

# Annual Report 2012-13



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## Corporate Overview

### Vision

Medical technology for a healthier Australia

### Corporate Goals

To be recognised as the national body representing the medical technology industry

To deliver indispensable value to members

To be an influential partner in the healthcare environment

To provide leadership in ethical interactions with the Australian healthcare community

### Values

● Leadership ● Influence ● Collaboration ● Integrity

### Mission

To ensure the benefits of modern, innovative and reliable medical technology are delivered to the community for a healthier Australia.

## About MTAA

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA represents manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse with products ranging from familiar items such as syringes and wound dressings, through to high-technology implanted devices such as pacemakers, defibrillators, hip and other orthopaedic implants. Products also include technologies such as robotic surgery equipment and complex hospital equipment, diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines.

MTAA members supply the majority of the non-pharmaceutical products used in the treatment of disease and disability in Australia. Our member companies also play a vital role in providing healthcare professionals with essential education and training to ensure safe and effective use of medical technology.



## Message from the Chair

This is my first report as the Chair of the Board of the Medical Technology Association of Australia (MTAA) on activities for the financial year ending 30 June 2013. I was appointed after the AGM in October 2012, taking over from Dr Bronwyn Evans.

2012-13 has been an interesting financial year politically and economically, and for the medical technology industry. While politically the dominant issue was the continued leadership speculations for the government, the reforms for the regulation and reimbursement of medical technology continued.

Economically the majority of this year has been characterised by the high Australian dollar affecting exporters, while at the same time the slide of the local manufacturing sector continued.

MTAA has been very vocal in positioning the industry as a significant contributor to the Australian economy and worthy of attention from policy makers. Some of the fruits of this labour are slowly developing with the federal government's Industry Innovation Precincts forming part of the *A plan for Australian jobs* funding and the first round of recipients of the Medical Device Funds grants announced recently by the NSW Government.

The Board has been busy this year with developing a strategic plan to communicate the association's vision and policy objectives to key people within the major parties in the lead up to the federal election.

The Board also emphasised the importance of the Medical Technology Industry Code of Practice and its role in governing ethical interactions by adding a fourth corporate goal to the MTAA's corporate objectives. *To provide leadership in ethical interactions with the Australian healthcare community* is a statement of continued support for the Code as the industry standard. We will continue to work towards making the Code applicable to all companies within the industry sector regardless of membership of the association.

This year the Board has renewed its commitment to have the diversity of medical technology and company structures reflected in the appointments to the Board. Small to medium size companies make up a significant proportion of the industry and the association membership is increasingly reflecting this. To this end the Board is currently drafting a diversity statement to help ensure that the views of all our members are represented.

Thank you to members for their support of the association through the many opportunities provided. Please keep up the engagement through continued membership, attendance at events and training, and your work in committees and consultations. It is only through active participation that we are able to shape a positive future for all members of our industry.

I would like to thank past and present Board Directors for their support and work throughout the year.

I would also like to acknowledge the efforts and work accomplished by Chief Executive Officer, Anne Trimmer, and the staff of the association. Anne left MTAA in July 2013, after almost seven years as the public face of the association. During her time at MTAA she achieved much, some of which is outlined in her report in this annual report. Her leadership, professionalism and skills will be missed by all.



I look forward to working with you in 2013-14 in what is shaping up to be another interesting year.

A handwritten signature in black ink, appearing to read 'K Barrow', written on a light-colored background.

Kevin Barrow  
Chair

# CEO's Report

The past year has produced several significant developments for the medical technology sector, some of which have been part of MTAA's advocacy for a considerable time. The year has seen the commencement of regulatory reforms by the Federal Government in response to the Therapeutic Goods Administration (TGA) Blueprint; introduction of activity based funding across the Australian public hospital system; completion of product grouping and benefit setting for products listed on the Prostheses List and the start of work to provide reimbursement for innovative technologies not covered by the Prostheses List; strategic reviews of health and medical research in NSW and at the federal level; and reviews of manufacturing both in States and at the federal level.

In all of these areas MTAA has been front and centre of the debates and consultations. Many of these activities have laid the groundwork for the years to come.

## Political engagement strategy for Federal election 2013

With the 2013 Federal election approaching, MTAA acted early to put in place a well-developed engagement strategy to ensure that MTAA's policies were well-understood and able to be implemented by an incoming government. A strategic workshop of the Board was held in mid 2012 to identify the key policies and relevant politicians with whom MTAA needed to engage. A further forum was held involving Board members and the Government Affairs and Policy Committee to work up the messages for each of the key policy areas.

The key policies are:

- improving reimbursement of medical technologies by private health insurance, both to expand coverage and to review current benefits
- reforming the regulation of medical devices to focus on post-market surveillance and to press for third party conformity assessment
- reforming the public health system to facilitate a more flexible approach to the introduction of new technologies
- improving the support for patients in the community through expanded and comprehensive telehealth policies and funding for essential medical products such as modern wound care
- developing a sustainable medical technology industry in Australia through integration of policies to support development and better integration between the health system and industry development policies.

