



Human Tissue Review

Submission by
Medical Technology Association of Australia

June 2009

Medical Technology for a Healthier Australia

1. Executive summary

The Medical Technology Association of Australia has provided a comprehensive submission to the Health Technology Assessment Review. Proposals in that submission regarding the health technology assessment of medical technology are equally applicable to the assessment of human tissue products. This submission should be considered in conjunction with the MTAA Health Technology Assessment Review submission and applicable resulting reforms should be implemented as part of a coordinated reform package.

It is evident that the conduct of Part B, the Human Tissue List of the Prostheses List is a considerably smaller activity than Part A, and as a consequence has not been subjected to the same level of process engineering. Part B processes are not the subject of formal and adequate guidance, and are predominantly conducted by officials of the Department of Health and Ageing. It is unclear to what extent expert clinical assessment is conducted. Expenditure and utilization data is not available for Part B.

MTAA:

- Recommends that the meaning of “human tissue” and “human tissue products” be officially defined in order that processes applied to produce human tissue products may be acknowledged
- Agrees that profit should not be derived from trade in human tissue
- Recommends that the commercialisation of human tissue products be accepted as a legitimate element in the processing of human tissue to produce human tissue products
- Recommends that the health technology assessment of human tissue products be in accordance with the MTAA proposed HTA model which will operate with an independent and professional HTA body and a separate pricing function
- Recommends that formal guidance on the processes for listing human tissue products be developed and published
- Recommends that the structure of the Human Tissue List be reviewed in consultation between suppliers of human tissue products and specialist clinicians to establish an equitable and appropriate grouping matrix which will ensure that as far as practical, clinically comparable items are grouped together
- Recommends that autologous items be retained as an appropriate and discrete category of Part B of the Prostheses List
- Recommends that procedures be introduced to monitor expenditure on, and utilisation of Part B of the Prostheses List

2. About the medical technology industry

MTAA represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability.

There are 9,492 products listed on the Prostheses List (PL) at February 2009, of which the majority are listed by member companies of MTAA. Part B, Human Tissue List, of the PL contains 267 listings. Two MTAA members list products on Part B.

The Australian market for medical technology is approximately 2% of the global market. Because of its small size, this means that companies developing innovative technologies will always need to consider the potential return on investment in making a decision as to whether to bring a technology into Australia or invest in development of a new technology in Australia.

3. Current arrangements for reimbursement of human tissue products

Current arrangements for the listing of human tissue products, Part B of the PL, lack the structure and organisational processes that have been applied to Part A of the Prostheses List. MTAA believes that the Part A PL processes are flawed and therefore this submission does not hold up Part A as a model to be applied to Part B. This has been covered in MTAA's submission to the HTA Review and can be accessed at:

<http://www.mtaa.org.au/pages/page5.asp>

Specifically MTAA makes the following observations with regard to the operations of Part B, Human Tissue List, of the PL:

- *The Prostheses List Guide to listing and setting benefits for prostheses* is in two parts:
 - *Part 1 – Understanding the Prostheses Arrangements* (61 pages)
 - *Part 2 – Making an application for inclusion in the Prostheses List* (34 pages)
- The Guide is supported by numerous application forms
- There are three application forms available on the Department of Health and Ageing's website under the title "Application Forms for the Prostheses List", that are applicable to suppliers of human tissue products:
 - *Prostheses List Application to Amend Human Tissue Listings*, and
 - *Prostheses List Application to list a prostheses Human Tissue form*
 - *Prostheses List Application to list a prostheses, Duplication, Expansion, Compression and Transfer Form*
- There is no guidance in Part 1 or Part 2 of the Guide regarding the Human Tissue List and scant guidance contained within the forms. While the first two forms remind suppliers of human tissue items of their obligations to comply with relevant state and territory legislative requirements in relation to the sale of their products and the service cost, the Department's position with regard to profiting from the sale of human tissue and human tissue products is not explicitly stated.
- There is no definition of human tissue or human tissue product in the covering legislation, *Private Health Insurance Act 2007*, however the Private Health Insurance (Prostheses Application and Listing Fee) Rules define human tissue prosthesis as:
 - **human tissue prosthesis** means a product that is substantially derived from human tissue where the tissue has been subjected to processing

or treatments and the supply (however described, including trade, sell, give or gift) of which is governed by State or Territory law.

