trend analysis and reporting to sponsors; and
(g) monitoring of information from relevant databases such as the National Joint Replacement Registry.

60. The current regulatory framework for medical devices adopts an approach based on the product life-cycle, from inception to end of product life. The manufacturer is expected to have, as part of its quality management system (see Glossary), a procedure for gathering information on the performance and safety of the device in the post-market phase and to consider that information to demonstrate the continued compliance of the device with the Essential Principles throughout the product life. This includes requirements for the manufacturer to maintain a system for receiving and investigating problem reports and complaints and for undertaking corrective action for a device.

61. Using data generated from such programs (e.g. safety reports, including adverse event reports, results from published literature, any further clinical investigations and formal post market surveillance studies; etc), a manufacturer is expected to periodically review performance, safety and the benefit-risk assessment for its device through a clinical evaluation, and update the clinical evidence accordingly. This ongoing clinical evaluation process should allow manufacturers to communicate with conformity assessment bodies and regulatory authorities any information that has an important bearing on the benefit-risk assessment of the device or that would indicate a need for labelling changes regarding contraindications, warnings,

precautions or instructions for use etc.

62. Sponsors are required to report individual adverse incidents involving their medical devices to the TGA within statutory timeframes that depend on the seriousness of the incident. Adverse incidents involving serious public health risks are to be reported within 48 hours. Serious adverse incidents that resulted, or may have resulted in death or serious injury are to be reported within 10 working days. Other adverse events that resulted in injury or may have resulted in injury are to be reported within 30 working days. The TGA reviews all individual adverse incidents reports and undertakes its own investigation if required.

63. The TGA refers all incidents and reports to the Medical Device Incident Review Committee (MDIRC) as part of its continuation of the nedd for further regulatory actions. In the case of orthopaedic implants the TGA uses advice from the OEWG and data from the National Joints Replacement Registry (NJRR) when considering further regulatory action.

64. The outcomes of the TGA's investigations may result in product recovery (recalls) or hazard and safety alerts, product modification/improvement by a manufacturer, surveillance audits of manufacturer sites and in extreme cases, suspension and cancellation of a product from the ARTG.

Enforcement framework

65. The Act includes a range of criminal and civil offences to ensure that the requirements in relation to medical devices are complied with. These include criminal and civil offences for:

    (a) importing, supplying or exporting a medical device that does not comply with the Essential Principles;
    (b) manufacturers and sponsors who supply medical devices to which the conformity assessment procedures have not been supplied;
    (c) for importing, exporting supplying or manufacturing medical devices that are not included in the ARTG;
    (d) breaching conditions attaching to the inclusion of a kind of medical device in the ARTG;
    (e) failing to report adverse incidents; and
    (f) providing false and misleading statements in relation to matters required by the Act.

66. The Act provides the Secretary with various administrative powers including the power to:

    (a) suspend or revoke conformity assessment certificates;
    (b) suspend or cancel entries in the ARTG;
    (c) to obtain information about a range of matters in relation to medical devices; and
    (d) require the recovery of medical devices, or to inform the public about medical devices, where the devices do not comply with the requirements of the legislation.

(Further information on can be found at < http://www.tga.gov.au/pdf/devices-argmd.pdf>)

Attachment 3 – Criteria for Listing on the Prostheses List

2.1. Criteria for listing on the Prostheses List

The legislation underpinning the prostheses arrangements does not define 'prosthesis'. Instead, criteria for listing products on the Prostheses List are applied by the advisory committee to each product assessed for listing. This helps to ensure that every product is considered in the same way, and that the advisory committee's recommendations for listing are consistent, fair and equitable.

Products meeting all of the following criteria are eligible for consideration for inclusion on the Prostheses List:

1. The product must be included on the Australian Register of Therapeutic Goods; and
2. The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment; and
3. A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist); and
4. The product should:
   (a) be surgically implanted in the patient and be purposely designed in order to:
      (i) replace an anatomical body part; or
      (ii) combat a pathological process; or
      (iii) modulate a physiological process; or
   (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted; or
   (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and
5. The product has been compared to alternate products on the Prostheses List or alternate treatments and:
   (i) assessed as being, at least, of similar clinical effectiveness; and
   (ii) the cost of the product is relative to its clinical effectiveness.

An explanatory note for the criteria is located at Attachment A to Attachment 5.

For new products and existing products on the Prostheses List, the CAGs and/or PoCE will determine whether or not a product meets criterion 2, 3, 4 and 5. Review against criterion 1 is undertaken by the Department and the Department assists with advice about whether or not the product meets criterion 3.