## Regulatory reform

MTAA has long supported expansion in the availability of conformity assessment bodies to ensure that Australian manufacturers are not disadvantaged by either cost or time delay in having products assessed. This reform was finally put on the table by TGA as a package of reforms that also increase premarket scrutiny of higher risk and long-term surgically implantable medical devices. Working with member companies MTAA was able to show not just the cost impact of the proposed reforms but also absence of justification based on available evidence. MTAA argued that the combination of current reforms to the regulation of orthopaedic hips, knees and shoulders, combined with improved utilisation of information already available to TGA, addressed the concerns which gave rise to the reform proposal.

MTAA endorsed the introduction of the ANZTPA joint regulatory agency for a common market with New Zealand and in its submission encouraged the governments of Australia and New Zealand to examine ways to refine and improve the current regulatory structure where deficiencies are identified. MTAA proposed that ANZTPA operate as a Competent Authority, in alignment with the European model, nominating third party conformity assessment bodies based on designated requirements, such as knowledge, experience, independence and resources, to conduct the conformity assessments.

MTAA supported transparency of decision-making by TGA, and the publication of information which substantiates the basis of the decision which has been taken. MTAA believes that transparency of decision making will lead to more consistent TGA decisions and an improvement in the quality of submissions.

In late May TGA released a Consultation Regulatory Impact Statement on the advertising of therapeutic goods to the general public. The advertising of therapeutic products remains a complex area of intersecting regulations, addressed in part by TGA and in part by the self-regulatory codes of industry associations. The nature of advertisements has also changed with increasing use of internet advertisements which fall outside the current regulatory regime. MTAA strongly supported the stated objective of regulatory reform, namely to improve the simplicity of the advertising controls. MTAA has argued for improvements to the complaints processes, with approval of advertisements limited to those products of higher risk to consumers.

## Reimbursement of high technology medical devices

MTAA participates in the work of the HTA Consultative Committee (HTACC) of the Department of Health and Ageing. HTACC has had as its primary focus the finalisation of the grouping of, and benchmark-setting for, products on the Prostheses List. The HTACC is now turning its attention to an area that has long been a focus of MTAA's advocacy – to provide reimbursed access to other beneficial high technology medical devices which are not eligible for the Prostheses List. This work is at an early stage but promising for the future.

## Activity Based Funding

From 1 July 2012 national health reform saw the introduction by the Independent Hospital Pricing Authority (IHPA) of activity-based funding based on a national efficient price. MTAA was actively engaged in the development of the framework for the new arrangements, including the pricing framework. We have been concerned to ensure that the system is sufficiently flexible to provide for the introduction of new technologies, and to ensure that aspects of home-based care are included in the definition of hospital services. The final pricing framework accommodated hospital in the home arrangements.

MTAA continues to press for flexibility in the pricing framework to include adjustments for the incorporation of new technology. While IHPA, through its Clinical Advisory Committee, will monitor the potential impact of new technology and innovations in the model of care, it will continue to be the responsibility of the States and Territories to establish processes that will facilitate the introduction of, and funding for, new technologies.

## Medical technology manufacturing – an industry for Australia's future

Over the past 12 months there have been several reviews at both State and Federal level with the common theme of addressing Australia's declining manufacturing sector and identifying solutions. MTAA has made significant contributions to each of these reviews – the NSW Manufacturing Industry Action Plan, the SA Government's Advanced Manufacturing Green Paper, and the Prime Minister's Manufacturing Taskforce.

The recommendations from each of these reviews identify the opportunities for sectors like medical technology. The non-government members of the PM's Manufacturing Taskforce included many recommendations in their report which reflected MTAA's submission. These included support for the development of Smarter Australia Precincts and innovation hubs, a theme which was taken up in the Prime Minister's *Plan for Australian Jobs*.

In June 2013 MTAA coordinated a very diverse range of participants in an application to the Government for funding to establish a medtech precinct under the name Medtech Australia. The proposal combines a small staff on the ground in Sydney, Melbourne and Adelaide with a virtual network which will connect the many participants in the medtech ecosystem, from researchers and clinicians, to incubators and manufacturers. The Medtech Australia Precinct was successful in the first stage result of the selection process.

## Medtech industry pilot project

MTAA has been a core participant in a pilot project of Commercialisation Australia to develop strategies to grow the medtech industry in Australia. The first phase will map the medtech ecosystem to provide data which will measure future growth and then identify the policy building blocks to support development of the industry.

The plan is to have a report on the pilot phase to Government by late 2013. The pilot provides a great opportunity to identify and then tackle the policy impediments to growth.

## Membership and outreach activities

The past year has seen the development of MTAA's new website with improved member access to a wide range of information. The professional development offerings have increased, particularly in availability of online learning.

Another successful conference was held in November 2012 with a good quality speaker faculty which attracted strong support from the membership. Medtech seminars and networking evenings have provided further opportunities for members to come together and listen to a range of interesting speakers.