- There is no application or listing fee applicable to Part B of the Prostheses List as there is to Part A which is \$600 and \$200 respectively.
- Assessment of applications and negotiation of benefits is conducted “in-house” by members of the Department’s Prostheses Secretariat.
- Part B of the Prostheses List contains 267 listings in three categories: cardio-thoracic, ophthalmic and orthopaedic. The List has a further 175 product category titles throughout. Judging by the variation in benefits, products may not be consistently listed with other comparable products.
- In his report, Mr Doyle noted that “there were very few submissions which addressed this term of reference,¹ and most parties I consulted did not have a view on it.”² A review of the list of submissions³ and relevant contributors confirms that Mr Doyle would have had little upon which to base any noteworthy observations. This would also explain why his first recommendation in response to the “human tissue” term of reference was to recommend a further review.
- Unlike Part A, it is noted that Part B has minimum benefits only, i.e. there are no entries in the column titled “maximum benefit” as it is understood that co-payments are not permitted.
- Although the Private Health Insurance Administration Council collates the total expenditure by health funds on Part A of the PL, such figures are not available in respect to Part B. The existence of total utilisation statistics is not known. These data should be available to inform decision makers and stakeholders.

It can be concluded that there has been a low constituency for change to a scheme that notably lacks formal structure, processes and official guidance. Even if the MTAA HTA model were to be applied to Part B listing processes, the requirement would remain to address the following:

- Officially define the meaning of “human tissue” and “human tissue products”
- Formally pronounce the approved position with regard to profiting from the sale of human tissue products
- Publish formal guidance on the processes for listing human tissue products
- Review the structure of the Human Tissue List to ensure that as far as practical, clinically comparable items are grouped together
- Introduce procedures to monitor expenditure on, and utilisation of Part B of the PL

¹ ToR 5. recommend appropriate arrangements to cover human tissue products included on the Prostheses List

² Report of the Review of the Prostheses Listing Arrangements, October 2007(the “ Doyle Report”) page 34

³ Ibid pp 36 - 38

4. Discussion of the Terms of Reference and related questions

This section will examine the Review's Terms of Reference, following the guidance and questions provided in the Human Tissue Review Discussion Paper of 11 May 2009.

Term of Reference No 1

To assess items (and their sponsors) currently on Part B of the Prostheses List to ensure they meet Australian legislative requirements (including the Private Health Insurance Act 2007 and the various states/territories Human Tissue Acts) and are consistent with Government policy objectives.

Consideration to be given to:

- **whether a Medicare benefit is payable for the medical act associated with the provision of the prosthesis;**
- **whether autologous items should be listed;**
- **whether the listing of items is consistent with the principle that no profit should be derived from trade in human tissue; and**
- **whether TGA licensing requirements are met.**

QUESTIONS

1. Are all items on Part B Human Tissue of the Prostheses List consistent with legislation?

Although PHI legislation does not provide a definition of human tissue items, the Rules do. MTAA members' involvement in PL Part B at this time is primarily with autologous products and their eligibility for listing is addressed below. MTAA has no issue with parallel regulatory or MBS item requirements.

2. Should autologous items be removed from the Prostheses List? Why? Why not?

MTAA notes that the Doyle Report stated that "autologous products... are produced by taking an individual's tissue, manipulating it in some way and then implanting it in that individual...this is essentially a therapeutic process rather than a manufacturing one, and these items should be removed from the List."⁴ As the definition of "human tissue prostheses"⁵ contained in the PHI Rules does not specifically differentiate autologous human tissue products from allogeneic human tissue products⁶, Doyle's proposed removal of these products from Part B is not substantiated and it is not evident in any official guidance why this should occur.

⁴ Report of the Review of the Prostheses Listing Arrangements, October 2007, (the "Doyle Report") page 21.