Attachment 4 – Prostheses List Products

	Types of Products	% of Total Products	% of Total Benefits
Knee	Femoral components, tibial tray components, tibial inserts, patello femoral replacements, patellar components, tumour prostheses, and accessories	11%	14.5%
Hip	Femoral components (primary and revision) and heads, acetabular components and reconstruction devices, special needs devices and accessories	13%	15.4%
Specialist Orthopaedic	Ankle joint components, sinus tarsi implants, replacements of other joints of foot, wrist, finger joint articulations, elbow and shoulder joints and accessories, intramedullary nails and accessories, plates, screws, pins and rigid wires, wires/cables/bands and accessories, staples, soft tissue fixation devices and substitutes, external fixateurs, bone cement and bone graft substitutes, metallic meshes	25%	13%
Neurosurgical	Aneurysm clips, dura defect repair grafts and liquid sealant, hydrocephalus devices, deep brain stimulation devices, neurostimulation therapies for pain management, intrathecal drug delivery stems, neurostimulation therapies for seizure control and neuro intervention stents, coils thrombectomy devices and assist devices	4%	5.0%
Ophthalmic	Anterior and posterior chamber intraocular lenses, viscoelastic fluids, capsular tension rings, iris prostheses, glaucoma drainage devices, eyelid prostheses, lacrimal duct drainage, orbital and retinal detachment prostheses	2%	0.4%
Cardiac	Implantable cardioverter defibrillators and leads, pacemakers and leads, coronary stents, special purpose percutaneous cardiovascular devices, implantable cardiac event recorders, endovascular therapeutic devices	3%	26.9%
Vascular	Bare metal stents, stent grafts for proximal and peripheral vessels, grafts, patches, vessel bands embolic protection devices, arterial closure devices, occlusion devices, longer-term vascular access devices, long-term catheters for peritoneal dialysis and drug eluting stents	5%	5.4%
Spinal	Fixation bone screws, plates, rods, washers, staples, C-rings, couplings, spacers interbody/fusion cages, replacement discs, nucleus and vertebral bodies	12%	7.5%
Urogenital	Incontinence prostheses, ureteric and urethral stents, urogenital reconstructive materials, penile and testicular prostheses, sacral neuromodulation and tubal obstruction devices, neophrostomy catheters	2%	2.0%

	Types of Products	% of Total Products	% of Total Benefits
Cardiothoracic	Mechanical and tissue valves and conduits, atrio-ventricular rings and bands, membranes and patches, assisted anastomotic devices, assisted fixation devices, grafts (proximal aorta), implantable cardiac assist devices	1%	1.4%
Plastic & Reconstructive	Bone reconstruction and fixation devices, craniomaxillofacial devices, dental implants, distractor systems, soft tissue, mammary implants and tissue expanders,	11%	3.6%
Ear, Nose & Throat	Ear: canal wall repair devices, cochlear implants and accessory kits, speech processors, implantable bone conduction hearing systems, ossicle/middle ear prostheses, ventilation tube/grommets. Nose: septal buttons and other nasal bone prostheses. Throat: tracheal speaking valves, oropharynx, vocal reproduction devices, vocal chord medialisation implants, tracheostomy stents, tracheal reconstruction and thyroplasty prostheses, injectable material for vocal fold augmentation/laryngeal reconstruction devices.	2%	1.9%
General Miscellaneous	Brachytherapy products, drug delivery devices including infusion and injection ports, external infusion pumps and accessories, pharmaceutical beads, vascular access and dialysis catheters; enternal tubes including enternal feeding tubes, gastrostomy tubes, jejunostomy tubes and caecostomy tubes; Gastric bands; haemostatic application devices; luminal stents; pleural and intraperitoneal effusion shunts and drainage catheters, end bronchial valves, implantable ECG recorders; tissue closure devices, adhesion barriers, legating clips, meshes, staples,	9%	3.0%

Attachment 5 – PLAC Terms of Reference and Protocol for Reporting Concerns to TGA

PROSTHESES LIST ADVISORY COMMITTEE (PLAC)

Terms of Reference and Business Rules

SEPTEMBER 2010

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1. Introduction

The Prostheses List Advisory Committee (PLAC) is established and members and the chair are appointed by the Minister for Health and Ageing. Its primary role is to advise the Minister about the listing of prostheses and their appropriate benefits in the Commonwealth Prostheses List. The List is made under the *Private Health Insurance Act 2007* and the Private Health Insurance (Prostheses) Rules which require private health insurers to pay benefits for those prostheses.

The Prostheses List arrangements, the PLAC and its predecessor, the Prostheses and Device Committee, were established to control inflation in private health insurance benefits paid for prostheses. The Prostheses List plays an important role in ensuring the sustainability of the Australian private health insurance system, and helps to achieve the Government's policy objective of ensuring private health insurance remains affordable and accessible to all Australians.

The PLAC forms part of the Commonwealth Health Technology Assessment (HTA) system. As outlined in the report of the *Review of Health Technology Assessment in Australia, 2009* (HTA Review), Commonwealth HTA processes should be:

- sustainable;
- transparent, accountable and independent;
- consultative and reflective of Australian community values;
- administratively efficient;
- flexible and fit for purpose; and
- informed by robust and relevant evidence.