A new forum was established for compliance officers from member companies to share best practice with implementation of the industry Code of Practice. During the year a program was instituted to engage non-members and other stakeholders with the Code.

MTAA's research activities have also continued to grow with further reports published as part of the Value of Technology project. One of the reports, on the cost-benefits of modern wound care devices, was accepted as a poster presentation at the HTAi meeting in June 2013.



I wish the members of MTAA all the very best for a successful future.

A handwritten signature in black ink, appearing to read 'Anne Trimmer'.

Anne Trimmer  
Chief Executive Officer

MTAA has taken a lead in advocacy for improved funding for telehealth solutions to better support both the ageing population and those with chronic illnesses, outside the hospital setting. The research has been published in several articles during the year.

MTAA has continued to support the Alliance for Sharps Safety and Needlestick Prevention in Healthcare – an important grouping of organisations committed to ensuring a safer workplace for healthcare workers through the avoidance of needlestick, scalpel and other sharps injuries.

The past year has been a successful one for MTAA with several policy wins, growth in the coverage of activities, strong engagement with decision-makers, and improved services for members.

I would like to pay tribute to the great team within the MTAA secretariat, to the Board, and in particular to its Chair, Kevin Barrow. This is my last report as CEO of MTAA as I leave to take up the position of Secretary General of the Australian Medical Association. It has been a great privilege for me to have worked for the medical technology industry over the past almost seven years. I have great admiration for the extraordinary products developed by companies in the industry which bring life-transforming benefits to patients.



# MTAA Board Directors

## David Akeroyd

Managing Director & Region Head ANZ,  
Baxter Healthcare Pty Ltd  
B. Sci (Victoria University of Wellington)

David's career has been spent entirely in the medical industry. Leaving New Zealand in 2002 as Country Manager (Diagnostics) for Abbott Laboratories, he took up a dual regional in Japan as a Commercial Director, Asia Pacific and Marketing head for Abbott's Japanese affiliate. In 2005 David was offered a role as a Vice President with Baxter Healthcare based in Singapore and set up business development teams in the Asia Pacific. Later regional roles included General Manager for the North Asia group of countries and later India. David took up his current role in 2008.



## Kevin Barrow

Managing Director, Australia and  
New Zealand, Becton Dickinson Pty Ltd  
B. Sci, M. Sci (Hons 1) (Waikato University),  
MBA (MGSM)

In 2004 Kevin joined Becton Dickinson (BD) as the Business Director for BD Medical. In 2006 he assumed the role of Managing Director for BD Australia and New Zealand. Prior to joining BD, Kevin worked with Eli Lilly; a United States based multi-national pharmaceutical company. There he held numerous roles in sales and marketing management in both Australia and New Zealand. His final role at Eli Lilly Australia was as Sales Director. Born in New Zealand, Kevin has always had an interest in science and healthcare. Kevin is currently the MTAA Chair.



## Paul Braico

Vice President and Managing Director,  
Boston Scientific Pty Ltd  
B.Eng. (UNSW), MBA (MGSM)

Paul has over 27 years experience in the medical technology industry, working in diverse organisations including Australian manufacturing, medical equipment, medical distribution, and medical device multinationals. Prior to his current role, Paul has held several senior leadership roles in Australia and Japan.



## Carmen Byrne

General Manager Health Care, Australia and  
New Zealand, 3M Australia Pty Ltd  
B. Scie (CCAE), MBA (MGSM), Post Grad  
Cert Health Policy (Sydney University),  
GAICD

Carmen has worked in the healthcare industry for over 21 years in the areas of clinical research, quality management, and sales and marketing. With an interest in wider health policy issues, Carmen has completed post graduate studies in Health Policy at the University of Sydney. Carmen has experience managing a diverse business portfolio, with current responsibilities spanning dental, orthodontics, food safety, medical consumables and health information software. Carmen is a Vice Chair of MTAA.



## Patrick Callanan

Country Manager ANZ, American Medical  
Systems Australia Pty Ltd

Pat commenced his career in healthcare over 21 years ago, having previously spent nine years in the finance industry, the final three as a principal in a small broking firm. Pat's experience in healthcare encompasses sales, marketing, sales management and senior management, working across a wide variety of surgical specialties to develop his understanding of healthcare and how to serve customers most effectively. Pat has been with American Medical Systems (AMS) since July 2010, having previously worked for large global device manufacturers Howmedica and Stryker. Prior to joining AMS, Pat was Managing Director for Advanced Surgical Technologies, a privately owned medical device distribution business.



## Gavin Fox-Smith

Managing Director, Global Surgery, Johnson  
& Johnson Medical ANZ  
B.Sci (USyd), Grad Cert Mktg (CSU), MBA  
(Deakin) AFAMI, CPM

Gavin has over 27 years experience in the medical technology and devices sector. He commenced his career with Howmedica Orthopaedics where he served in several roles of increasing responsibility in sales and marketing in ANZ before being appointed Director of Marketing for Asia. Gavin joined J&J Medical ANZ in 1997 as a Regional Business Director and held diverse leadership roles in sales, marketing and general management across the J&J family including Ethicon, EES, DePuy and Cordis. He was appointed to his current role of Managing Director in 2012.