⁵ Human Tissue Review Discussion Paper 11 May 2009, p 18 - "a human tissue prostheses means a product that is substantially derived from human tissue where the tissue has been subjected to processing or treatments..."

⁶ And neither does the NHMRC issues paper: Ethics and the Exchange, Sale of and Profit from Products derived from Human Tissue: an issues paper. NHMRC April 2009

MTAA notes and supports the proposal by Genzyme⁷ in their submission to the review that a new category be established for autologous products as an appropriate way of identifying a subset within the spectrum of human tissue products.

3. What implications are there from the statement – no profit should be derived from trade in human tissue?

There is a need to separate this supposition into two elements the first of which relates to deriving profit from trade in human tissue. MTAA readily acknowledges the broad public support for the prohibition on commercialisation of human tissue that has been identified by the National Health and Medical Research Council⁸ and does not propose a change to this position. However we note that it may be necessary to recover costs associated with movement and holding of human tissue and that this is not unlike current practice in blood, bone and eye banks.⁹

The second element of this question relates to obtaining a return on investment from the processes applied to human tissue which deliver human tissue products to patients. MTAA believes that capital and intellectual investment will not be nurtured for the achievement of better health outcomes and improvement in patients' quality of life if this principle is applied to the processing of human tissue. In particular we note three observations in the NHMRC issues paper of particular relevance here:

- NHMRC has previously “recognised that human-derived products are often superior to synthetic products”¹⁰
- “Commercialisation of human tissue products may result in increased costs in order to cover the cost of associated research and development, marketing, infrastructure and profit...However it may be in those research and therapeutic areas where community benefit is the greatest that commercialisation is most needed to fund the high costs and significant risks of research and development.”¹¹
- “The Working Committee believes that the current legislation and guidelines applying to human tissue do not adequately provide for the regulation of products derived from human tissue.”¹²

We accept that the Australian Health Ethics Committee has further work to do on the issue but note the projected approach that with qualification, commercialisation of human tissue products may be beneficial.

4. The draft Issues Paper, *Ethics and the exchange, sale of and profit from Products derived from Human Tissue: an issues paper*, (available for consultation from the Australian Health Ethics Committee), proposes a

⁷ Genzyme Australasia Pty. Ltd. Submission to the Human Tissue Review June 2009, page 11

⁸ Ethics and the Exchange, Sale of and Profit from Products derived from Human Tissue: an issues paper. NHMRC April 2009, page 9

⁹ Ibid, p21

¹⁰ Ibid, p21

¹¹ Ibid, p50

¹² Ibid, p28

distinction between human tissue and products derived from human tissue and suggests that in some circumstances such products may be used to generate a profit. What ramifications would that proposal have for the way in which products derived from human tissue for therapeutic purposes may be regulated?

We support the Australian Health Ethics Committee's differentiation of the terms "human tissue product" from "human tissue".¹³ Recognition that there are transformational processes, employing advances in medical technology which are involved in the production of human tissue products will be a necessary precursor to the approval of commercialisation, with conditions.

Unlike products listed on Part A of the PL, there is no cost recovery levied on Part B. It is assumed that this situation applies because "the benefit for a human tissue prosthesis is based on the service cost of providing the product...those costs legitimately incurred for the retrieval, processing, storage and transport of the product from the supplier to the hospital, or from one supplier to another"¹⁴, i.e. there is no allowance for profit. Should profit be approved as a legitimate cost factor, Departmental cost recovery for participation in Part B of the PL could expect to apply.

Term of Reference No 2

To assess the appropriateness of the current structure of Part B of the Prostheses List and to make recommendations to ensure the use of consistent nomenclature for human tissue items.

QUESTIONS

1. Is the current structure of Part B of the Prostheses List appropriate? Should there be more categories or subcategories?

The allocation of 267 human tissue products into three broad Part B listing categories of cardio-thoracic, ophthalmic, orthopaedic, albeit with 127 informative but informal subject headings, with benefits ranging from \$5 to approximately \$12,000, lacks structure and methodology. In Part A of the PL, product groups are an "indicator of comparable clinical effectiveness in the determination of the most appropriate benefit for each product recommended for listing".¹⁵ In order to achieve equity, transparency and comparative value for money, it is appropriate that comparable clinical products be more definitively identified and grouped where it is clinically practical and reasonable to do so.