HTA provides a means by which new technologies can be assessed and prioritised against existing health care interventions. This is achieved by determining best value for money for the Australian community by considering clinical and cost effectiveness to ensure that resources are used to support the lowest cost health care interventions for achieving the maximum health improvement.

The HTA Review recommended the processes supporting the Prostheses List be streamlined, and that these processes should be efficient, measured and proportionate. The terms of reference for the PLAC and arrangements supporting the Prostheses List will evolve over time as recommendations of the HTA Review are progressively implemented.

2. Role of the PLAC

2.1 Role of the PLAC

Box 2.1 lists the main roles of PLAC. Further details are set out below.

Box 2.1 – Main Roles of the Prostheses List Advisory Committee

- Provide advice to the Minister for Health and Ageing in a timely manner about prostheses submitted for inclusion on the Prostheses List, having regard to comparative qualitative clinical function and effectiveness, comparative cost effectiveness and comparative safety.
- Provide advice to the Minister for Health and Ageing in a timely manner about the grouping and description of prostheses included on the Prostheses List, having regard to whether listed prostheses have comparable qualitative clinical function and/or similar technical attributes.
- Provide advice to the Minister for Health and Ageing in a timely manner about appropriate private health insurance benefits for products included on the Prostheses List, having regard to comparative qualitative clinical function and effectiveness, comparative cost effectiveness, comparative safety and whether clinically relevant superiority vis-à-vis similar prostheses has been established.
- Refer evidence of identified concerns about the safety of prostheses in a timely manner to the Therapeutic Goods Administration for action.
- Provide advice about other matters as requested by the Minister for Health and Ageing.

2.2 Advice regarding prostheses submitted for listing

The PLAC provides advice to the Minister about whether prostheses should be included on the Prostheses List. This includes assessment of new applications for listing, and advice about whether existing listings should be maintained, amended or removed. In order to provide advice to the Minister, the PLAC considers:

- whether a submitted or listed product is a 'prosthesis' (see Box 2.2 on the next page);
- whether the prosthesis under consideration has similar clinical function, effectiveness and safety compared with other prostheses included on the Prostheses List intended to treat similar clinical conditions;
- whether the cost of the prosthesis under consideration is similar to other prostheses included on the Prostheses List intended to treat similar clinical conditions; and
- whether the prosthesis under consideration should only be listed on a conditional basis, and, if so, appropriate conditions that should be applied to its listing.

Box 2.2 – What is a prosthesis for the purposes of the Prostheses List?

1. The prosthesis must be included on the Australian Register of Therapeutic Goods (an application can be assessed by the PLAC before an ARTG number is issued, but no prosthesis may be included in the published Prostheses List without an ARTG number); and

2. The prosthesis must be able to be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment or the provision of the prosthesis is associated with podiatric treatment by an accredited podiatrist; and

3. A Medicare benefit must be payable in respect of the professional service associated with the provision of the prosthesis as part of an episode of hospital treatment or hospital-substitute treatment (an application can be assessed by the PLAC before a Medicare Benefit Schedule (MBS) item is issued, but no prosthesis can be included in the published Prostheses List until there is an MBS item for the associated professional service); and

4. The prosthesis is:

   (a) surgically implanted in the patient and is purposely designed in order to:

      (i) replace an anatomical body part; or

      (ii) combat a pathological process; or

      (iii) modulate a physiological process; or

   (b) is essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted; or

   (c) is critical to the continuing function of the surgically implanted product to achieve (a) (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and

5. Other devices, which do not meet this definition of prosthesis, but which meet legislated criteria for 'Part C' of the Prostheses List, are taken to be prostheses for the purpose of these terms of reference.

2.3 Advice about the grouping and description of prostheses

The PLAC advises the Minister about:

- the establishment and maintenance of groups of prostheses on the Prostheses List and the appropriate group in which a particular prosthesis should be included on the Prostheses List;
- appropriate grouping schemes for categories of prostheses, which will include sufficient subgroups and suffixes to appropriately distinguish between prostheses with different comparable clinical function, effectiveness and safety; and
- appropriate relativities between the benefits for prostheses with similar clinical function but with different effectiveness and/or safety and also across different groups containing similar prostheses.

Advice about the establishment and maintenance of groups of prostheses and the appropriate group for a prosthesis is critical in order to support single (benchmark) benefits for prostheses with similar clinical function, effectiveness and safety which will progressively be developed by the Department of Health and Ageing in implementing recommendation 12 of the *Review of Health Technology in Australia, 2009* (HTA Review). There is a very broad range of prostheses available in Australia, and it is necessary for the Prostheses List to include sufficiently detailed grouping schemes to allow all prostheses which have similar clinical function, effectiveness and safety to be grouped together with a single benefit.

Where there is insufficient evidence to provide advice about the comparable clinical function, effectiveness or safety of a prosthesis, the PLAC may advise the Minister based on whether the prosthesis has similar technical attributes, if it can be reasonably concluded that the prosthesis with the same or similar technical attributes is likely to have a similar clinical function, effectiveness and safety.