## Tony Harrington

Managing Director, Biomet Australia and  
New Zealand  
B.Sc. Materials (UTS), MBA (AGSM, UNSW),  
GAICD

Tony has over 24 years experience in the medical technology sector in a wide variety of senior management and director roles in Australia, New Zealand and the UK. Tony held the position of Managing Director for Biomet Australia and New Zealand from early 2009 to mid 2013. In those roles Tony has been principally focused on organisational change management to realign performance with corporate objectives.



## Graham McLean

Managing Director, South Pacific, Stryker  
Australia Pty Ltd  
BSc (Hons) Geography, FCMA, CPA, GAICD

Graham has worked for Stryker for over 8 years and is currently Managing Director for South Pacific (ANZ). He took up his current appointment in 2012 having previously held a number of other roles including Finance and Operations Director and international assignments. Prior to working at Stryker, Graham had extensive international experience working in general management roles in food and drinks business, such as Lion Nathan, Smiths Snackfoods, Guinness and United Biscuits in Europe and Australia. Having been raised in the UK, Graham has lived in Sydney for 16 years.



### Doug North

Managing Director Surgical Specialties Pty Ltd  
BA (ECU)

Doug is the major shareholder and Managing Director of Surgical Specialties. From 1984 to 2000 Doug worked in numerous sales roles at Howmedica including National Sales Manager. Following Howmedica's integration with Stryker he held the role of General Manager, Stryker NSW. Through 2000 to 2005 Doug established his own business and was the Exclusive Distributor in NSW/ACT for Smith and Nephew's Orthopaedic and Endoscopy products. In 2006 Doug established Surgical Specialties which now employs 65 people.



### Jamie Stanistreet

Managing Director, Australia and New Zealand, Medtronic Australasia Pty Ltd  
Accounting and Marketing (UNSW)

Jamie joined Medtronic in 1999 following the acquisition of AVE Inc and was appointed to the Managing Director role in 2001. Prior to joining Medtronic he worked in senior sales and marketing roles with Bard Australia. Jamie has also worked with 3M and Biospectrum.



### Mark Taffa

Managing Director, Horten Medical Pty Ltd  
B.Bus (CSU)

Mark is the founder and Managing Director of Horten Medical, a company distributing medical devices, established in 2005. Actively involved in the healthcare industry for over 15 years, Mark has worked with both large multinationals and small business. At GE Medical Mark had product responsibility for all of Asia in digital imaging which included living in Singapore and consulting to the Brunei government on e-health. Mark has experience in running small scale local manufacturing of complex medical equipment for local and export sales.



### Michael Trevaskis

Director Sales and Marketing, Device Technologies  
BHLthSci, Dip Hth Sci (Nursing), Latrobe

Mick commenced his medical career as a registered nurse in Melbourne in 1993 before running a family owned business for two years. In 1998 he joined Device Technologies as an orthopaedic product specialist. Since then Mick has held a number of senior positions overseeing orthopaedic products. From 2003 Mick moved to Sydney to take on the role as Australasian Sales Manager and in 2005 commenced as the Director Sales and Marketing.



## Previous Board Directors

### Bronwyn Evans

Senior Vice President, Quality, Clinical and Regulatory, Cochlear Ltd  
BE (Elec), Hons I, PhD (UoW) FIEAust, EngExec, GAICD

### Phil Nicholl

President Asia Pacific, Stryker Pty Ltd  
Bachelor of Business (Marketing), CSU

### Julianne Prowse

General Manager, Coloplast Pty Ltd  
MBA (Swinburne)

## Meeting Attendance

1 July 2012 - 30 June 2013

	13-Aug-12	23-Oct-12	23/10/2012 - meeting two	4-Dec-12	19-Feb-13	17-Apr-13	18-Jun-13	Eligible to Attend
Mr David Akeroyd	Present	Present	Present	Apology	Apology	Apology	Present	4 of 7
Mr Kevin Barrow	Present	Apologies	Apologies	Present	Present	Present	Present	5 of 7
Mr Paul Braico	Present	Apologies	Apologies	Apology	Present	Apology	Present	3 of 7
Ms Carmen Byrne	Apologies	Present	Present	Present	Present	Present	Present	6 of 7
Mr Pat Callanan			Present	Present	Present	Present	Present	5 of 5
Dr Bronwyn Evans	Present	Apologies						1 of 2
Mr Gavin Fox - Smith	Present	Present	Present	Apology	Present	Present	Present	6 of 7
Mr Tony Harrington	Present	Present	Present	Present	Present	Apology	Present	6 of 7
Mr Graham McLean						Present	Present	2 of 2
Mr Phil Nicholl	Present	Present	Present	Apology				3 of 4
Mr Doug North						Present	Present	2 of 2
Ms Julianne Prowse	Present	Present	Present					3 of 3
Mr Jamie Stanistreet	Present	Present	Present	Present	Present	Present	Apology	6 of 7
Mr Mark Taffa						Present	Present	2 of 2
Mr Mick Trevaskis	Present	Present	Present	Present	Apology	Present	Present	6 of 7

# Committee Reports

MTAA would like to thank member companies for enabling their staff to participate in the work of all committees and forums. Furthermore, MTAA would like to thank all individuals who contributed to the work of committees, forums and ad-hoc working parties for their efforts and insights.