2. What are appropriate naming conventions for each of the categories?

The identification of product sub-groups in Part A of the PL has been problematic when decided in isolation of the sponsors of those products. The identification and appropriate naming of product groups and the subsequent allocation of products to sub-groups will require effective consultation between relevant specialist clinicians

¹³ Ibid, p15

¹⁴ Prostheses List Application to list a prosthesis Human Tissue form, Approved 24 December 2008, p6

¹⁵ Prostheses List Guide to listing and setting benefits for prostheses, Part 1 – Understanding the Prostheses Arrangements, December 2008, p11

and a representation of sponsors, with responsible members of the Prostheses Secretariat.

Term of Reference No 3

To assess current benefits for human tissue items on Part B of the Prostheses List taking into account:

- **apparent anomalies for similar human tissue items; and**
- **freight and handling costs.**

QUESTIONS:

1. What cost components should be included in the setting of the benefit?
2. Should similar products have similar benefits? Are there costs specific/unique to a State or Territory that may warrant a different benefit?
3. How should financial information be supplied to clearly identify costs associated with specific items?

MTAA notes that in respect to human tissue, recognised legitimate costs in determining pricing are for retrieval, processing, storage and transport. Subject to agreement that a return on investment is permissible for human tissue products in respect to the processes applied to the tissue, a profit factor should be added to the allowable costing base. Other factors such as the cost of research and development and infrastructure should also be acceptable.

As previously mentioned, for Part A of the PL, product groups are an “indicator of comparable clinical effectiveness in the determination of the most appropriate benefit for each product recommended for listing”¹⁶ and so accordingly, it will be equitable and reasonable to expect that similar products have similar benefits. Suppliers of human tissue products should always have the opportunity to make representation to the benefit setting authority for benefit review, any irregularity or aberration in costings which would include state based variations.

Term of Reference No 4

To recommend a sustainable and efficient model to consider applications to list or amend human tissue items that is supported by appropriate clinical and financial expertise and is complementary to existing TGA and MSAC processes.

QUESTIONS:

1. What is an appropriate model for assessing (both clinically and financially) human tissue applications?

¹⁶ Op cit

MTAA's submission to the Health Technology Assessment Review provides a model for assessment of medical technology which is equally applicable to human tissue products. The submission can be accessed at:

<http://www.mtaa.org.au/pages/page5.asp>

A copy of the MTAA submission's Executive Summary is at Appendix 1. The following characteristics of an HTA and reimbursement system are of relevance to the reimbursement of human tissue products:

- An independent and professional health technology assessment body (HTA body) – this body will receive and clinically assess applications for listing human tissue products. The HTA output of this body should also provide the basis of use in the public sector.
 - A separate benefit (price) determining body – acting on the assessment from the HTA body, a benefit will be determined in relation to comparators from within and external to the List
2. Are there merits for applying the current arrangements for assessing applications for Part A to assessing applications for Part B of the Prostheses List?

MTAA has proposed significant changes to the manner in which health technology assessment is conducted within Australia and this encompasses reforms to the reimbursement of surgically implanted prostheses. If implemented, current Part A PL processes would evolve into markedly different arrangements. Accordingly MTAA does not support this course of action. However it is appropriate that intermediate changes to human tissue product arrangements could occur in the near term, e.g. professional clinical assessment of new applications for listing; structured clinical grouping of similar products; and acceptance that while profit should not be derived from human tissue, it can be legitimately derived from human tissue products.

3. Should the classes of human tissue defined in the HCT Regulatory Framework guide the level of assessment required for human tissue applications?

MTAA supports a risk based regulatory and evaluation approach combined with coverage with evidence development where conditional approval may be indicated.¹⁷

4. Is the Prostheses List the appropriate tool for establishing the benefit to be paid by Private Health Insurers?

Pending a more functional reimbursement model, continuing inclusion of human tissue products in the PL is acceptable.