The PLAC may consider and provide advice to the Minister about changes to the description and/or product name for listed prostheses, and necessary expansions or compressions of billing codes for new applications or existing listings. These types of changes may require clinical assessment. Product descriptions need to be accurate and unambiguous to assist in correct grouping of prostheses on the Prostheses List.

The PLAC may review at the request of the Minister or on its own motion, Prostheses List groupings to ensure that the groupings remain up to date and include appropriate benefits for groups of similar prostheses and appropriate benefit relativities across different groups of related prostheses on the Prostheses List. Following these reviews, the PLAC may advise the Minister regarding changes to the Prostheses List. These reviews will not commence until after implementation of recommendation 12 of the HTA Review for particular groups of prostheses.

2.4 Advice about appropriate private health insurance benefits

The PLAC advises the Minister about appropriate benefits that are to be paid by private health insurers for prostheses included on the Prostheses List. This advice informs the Minister's consideration of benefits that are prescribed under the Prostheses Rules, and must be paid by a private health insurer when a prosthesis is provided in accordance with section 72-1 of the *Private Health Insurance Act 2007*.

The PLAC provides advice about appropriate benefits for prostheses that are recommended for or listed on the Prostheses List. This includes new applications for listing, and advice about whether benefits for existing listings should be maintained or amended. In order to provide advice to the Minister, the PLAC considers:

- whether or not the prosthesis under consideration has similar clinical function, effectiveness and safety compared with other prostheses included on the Prostheses List intended to treat similar clinical conditions; and
- whether the benefit for the prosthesis under consideration is cost effective compared with other prostheses included on the Prostheses List intended to treat similar clinical conditions.

The PLAC may from time to time, at the request of the Minister or on its own motion, review benefits to ensure that the benefits remain up to date, equitable, and include appropriate relativities across different groups containing similar prostheses on the Prostheses List. Following these reviews, the PLAC may make appropriate recommendations to the Minister about changes to the Prostheses List. These reviews will not commence until after implementation of recommendation 12 of the HTA Review for particular groups of prostheses.

2.5 Refer concerns about the intrinsic safety of prostheses to the Therapeutic Goods Administration

Where the PLAC identifies concerns about the intrinsic safety of a prosthesis in carrying out its functions under these terms of reference, it must refer these concerns to the Therapeutic Goods Administration (TGA) in accordance with the formal protocols in place between the PLAC and the TGA. The TGA will action and respond to these concerns as required under the protocols.

2.6 Provide advice about other matters as requested by the Minister for Health and Ageing

The PLAC will provide advice to the Minister about matters in addition to those outlined above, as requested by the Minister.

3. Chair

The chair of the PLAC will be an independent person appointed by the Minister, usually for a four year period. The chair will report to the Minister on the activities of the PLAC, its sub-committees and working groups.

The chair will work closely with the PLAC secretariat and will oversee any other work requested by the Minister or the Department. If unavailable for all or part of a scheduled PLAC meeting, the chair will delegate the role to an experienced member of the PLAC.

4. Structure

4.1 Membership of the Prostheses List Advisory Committee

Members of the PLAC are appointed by the Minister, and include an independent chair and members with expertise in specialist surgery/interventional work, consumers' issues, health economics, hospital administration, private health insurance and the medical device industry.

Terms are for four years, with members able to nominate for consecutive terms. Appointments may be staggered to allow for continuity of committee membership.

To enable a PLAC meeting to proceed and for decisions to be valid, a quorum constitutes half the number of members plus one. The chair (or their alternate) must also be present.

The PLAC may establish subcommittees, comprising members or co-opted individuals with appropriate expertise, to help it perform its roles under these terms of reference. The PLAC is not bound to accept the advice of its subcommittees in providing advice to the Minister.

4.2 Subcommittees

Current standing subcommittees of the PLAC include:

- the *Panel of Clinical Experts* which provides clinical advice about neurosurgical, plastic and reconstructive, ear/nose/throat, and general and miscellaneous prostheses;
- the *Cardiac Prostheses Clinical Advisory Group* which provides clinical advice about cardiac prostheses;
- the *Cardiothoracic Prostheses Clinical Advisory Group* which provides clinical advice about cardiothoracic prostheses;
- the *Hip Prostheses Clinical Advisory Group* which provides clinical advice about hip prostheses;
- the *Knee Prostheses Clinical Advisory Group* which provides clinical advice about knee prostheses;
- the *Ophthalmic Prostheses Clinical Advisory Group* which provides clinical advice about ophthalmic prostheses;
- the *Specialist Orthopaedic Clinical Advisory Group* which provides clinical advice about orthopaedic prostheses excluding hip, knee and spinal prostheses;
- the *Spinal Prostheses Clinical Advisory Group* which provides clinical advice about spinal prostheses;
- the *Urogenital Prostheses Clinical Advisory Group* which provides clinical advice about urogenital prostheses;
- the *Vascular Prostheses Clinical Advisory Group* which provides clinical advice about vascular prostheses; and
- the *Negotiating Oversight Committee,* which provides advice about benefits for listed prostheses and new applications.