## Access

The Access Committee continued to play an active role in industry policy development, and the preparation of responses to government reviews and draft guidance documents. The committee is one of three strategic committees reporting to the Board, since 2013 chaired by a Board Director. The committee met on three occasions during the reporting period and also considered issues outside of these meetings.

The Access Committee reviewed an Australian Commission on Safety and Quality in Health Care (ACSQHC) discussion paper on clinical registries for high-risk implantable devices and informed MTAA's policy response and submission.

The Access Committee continued to monitor DoHA's actions in attempting to improve processes of the Medical Services Advisory Committee (MSAC). The committee reviewed two DoHA draft papers on MSAC which formed the bases for submissions on the assessment of applications to MSAC and on draft *Technical Guidelines (Therapeutic)*.

## Reimbursement Subcommittee

The Reimbursement Subcommittee (RSC) is a subcommittee of the Access Committee and met on five occasions during the reporting year. The focus of RSC is on Prostheses List reimbursement issues.

The committee managed industry responses to Prostheses List policy developments during the period and considered operational matters referred to it by the Access Committee and the MTAA Secretariat.

The committee has continued its constructive engagement with the Private Health Insurance Branch of DoHA. Following an inaugural meeting with DoHA staff last year, the RSC met again during the reporting period with staff at the senior executive level at which a range of operational issues were addressed. The meeting was followed by a display of medical technology to departmental staff.

The RSC also provides supporting input to the deliberations of the Access Committee, and provided advice on training and information topics for MTAA events.

## Regulatory Subcommittee

The Regulatory Subcommittee (RegSC) is a subcommittee of the Access Committee and met on a monthly basis during the reporting year. The RegSC is comprised of 12 senior regulatory professionals. The focus of the committee is on strategic regulatory issues and providing comment on the following key issues.

- Changes to premarket assessment of medical devices
- The framework for the Australia and New Zealand Therapeutic Products Agency (ANZTPA)
- Engagement with TGA
- Confidence building between TGA and European Notified Bodies
- International Medical Device Regulators Forum (IMDRF) work items

The committee has been very engaged in numerous TGA consultations including providing comments on Regulation Impact Statements on premarket assessment and advertising, and TGA's Key Performance Indicators.

The RegSC has provided advice to the Access Committee particularly on engagement with TGA and proposed regulatory reforms.

## Code of Practice

The Medical Technology Industry Code of Practice is administered by the Code of Practice Committee (CPC) which is responsible to the MTAA Board. It is headed by an independent chair, and is made up of industry members and consumer representatives.

CPC has overseen the promotion of the code to members, the wider industry and relevant stakeholders. CPC considered a number of matters referred from the Code Monitoring Committee and members for clarification and possible change.

CPC major piece of work during the year was the development and ultimate approval by members of the 8<sup>th</sup> edition of the code.

## Code Monitoring Committee

The Code Monitoring Committee (CMC) supports compliance with the code by proactively monitoring the promotions and activities of members on a regular basis. The CMC has an independent and legally qualified chair, and is made up of two representatives of healthcare professional associations, two representatives of healthcare institutions and a consumer representative. A panel of industry representatives provides the two members required on CMC.

Through 2012-13 CMC was able to review the activities of member companies. CMC continues to take an educative approach. CMC continues to find the overall level of understanding and compliance with the code reasonable.



## Code Complaints and Appeals Committees

Both the Code Complaints Committee (CCC) and the Code Appeals Committee (CAC) are independent, chaired by legally qualified individuals and formed from a panel made up of representatives from professional associations, institutions, consumers and industry. Committees are formed by the Complaints Secretary from the panel, as required with regard to actual or perceived conflicts of interest. The Code Complaints and Code Appeals Committees met during the year with information placed on the MTAA website as appropriate under the code.

## Government Affairs and Policy

The Government Affairs and Policy Committee is one of MTAA's three strategic committees, chaired by a Board member. It works closely with both the Board and the Access Committee on strategies to influence political consideration of MTAA's key policies. During 2012-13 the committee has focused on refinement of MTAA's key policies for the 2013 federal election. In conjunction with the Board the committee developed and instituted a comprehensive engagement plan to ensure that MTAA's policies were well-understood by both the Government and the Opposition.

## Regulatory Affairs

The Regulatory Affairs Committee is comprised of 24 regulatory professionals and met on a monthly basis during the reporting year. The focus of the committee is on operational regulatory issues which representatives of the committee raise at the TGA's Regulatory and Technical Forum on a quarterly basis. Issues raised at the forum have included industry training, comment on unpublished sections of TGA's Australian Regulatory Guidelines for Medical Devices, conformity assessment applications and common submission problems including the use of Global Medical Device Nomenclature (GMDN) codes.

