



Medical Technology
Association of Australia



*Assessment of co-dependent
technologies
Recommendation 6(e) HTA Review*

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MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA

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1. 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. Products range from commonplace, everyday items such as surgical gowns, bandages and syringes, to high technology items such as implantable cardiac and orthopaedic devices, cochlear implants, in vitro diagnostic products and diagnostic imaging equipment such as ultrasound, computed tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET) machines. Many newer products combine biological products with biomechanical devices, and employ converging technologies.

Sales of medical technology in Australia in 2008/2009 were \$7.4 billion, with \$1.6 billion earned from exports of medical technology manufactured in Australia. Approximately 80 per cent of the medical technology products used in Australia are imported and nearly all of the products manufactured in Australia are exported. The industry employs over 17,500 people. It is a highly innovative industry which invests heavily in research and development.

2. MTAA submission to the HTA Review

In its submission to the Review of Health Technology Assessment in May 2009, MTAA stated that it saw the Review as an opportunity to implement reforms to an area of the healthcare system overdue for examination¹. 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.

These arguments followed similar positions put to, and accepted by, several earlier reviews by the Productivity Commission. In submissions to the Productivity Commission extending over several years MTAA advocated a system that enables:

- a streamlined process for the registration, assessment and reimbursement of new technologies
- a process that is aligned or at least harmonised globally so that Australian companies are not disadvantaged by the imposition of additional burdens
- a transparent process so that requirements are clearly understood and articulated and applied in a uniform manner
- an accountable process that is open to review in the event that an element of the process has been applied incorrectly.

Medical technology refers to the diagnostic or therapeutic application of science and technology to improve the management of health conditions. Technologies may encompass any means of identifying the nature of conditions to allow intervention

¹ MTAA submission to *Review of Health Technology Assessment* May 2009, accessible at <http://www.mtaa.org.au/pages/images/Health%20Technology%20Assessment%20Review%20MTAA%20submission%20May%202009%20final.pdf>

with devices, pharmacological, biological or other methods to increase life span and/or improve the quality of life².

The range of medical technologies is far-reaching and includes diverse products:

- cardiac devices such as implantable defibrillators and catheters for ablation of atrial fibrillation
- implantable orthopaedic joints and intraocular lenses
- diagnostic tests for general pathology such as cholesterol and glucose, and infectious disease tests such as HIV and hepatitis
- diagnostic tests such as markers for HER-2 antibodies for breast cancer and K-RAS gene for bowel cancer
- radiology imaging equipment such as positron emission tomography and computed tomography x-ray scanners
- human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue.

3. Assessment of co-dependent technologies

The document, *Draft Information Requests for Assessing a Pair of Co-dependent Technologies*, proposes a methodology for pairing a proposed diagnostic test with a proposed drug as a mechanism to “ensure the timely assessment and appraisal of co-dependent and hybrid technologies”.

MTAA does not offer any comment on the draft document. MTAA member companies produce many technologies which are co-dependent on other technologies, or are hybrid technologies. However these types of products are not addressed in the draft document.

MTAA assumes that there will be further development of the scenarios to ensure that the full range of technology co-dependencies is addressed. An example of a co-dependent technology that would provide an improved clinical outcome, in the context of the examination of a prosthesis for reimbursement through listing on the Prostheses List, is trial leads for neural stimulators. Trial leads are used to determine the likely clinical effectiveness in terms of patient responsiveness to the implanting of a neural stimulator. Unresponsive patients are identified thereby avoiding nugatory surgery and associated unnecessary risk and financial waste. MTAA believes a case can be sustained for reimbursement of trial leads through the Prostheses List process. It is clear that the two items are co-dependent technologies for which a well defined pathway to reimbursement should be available.

Another example is the continuous glucose monitor (a diagnostic) connected to an insulin pump. Although the insulin pump is reimbursed, the continuous glucose monitor is not and must be paid for by other means (often self-funded by the patient). As insulin pumps become technically more responsive to continuous glucose monitors, the clinical benefits of the working partnership of the two devices will have more to offer patients and its lack of reimbursement will have greater impact.

² Wikipedia. Wikipedia definition of medical technology. Retrieved 15 April 2009 from http://en.wikipedia.org/wiki/Medical_technology.

A recent patent application in Australia foreshadows emerging developments. The application discloses a method and apparatus to deliver medical devices to targeted locations within human tissues using imaging data. The method enables the target location to be obtained from one imaging system, followed by the use of a second imaging system to verify the final position of the device. In particular, the invention discloses a method based on the initial identification of tissue targets using magnetic resonance imaging, followed by the use of ultrasound imaging to verify and monitor accurate needle positioning. The invention can be used for acquiring biopsy samples to determine the grade and stage of cancer in various tissues including the brain, breast, abdomen, spine, liver, and kidney. The method is also useful for delivery of markers to a specific site to facilitate surgical removal of diseased tissue, or for the targeted delivery of applicators that destroy diseased tissue in-situ. While the invention is yet to be developed into a commercially viable apparatus, the concept illustrates current research and development trends.

Developments in nanotechnology, or more specifically the delivery of nanotechnology therapy, are being pursued in many countries. These developments see technology convergence of microscopic diagnostic and therapy or intervention technologies which will strain the regulatory definitions of medicines, medical devices and possibly biologicals.

There are also many hybrid products, such as drug-eluting stents, and drug delivery devices. Increasingly there are also hybrid products using biologicals with a medical device scaffold, for example, in knee replacement procedures.

In its submission to the HTA Review, MTAA included extensive discussion on the challenges of developing a whole system response to co-dependent technologies and refers the Department to that discussion. The key issue is the fragmentation, lack of co-ordination and replication within the current system. Different bodies look at different elements of the same product, as evidenced in the case study on administration of apomorphine to patients suffering from Parkinson's disease, cited in MTAA's submission. Apomorphine is a dopamine agonist registered for use in patients with Parkinson's disease severely disabled by motor fluctuations which do not respond to other therapy. Apomorphine is administered via injection. For patients with increasing requirements, treatment is administered via continuous infusion using a specific pump.

Therapy involves administration of the pharmaceutical itself, using a specific ambulatory infusion pump and associated consumable equipment (syringe, extension tubing, butterfly clip, swabs). Patients are initiated on treatment after a protocolised 'apomorphine challenge' conducted by a qualified specialist, and undergoing appropriate training.

There is a lack of clarity in the different roles of each body and in the responsibilities attaching to each role. There is an inconsistency in approaches and methodologies. Another example is the case study of DC Beads, a product which is listed on the ARTG as a medical device, being an embolisation device which can be loaded with a drug. The primary intended action of the product is as a device, consistent with the manufacturer's intended purpose. However when the product came to be considered for listing on the Prostheses List the Prostheses and Devices Committee's initial assessment was that the product was a pharmaceutical and was refused listing.

The end result of these shortcomings is a gap in coverage and access by patients.

4. Conclusion

MTAA supports the development of tools to assess co-dependent drug/diagnostic tests pairings. However there are many other technology co-dependencies that do not fit within the framework outlined in the draft paper. MTAA looks forward to seeing further development of tools to streamline assessment of co-dependent technologies.