The chairs of subcommittees must be considered experts in their field and may be required to attend PLAC meetings when necessary. Each subcommittee will be required to regularly report to the PLAC on progress of issues.

Each subcommittee will operate according to terms of reference approved by the PLAC. Membership will include subject matter experts and, may from time to time call upon the advice of other external and/or expert advisors at the discretion of the individual subcommittee chair.

5. Meeting Arrangements

5.1 Frequency, attendance and costs

The PLAC will meet approximately 14 times per year either face to face or via teleconference. Members will agree to the schedule of meeting dates six-monthly following the publishing of the Prostheses List. The meeting venue will be arranged by the secretariat at the discretion of the chair.

The Department will meet the cost of the participation of the chair and members of the committee with expertise in specialist surgery/interventional work, consumers' issues, health economics, hospital administration, private health insurance and the medical device industry.

Members are appointed as individuals to the PLAC, for their expertise. Members are not permitted to discuss the business of PLAC meetings with individuals who are not part of the PLAC. However, members are expected to present the views and positions of the groups they have been nominated by to the best of their individual understanding.

Proxies are not permitted to attend PLAC meetings. If a member is unable to attend a meeting, an observer may attend the meeting subject to prior arrangements made with the secretariat, in consultation with the Chair. Observers will not be remunerated for any expenses. Observers must complete the deed of confidentiality and conflict of interest and will not have voting/decision making rights.

5.2 Agenda, meeting papers and minutes

The secretariat will call for meeting agenda items from members ten working days prior to the scheduled meeting. The draft agenda will then be cleared by the PLAC chair before it is circulated to members.

Agenda papers are required to be submitted to the secretariat seven working days prior to the meeting. This will allow the secretariat to circulate the meeting agenda and papers five working days prior to each meeting.

Minutes of PLAC meetings including a list of action items will be circulated by the secretariat to Departmental staff within three weeks following the meeting and will be provided to PLAC members prior to the next PLAC meeting.

6. Conflict of Interest

All members of the PLAC are required to identify, in writing, any personal interest that may give rise to a perceived, potential or actual conflict of interest with their role on PLAC (that is, with their fiduciary duty to the Minister for Health and Ageing).

Within one month of being appointed to the PLAC, the chair of the PLAC must give to the Minister, and the members of the PLAC must give to the chair, a written declaration of interests the member has that may relate to any activity of the PLAC, and sign the Department of Health and Ageing 'Deed of Undertaking in Relation to Confidential Information and Conflict of Interest', which outlines each member's obligations in respect to managing conflict of interest.

If any situation that may give rise to a perceived, potential or actual conflict of interest subsequently arises, the member must immediately declare in writing to the chair of the PLAC and the chair must notify the Minister for Health and Ageing (or delegate) and seek the Minister's agreement to the manner in which the conflict is managed.

The chair will ensure that all members are asked to declare any conflicts of interest at the beginning of each meeting of the PLAC, and that all conflicts reported and actions arising are documented in the minutes of the meeting.

Perceived, potential or actual conflicts of interest may include, but are not limited to, the PLAC member or their immediate family having:

- a direct or indirect financial interest in a company which has applied for listing on the Prostheses List, or is a competitor of companies which have applied for listing on the Prostheses List;
- employment by a company which has applied for listing on the Prostheses List, or is the competitor of companies which have applied for listing on the Prostheses List;
- employment by a company which has a direct or indirect financial interest in a company which has applied for listing on the Prostheses List, or is a competitor of companies which have applied for listing on the Prostheses List;
- participation in legal action against a company which has applied for listing on the Prostheses List, or is the competitor of companies which have applied for listing on the Prostheses List;
- participation in clinical trials for a company which has applied for listing on the Prostheses List, or is a competitor of companies which have applied for listing on the Prostheses List;
- financial payments or gratuities from a company which has applied for listing on the Prostheses List, or is a competitor of companies which have applied for listing on the Prostheses List;
- the receipt of sponsorship or payment to attend conferences or other events provided by a company which has applied for listing on the Prostheses List; or

- the receipt of other non-financial benefits provided by a company which has applied for listing on the Prostheses List.

If a conflict of interest is identified, the member may be required to remove themselves from any discussion or the decision-making process pertaining to the conflict of interest.

7. Key Performance Indicators

To be developed (consistent KPIs for all Commonwealth HTA processes).

8. Review of Recommendations of PLAC

To be developed (consistent review processes for all Commonwealth HTA processes).

9. Prostheses List Guide

The Prostheses List Guide available on the Department of Health and Ageing website provides detailed information about how the PLAC and its subcommittees fulfill their roles, including any guidelines or protocols that may be developed. The Prostheses List Guide also has information about the Prostheses List application process.