## Orthopaedic

The Orthopaedic Committee met three times during the reporting year. The committee considered issues affecting industry's relationship with orthopaedic healthcare providers and informed industry responses as necessary. The report of the NJRR review was released during the period which unfortunately addressed little of industry's concerns with the operations of the registry, including its autonomous governance.

## Industry Statistics

In 2011-12 the Australian medical technology industry:

- employed more than 19,000 people
- had total annual revenue in the order of \$10 billion
- was responsible for 41,292 medical devices listed on the ARTG (including IVDs and dental) with up to a million different devices linked to them
- included over 500 medical technology companies with products listed on the ARTG
- was mainly located in NSW (55%) followed by Victoria (24%) and Queensland (12%)
- imported goods to the value of \$4.4 billion and exported goods to the value of \$1.9 billion
- imported the majority of medical technology products from the USA, followed by Germany and Ireland. Australia's most popular export destination is the USA, followed by New Zealand and the United Kingdom
- supplied the Australian market with single use technologies (11%), implantable devices (9%), anaesthetic/respiratory (8%) and orthopaedic devices (7%)
- was responsible for 9,863 devices listed on the February 2013 Department of Health and Ageing (DoHA) Prostheses List which are reimbursed by private health insurance (70% of these items are supplied by MTAA members).

Globally the medical technology market is valued at US\$325 billion with a compound annual growth rate (CAGR) of 7% between 2005-11.

## Forums & Working Groups

### Clinical Investigation

During 2012-13 the Clinical Investigation Forum met regularly to discuss topics relating to clinical investigations and trials for medical devices. Topics included a Clinical Research Agreement tailored specifically for device trials.

The forum was also involved in the MTAA submission to the Independent Hospital Pricing Authority (IHPA) on the consultation paper to develop a national efficient price for a list of standard items associated with conducting clinical trials.

### Commercial Issues

The Commercial Issues Committee made recommendations to the NEHTA Supply Chain Reference Group on data fields to be used in the NPC and standardised company information for use in tenders across jurisdictions.

The committee provided comment on conference guidelines to provide information to conference organisers on supplier requirements and code compliance.

MTAA represented members to Health Purchasing Victoria regarding its requirement for 20 years of product liability insurance post the end of the contract period and to NSW Health regarding its requirement for unlimited product liability insurance for product evaluations.

MTAA was successful in resolving issues with the loss of end user data for products shipped through the NSW Health central distribution centres.

### Communicators

The Communicators Forum provided a platform to share and discuss issues and opportunities facing the industry and communications practitioners in the medical technology industry. Individual forum participants provided feedback on and contributed to MTAA PR activities.

### Australian Medical Technology Innovation Group

The Australian Medical Technology Innovation Group provides a forum for SMEs which manufacture or conduct research and development activities in Australia to canvass priority issues. The group was established to identify barriers to growth and incentives for investment with the aim of creating a more sustainable domestic medical technology industry in Australia.

The focus for the group this financial year was on working collaboratively and understanding the strategies individual companies could adopt to support the development of a sustainable business. Speakers have provided insight into the strategies needed to progress a company through the various growth stages, and assistance available at the commercialisation stage.

This group has been central to progressing MTAA's industry policy agenda which is about developing an effective business environment for the industry. MTAA's suggestion that the sector required strong leadership from government to establish a sustainable industry was reflected in the government's Aussie Jobs Report (Manufacturing Report).

One of the outcomes from the Aussie Jobs Report was the establishment of Industry Innovation Precincts. MTAA facilitated the preparation of a MedTech Precinct application for this program and input from group members was invaluable. MTAA's leadership in this process has raised the profile of the association amongst non-members which resulted in a number of membership enquiries.

The group met every eight weeks by online meeting room and teleconference.

### Overseas Technology Aid Group

The Overseas Technology Aid Group was set up to better coordinate and improve the donation of medical goods for surgical mission organised through the international team at the Royal Australasian College of Surgeons.



## Legal Counsel/Compliance

The Legal Counsel/Compliance Forum met six times in 2012-13. The forum is open to personnel from member companies who have responsibility for the Medical Technology Industry Code of Practice, compliance and ethics. This includes staff in positions such as legal counsel and compliance.

The forum is intended to provide an opportunity for participants to network, receive updates and provide feedback on a range of code and ethics issues. In 2012-13 the forum provided input during drafting of the 8<sup>th</sup> edition of the code. The forum also identified a range of potential code FAQ topics which were referred to the Code of Practice Committee for review. Forum members also provided comment on projects such as the MTAA/Advanced Asia Pacific Compliance Working Group meeting.

## Orthopaedics Regulatory Working Group

The group identified key issues experienced by member companies with respect to the orthopaedic joint upclassification submissions. Representatives of the group met with TGA to work on the issues. This engagement has led to joint MTAA/TGA advice which was published on both organisations' websites. The group will continue to meet and engage with TGA throughout the upclassification transition process.