¹⁷ See MTAA's HTA Review Submission page 40, <http://www.mtaa.org.au/pages/page5.asp>

Appendix 1

Review of Health Technology Assessment in Australia Submission by Medical Technology Association of Australia May 2009

Executive summary

The Review of Health Technology Assessment announced jointly by the Ministers for Health and Ageing and Finance and Deregulation in December 2008 is an opportunity to implement reforms to an area of the healthcare system overdue for examination. Medical technology is a key contributor to optimal patient health outcomes and offers smart solutions to many health challenges. An efficient, transparent and flexible health technology assessment system underpins the value of medical technology.

The Medical Technology Association of Australia (MTAA) adopts the all-encompassing definition of health technology assessment put forward by the International Network of Agencies for Health Technology Assessment (INAHTA) as “a multidisciplinary field of policy analysis [studying] the medical, economic, social and ethical implications of development, diffusion and use of medical technology”¹⁸.

For the purposes of this Review, MTAA uses the term medical technologies to refer to all technologies excluding pharmaceuticals.

The Review provides the opportunity to address a cross-section of the shortcomings identifiable in current arrangements for the assessment of medical technology which are canvassed in detail in section 4 of the submission. To address these issues, MTAA proposes a simplified and streamlined model for an HTA body, supported by clearer definition of the regulatory, HTA, and reimbursement functions.

The framework recognizes and accounts for the differences between medical technologies and pharmaceuticals and the inherent need for a flexible approach to assessment. It draws on features of other HTA processes that incorporate principles of transparency and accountability. The proposed HTA body will consider all available evidence, where required, including from a societal perspective. The framework differentiates the health technology functions from the regulatory and reimbursement functions.

The submission supports the establishment of a professional, independent body, capable of building competency in assessment of medical technology and procedures. All relevant stakeholders are represented on the governing board of the assessment body.

The processes for regulatory approval and health technology assessment, and reimbursement where applicable, have a single entry point with contemporaneous and parallel examination of the technology. Regulatory approval and listing on the ARTG remains an essential pre-condition to releasing a product into the market, but there is greater alignment of process.

An early scoping meeting enables suppliers, regulators and assessors to determine the requirements for registration and assessment, although comprehensive HTA will not be required in every case. Triage of an application establishes the level of assessment required for each application – whether full, abridged, or confirmatory of a product grouping.

¹⁸ International Network of Agencies for Health Technology Assessment (INAHTA). INAHTA Resources. Retrieved 12 April, 2009, from <http://www.inahta.org/HTA>.

Where a product may require further clinical evidence, the assessment body has the option of granting conditional coverage with conditions requiring development of further evidence. This flexibility enables emerging and beneficial technology that meets the regulatory requirements of safety and efficacy, to be made available to patients with conditions.

Where a product is listed with no claim of superiority over comparator products, the reimbursement process is simplified by automatic listing at a benchmark price, once the HTA body has undertaken confirmatory assessment of correct product grouping.

The assessment body engages with the Pharmaceutical Benefits Advisory Committee through a jointly-resourced committee to consider hybrid and co-dependent technologies.

The HTA body will evolve as the 'umbrella' to deliver consistent national evaluation of a broad range of health interventions, including horizon scanning to identify emerging technologies and procedures of benefit to patients and the healthcare system.

MTAA supports a collaborative process of stakeholder engagement similar in function to the Access to Medicines Working Group to implement and review the reformed HTA process.

The key reforms that MTAA seeks from the Review, in line with principles of better and more efficient regulation, are:

- Simplification of HTA systems with a redesigned HTA body that applies rational, evidence-based decision-making that is sufficiently flexible to recognize the diversity of medical technology
- Removal of duplication and overlap in assessment processes by concentration of HTA capability in a stand-alone HTA body and separation of the HTA body from regulatory and reimbursement functions
- Improved interaction between stakeholders and assessment bodies, based on a collaborative and transparent framework in accordance with good governance principles
- Simplified reimbursement processes which link HTA outcomes to benefit setting.