PROSTHESES LIST ADVISORY COMMITTEE

Protocol for Reporting Concerns with Prostheses to the Therapeutic Goods Administration

OCTOBER 2010

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1. OVERVIEW

This document outlines the agreed processes for the Prostheses List Advisory Committee (PLAC) to provide information (including concerns about the safety of a prosthesis) to the Therapeutic Goods Administration (TGA) and for the TGA to respond to this information.

2. BACKGROUND

Both the *Review of the Prostheses Listing Arrangements, 2007* (Doyle Review) and the *Review of Health Technology Assessment in Australia, 2009* (HTA Review) highlighted concerns that the Prostheses and Devices Committee (PDC) (replaced by the PLAC) may be attempting to assess the intrinsic safety of prostheses it is assessing for private health insurance reimbursement.

The TGA has statutory responsibility for:

- *"assessing the quality, safety and efficacy*[1] *of medical devices entering the Australian market. In doing so, they assess the safety of a product itself ("intrinsic safety"), rather than comparing its safety with that of other comparable products*[2]*; and*
- *investigating issues with medical devices post-market, including pro-active reviews of device performance post approval."*

The terms of reference for the PLAC state that in providing advice to the Minister for Health and Ageing in a timely manner about prostheses submitted for inclusion on the Prostheses List, the PLAC (and its subcommittees) will have regard to comparative clinical function and effectiveness, comparative safety, and comparative cost effectiveness.

Any concerns that the PLAC has about the performance of a prosthesis (including intrinsic safety) that arise during the assessment of a new application or review of a currently listed product for the purposes of private health insurance reimbursement through the Prostheses List will be referred to the TGA for investigation.

3. THE THERAPEUTIC GOODS ADMINISTRATION'S POST-MARKET REPORTING MECHANISM

Post-market surveillance has an important role to play in protecting the community and in ensuring the efficiency and sustainability of the health system. The HTA

[1] The *Therapeutic Goods Act 1989* (Para 4(1A)) defines 'efficacy' for medical devices to be the performance of the device as intended by the manufacturer.

[2] It should be noted that, in many instances, clinical evidence supplied by a manufacturer in support of clinical efficacy and performance is often a 'comparative review' with similar devices, which may be literature based or clinical trial based. Comparative devices cited in such studies may or may not be supplied to the Australian market.

Review recommended action to improve the post-market surveillance of devices. These include adopting a more proactive and sustained approach to post-market surveillance for device safety, expanding the scope of post-market surveillance beyond the current focus on safety to include the collection of cost-effectiveness data to support future reimbursement decisions, and using data from post-market surveillance to evaluate technologies funded for reimbursement on an interim basis.

The TGA has a formal mechanism by which anyone (member of the public, the medical profession or any other stakeholder) can report problems with medical devices. The relevant website for further information is: http://www.tga.gov.au/problem/devices.htm.

The TGA has developed a reporting form (**Attachment 1**) which contains the necessary information to allow the TGA to investigate concerns with medical devices.

4. RESPONSIBILITY FOR THIS PROTOCOL

4.1 Maintenance of the Protocol

The Department of Health and Ageing will maintain this protocol as required.

4.2 Reporting Concerns to the TGA

The PLAC and its clinical subcommittees will report concerns about the intrinsic safety of products to the TGA. Concerns may arise during the clinical assessment process or during PLAC consideration of applications.

4.3 The TGA reporting back to the PLAC

The Director, Devices, Office of Product Review (OPR) has responsibility for reporting back to the PLAC on actions taken in response to a report being received.

5. STEPS FOR PROVIDING POST-MARKET FEEDBACK TO THE THERAPEUTIC GOODS ADMINISTRATION

5.1 Induction of PLAC members and its clinical subcommittees

The induction process includes information on the clinical assessment activities of the TGA and the PLAC – including an outline of the differences in purposes of the assessments, assessment processes and an overview of the reporting of adverse events to the TGA.

5.2 Regular meetings of the TGA and the Prostheses List Secretariat

Regular face-to-face meetings between the TGA and Prostheses List Secretariat are held. At a minimum, these are held twice a year (coinciding with the publication of the Prostheses List), with further meetings held as required.

The purpose of these meetings is to share information about the performance of medical devices to inform the TGA's regulatory functions and the PLAC's HTA for reimbursement function; and other relevant issues.

The PLAC Chair and/or clinical subcommittee chairs will attend these meetings where possible.

5.3 Formal reporting to the TGA

The PLAC will report concerns regarding intrinsic safety to the TGA immediately. Individual clinicians participating in Prostheses List assessment processes will be encouraged to report intrinsic safety concerns they have, either during their daily work or upon assessment of an application, immediately to the TGA.

Formal reporting to the TGA can occur in a number of ways:

- PLAC and subcommittee members may find the data they are reviewing while assessing applications for the Prostheses List raise issues about the performance and/or safety of a product (including intrinsic safety concerns); or
- through the use of products already on the Prostheses List and/or liaison with other clinicians, PLAC and subcommittee members may become aware of issues about the performance and/or safety of products.