## IMDRF working groups

Regulatory professionals with particular experience and interest in IMDRF work items have met to provide comment on the following work items:

- Medical Devices Single Audit Program (MDSAP)
- Regulated Product Submission – Table of Content
- Unique Device Identifier (UDI).

Providing comment to IMDRF is important to ensure that Australia as a small market is considered with respect to global regulatory practices.

## TGA and ANZTPA consultation working groups

MTAA coordinated regulatory professionals from member companies to take part in TGA online discussion forums, surveys and testing of TGA online systems. Working groups were also formed to provide comment on the following consultations:

- Description of a possible joint regulatory scheme for therapeutic products under ANZTPA
- TGA Proposal paper on changes to premarket assessment
- ANZTPA Trans Tasman Early Warning System
- TGA Database of Adverse Event Notification (DAEN) - Initial consultation on fields
- TGA DAEN - Feedback on database testing
- TGA Regulation Impact Statement (RIS): Changes to premarket assessment for medical devices
- TGA Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods
- TGA proposal to put aside TGA Blueprint for reform proposal 3.1 - product name
- TGA RIS: Regulating the advertising of therapeutic goods to the general public
- TGA Key Performance Indicators proposal paper

# External Committee Representations

MTAA represented members on a range of external committees and stakeholder groups.

- Alliance for Sharps Safety and Needlestick Injury Prevention in Healthcare: Anne Trimmer (Chair), Marion Demann (Secretariat), Susan Martland
- Bariatric Surgery Registry Steering Committee: David Ross
- Cardiac and Cardio-thoracic CAGs: Warwick Kitt (industry adviser)
- Centre of Research Excellence in post-market surveillance of medicines and medical devices, Centre Advisory Board: Sam Tham
- Complaints Resolution Panel: MTAA staff
- Hip, Knee, Spinal and Specialist Orthopaedic Clinical Advisory Groups (CAGs): Bernard O'Connor (industry adviser)
- Home Dialysis Advisory Group: David Ross
- HTA Consultative Committee: Anne Trimmer (member), David Ross (observer)
- IHPA Stakeholder Advisory Committee: Anne Trimmer
- Medicines Australia Transparency Working Group: Anne Trimmer
- National Joint Replacement Registry Consultative Committee: David Ross
- Ophthalmic CAG: Peter Abrahamson (industry adviser)
- Prostheses List Advisory Committee: David Ross
- Standards Australia  
MTAA is represented on 16 active committees, and in the last year representatives have contributed to standards for:
  - AS/NZS 3551 - Management programs for medical equipment
  - AS/NZS 4187 - Sterilization of Medical Devices
  - AS 4011 & AS 4179 - Medical Gloves
- Supply Chain Reference Group (NEHTA): Anne Trimmer, Warren Mitchell
- Therapeutic Goods (Codes of Conduct) Implementation Advisory Group: Anne Trimmer
- Therapeutic Goods Advertising Code Council: Alina Hughes
- TGA-Industry Consultative Committee: Anne Trimmer, Sam Tham
- TGA/Industry Regulatory & Technical Consultative Forum: Sam Tham
- Trusted Information Sharing Network (Health Sector Group): Warren Mitchell
- Urogenital and Vascular CAGs: Nick Shalley (industry adviser)



# Committee Membership

MTAA wishes to thank all committee members and forum participants who have helped shape the industry through their hard work, dedication and support throughout the year.

The following lists membership of the three strategic committees reporting to the Board and is representative of all individual members of all MTAA committees, forums and working groups.