In both instances, the member should immediately refer the concerns to the TGA through its post-market feedback mechanism, and also inform the PLAC. The concerns should be accompanied by evidence, and, where possible include information as required by the TGA's reporting form at **Attachment 1**.

To complement these reports, where a device has not been included on the Prostheses List due to comparative safety issues, the PLAC Secretariat will forward a copy of the non granting letter (which contains reasons for decline) to the Director, OPR.

5.4 Acknowledgment of reports by the TGA

The TGA will review and risk assess the information provided, investigate where necessary using its existing protocols and procedures and report to the PLAC on completion of its investigation. Two responses from the TGA will be provided:

1. Acknowledgement of receipt of the report (within one calendar month) and planned action (if any) – this may include future targeted post market surveillance and timeframes for investigation. This will be the only response if it is deemed that an investigation is not necessary.
2. If an investigation is undertaken, the results of the investigation, or six monthly progress reports (if the investigation is going take longer than six months).

The advice to the PLAC will be in the form of the Incident Report Investigation Scheme database investigation completion report or in the case of a review, a formal report outlining evidence reviewed, findings of the review including supporting rationale, and a recommendation to the PLAC.

Attachment 1

Users Medical Device Incident Report eg Doctors, Nurses, Patients, Public

What should be reported? A medical device is any material instrument, apparatus, machine, implement, contrivance, implant etc (including any component, part or accessory) which is used in health care and includes in-vitro diagnostics. Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design. Suggestions for rectifying the problem or improving product performance would be appreciated.

What should you do with the device? **Please keep the device and its associated packaging until you are contacted by the TGA/Medsafe**. To send the device please follow the instructions in this link http://www.tga.gov.au/problem/iris/devices-testing.htm

What happens to your report? The report will be investigated and discussed with the manufacturer/supplier. You may be contacted for further information. The report may also be reported to other Health Authorities. If action is considered necessary it may involve any of the following:

1. Recall - removal of goods from sale or use, or their correction, for reasons relating to safety, performance or quality.
2. Safety Alert – information relating to the correct use of the device to inform those responsible for the device, or affected by the problem.
3. Report in a TGA News Bulletin (a communication produced by the TGA and distributed in Australia and New Zealand to convey information on medical devices) or other appropriate journal(s).

Medical device manufacturers or suppliers should use form # MDIR03
http://www.tga.gov.au/docs/html/forms/iris_mdir.htm

A	**Product Identification**	*Please provide all available details*		Date of Report:	
1.	Brand/Trade Name				
2.	Device Description *(eg Urinary Catheter)*				
3.	Device Identification	Model	Serial Number	Batch Number	Lot Number
4.	Relevant Dates	Purchase (*Approximate*)	Expiry	If Device is Implantable *(eg pacemaker, venous port etc)* Date of Implant	Date of Explant
5.	Manufacturer's name address & telephone				
6.	Supplier's name address and telephone				
B	**Reporting the Problem**	*Please provide all available details*			
7.	Has the supplier been informed of the problem?	☐ YES ☐ NO	If YES Date Contacted	If YES add contact details Name	Phone / Fax
					( )
8.	Where is the device now?	☐ Place of use ☐ With Reporter ☐ With Supplier ☐ With Patient	Please **Do Not** discard the device or related consumables & packaging	Contacts for access to device Name	Phone / Fax
					( )
9.	Is this device supplied sterile?	☐ YES ☐ NO	Is this device reusable?	☐ YES ☐ NO	Is this device single use? ☐ YES ☐ NO
C	**Problem Description**	*Please provide all available details* *If you do not have enough space please add information onto another sheet of paper or into the body of your email.*			

10.	Add a brief description of the problem. Include what led to, or contributed to the problem.	
11.	Add a brief description of the consequences or outcome of the problem.	*Please add sketches and pictures if necessary and/or available*

D Reporter *Please provide all available details*

12. Do you want your identity to remain confidential?

*If **YES** your name & contact details will not be disclosed to manufacturers or suppliers without your permission. TGA will contact you if more information is needed.*

☐ YES
☐ NO

A report without contact details cannot be processed.

Name	Position / Occupation
Department, Institution & Address	**Phone** ( )
	Fax ( )
email	

E Initial Reporter *Please provide all available details*

13. Do they want their identity to remain confidential?

*If **YES** their name & contact details will not be disclosed to manufacturers or suppliers without their permission. TGA will contact them if more information is needed.*

☐ YES
☐ NO

If **YES or NO** add contact details below

Name	Position / Occupation
Department, Institution & Address	**Phone** ( )
	Fax ( )
email	

F TGA Feedback *Please provide all available details*

14. Who can TGA or Medsafe contact for more information regarding this incident?

☐ Reporter ☐ Initial Reporter ☐ Other Appropriate Person Phone & Fax

Name	*Name*	*Name*	*Phone:* ( ) *Fax:* ( )

G How to submit Post, Fax or email your completed form to:

	✉ Post to		🖱 email / intranet	🖷 Fax to	☎ Phone
Australian Reporters **TGA**	**Reply Paid 100** Medical Device IRIS TGA, PO Box 100 Woden ACT 2606 AUSTRALIA	**Courier delivery:** TGA 136 Narrabundah Ln, Symonston ACT 2609, AUSTRALIA	iris@tga.gov.au www.tga.gov.au/docs/html/forms/iris_udir.htm	**(02) 6232 8555**	**FREE HOTLINE 1800 809 361**
New Zealand Reporters **MEDSAFE**	✉ Post to		🖱 email / intranet	🖷 Fax to	☎ Phone
	Robert Jelas Senior Advisor Compliance Management MEDSAFE Ministry of Health Deloitte House 10 Brandon Street PO Box 5013 Wellington NEW ZEALAND		Robert_Jelas@moh.govt.nz www.medsafe.govt.nz www.moh.govt.nz	**(04) 819 6806**	**(04) 819 6881**

PROSTHESES LIST PRODUCTS

	Types of Products	% of Total Products	% of Total Benefits
Knee	Femoral components, tibial tray components, tibial inserts, patello femoral replacements, patellar components, tumour prostheses, and accessories	11%	14.5%
Hip	Femoral components (primary and revision) and heads, acetabular components and reconstruction devices, special needs devices and accessories	13%	15.4%
Specialist Orthopaedic	Ankle joint components, sinus tarsi implants, replacements of other joints of foot, wrist, finger joint articulations, elbow and shoulder joints and accessories, intramedullary nails and accessories, plates, screws, pins and rigid wires, wires/cables/bands and accessories, staples, soft tissue fixation devices and substitutes, external fixateurs, bone cement and bone graft substitutes, metallic meshes	25%	13%
Neurosurgical	Aneurysm clips, dura defect repair grafts and liquid sealant, hydrocephalus devices, deep brain stimulation devices, neurostimulation therapies for pain management, intrathecal drug delivery stems, neurostimulation therapies for seizure control and neuro intervention stents, coils thrombectomy devices and assist devices	4%	5.0%
Ophthalmic	Anterior and posterior chamber intraocular lenses, viscoelastic fluids, capsular tension rings, iris prostheses, glaucoma drainage devices, eyelid prostheses, lacrimal duct drainage, orbital and retinal detachment prostheses	2%	0.4%
Cardiac	Implantable cardioverter defibrillators and leads, pacemakers and leads, coronary stents, special purpose percutaneous cardiovascular devices, implantable cardiac event recorders, endovascular therapeutic devices	3%	26.9%
Vascular	Bare metal stents, stent grafts for proximal and peripheral vessels, grafts, patches, vessel bands embolic protection devices, arterial closure devices, occlusion devices, longer-term vascular access devices, long-term catheters for peritoneal dialysis and drug eluting stents	5%	5.4%
Spinal	Fixation bone screws, plates, rods, washers, staples, C-rings, couplings, spacers interbody/fusion cages, replacement discs, nucleus and vertebral bodies	12%	7.5%
Urogenital	Incontinence prostheses, ureteric and urethral stents, urogenital reconstructive materials, penile and testicular prostheses, sacral neuromodulation and tubal obstruction devices, neophrostomy catheters	2%	2.0%
Cardiothoracic	Mechanical and tissue valves and conduits, atrio-ventricular rings and bands, membranes and patches, assisted anastomotic devices, assisted fixation devices, grafts (proximal aorta), implantable cardiac assist devices	1%	1.4%
Plastic & Reconstructive	Bone reconstruction and fixation devices, craniomaxillofacial devices, dental implants, distractor systems, soft tissue, mammary implants and tissue expanders,	11%	3.6%
Ear, Nose & Throat	Ear: canal wall repair devices, cochlear implants and accessory kits, speech processors, implantable bone conduction hearing systems, ossicle/middle ear prostheses, ventilation tube/grommets. Nose: septal buttons and other nasal bone prostheses. Throat: tracheal speaking valves, oropharynx, vocal reproduction devices, vocal chord medialisation implants, tracheostomy stents, tracheal reconstruction and thyroplasty prostheses, injectable material for vocal fold augmentation/laryngeal reconstruction devices.	2%	1.9%
General Miscellaneous	Brachytherapy products, drug delivery devices including infusion and injection ports, external infusion pumps and accessories, pharmaceutical beads, vascular access and dialysis catheters; enternal tubes including enternal feeding tubes, gastrostomy tubes, jejunostomy tubes and caecostomy tubes; Gastric bands; haemostatic application devices; luminal stents; pleural and intraperitoneal effusion shunts and drainage catheters, end bronchial valves, implantable ECG recorders; tissue closure devices, adhesion barriers, legating clips, meshes, staples,	9%	3.0%