## Access Committee

**Eugene Salole** (Chair 2012), Manager, Pricing and Economic Affairs Patient Access, Pfizer

**Gavin Fox-Smith** (Chair 2013), Managing Director, Johnson & Johnson Medical

**Stuart Bruce** (2012), Regulatory & Corporate Affairs Manager, Boston Scientific

**Robyn Chu**, Health Outcomes Director, Johnson & Johnson Medical

**Hilary Crilly** (2013), Director of Health Economics, ANZ, BD

**George Faithfull**, Vice-President Regulatory Affairs & Quality Assurance, Stryker Pacific

**Sarah Griffin**, Director Corporate Affairs ANZ, St. Jude Medical Australia

**Georgina Sanderson**, Director Reimbursement, Quality, Regulatory, Cochlear

**Mick Shaddock** (2012), Senior Business Manager, Device Technologies Australia

**Ruth Shennan** (2013), Regulatory Affairs Manager, Device Technologies Australia

**Andrew Wiltshire**, Senior Director, Government Affairs, Medtronic Australasia

## Code of Practice Committee

**George Walck** (Independent Chair), Director, George Walck & Associates

**Camilla Chan**, Legal Counsel, Medtronic Australasia

**John Cooper**, VP Australia, New Zealand & India, Zimmer

**Michael Goldberg**, Financial Controller, St. Jude Medical Australia

**Patricia Greenway**, Consumer Representative, Consumers' Health Forum

**Anna O'Shea**, Senior Legal Counsel, Cochlear

**Michelle Wagner**, Compliance Director, Johnson & Johnson Medical

## Government Affairs and Policy Committee

**Jamie Stanistreet** (Chair), Managing Director, Medtronic

**David Cain**, Corporate Affairs & Market Access Adviser, Johnson & Johnson Medical

**Alasdair Godfrey**, Health Economics Consultant, Hospira

**Sarah Griffin**, Reimbursement & Government Affairs Manager, St. Jude Medical Australia

**Jodie Jansen**, Government Relations Manager ANZ, Baxter Healthcare

**Kristin King**, Manager, Government Affairs & Public Policy ANZ, Covance

**Susan Martland**, Manager, Government Relations and Public Policy, BD

**Michael Simmonds**, Health Economics and Government Affairs Manager, Boston Scientific

**Andrew Wiltshire**, Senior Director, Corporate Affairs, Medtronic Australasia

## Secretariat Staff

**Anne Trimmer**, Chief Executive Officer (*until 26 July 2013*)

**Brett Andrews**, Manager Corporate Services

**Marion Demann**, Corporate Communications Manager

**Alessandra Doolan** PhD, Health Outcomes Policy Manager

**Trish Flitcroft**, Office and PD Administrator

**Alina Hughes**, Code of Practice Manager

**Joanne Ince**, Events/Executive Assistant

**Fee Koch**, Public Health Policy Officer

**Fiona Landis**, Industry Policy Manager (*on maternity leave*)

**Kylie Maidment** PhD, Telehealth Policy Manager

**Warren Mitchell**, Manager Commercial Issues

**Roslyn Mitchelson**, Industry Policy Manager

**David Ross**, Director Healthcare Access

**Fiona Shipman**, Professional Development Manager

**Samantha Tham**, Director Regulatory Affairs

# Professional Development

Medical technology professionals require up-to-date knowledge, skills and understanding to deliver positive outcomes in the ever complex and changing healthcare environment. Professional development is central to achieving this outcome.

During 2012-13 the range of training, education and information sharing opportunities available through MTAA continued to expand in depth and breadth, enabling participants to foster excellence and strive to reach their personal best.

## Training

The training program is based on future national and global directions of the medical technology industry, and feedback gained from its workforce.

- Existing face-to-face training courses were reviewed with modules added or removed, pending identified learning needs
- Content for all online modules was updated
- Several face-to-face modules were redeveloped as online learning.

A blended learning approach was used to develop new self-paced online learning modules, webinars and face-to-face modules. This learning was delivered across five courses, with each hosting a series of modules. Face-to-face training was delivered following expressions of interest, scheduled or in-house. Of the 54 training modules offered by MTAA from the commencement of 2013, over 35% are VET accredited and 65% are delivered online.

- 1.0 Medical Technology Regulation and Clinical Activities:** ten face-to-face modules
- 2.0 Medical technology Industry Code of Practice:** three modules delivered online (1) or face-to-face (2)
- 3.0 Working with Healthcare Professionals:** twenty modules offered online (19) with two of these free, or face-to-face (1)
- 4.0 Reimbursement of Medical Technology:** four modules offered online (1) or face-to-face (3)
- 5.0 Workforce Development:** fifteen modules delivered online (14) with two of these free, or face-to-face (1)

With the introduction of the new website and database participant training is now tracked online. Participants can login to their *My MTAA Account* and directly access their training online and view or print their *Certificate of Participation*. They can also view their training history and access past certificates. This history travels with them while they remain in the industry, simply by updating their profile. In addition all training registrations can now be made online via the *Training Catalogue*.

## Education

Industry entry points are mainly facilitated through education and training pathways. This includes:

- VET institutions
- universities (undergraduate and post-graduate courses)
- ongoing professional development.

During 2012-13, MTAA continued to offer web-based resources that support the education of future, newly qualified and current medical technology industry personnel. The *Workplace Learning Directory* assists secondary and tertiary students to be exposed to the work of the medical technology industry. The *MyUniversities* website link provides an opportunity for undergraduate and post-graduate students to identify relevant education courses available through tertiary providers.

MTAA continues to partner with McCarthy Mentoring to offer the *Emerging Leaders Development Program*. This initiative aims to connect MTAA member company high potential aspiring leaders with the expertise, insights and networks of leaders from business, government and non-profit sectors.

## Information Sharing

To further support the professional development program, MTAA offered a number of information sharing events. These included:

- MedTech Forums designed to explore topical issues significant to the medical technology industry
- MedTech Seminars to discuss key operational issues
- member only free Webbytes accessed via an online live meeting room, or later via a recording viewed on the secured member website
- member briefings offered to members only and delivered as face-to-face meetings, online live meetings, or a combination of both.

## Career Support

This section of the MTAA website was further expanded to support the career choices available to the medical technology industry. MTAA career support opportunities are designed to foster industry progression at varying stages of a career.

# Industry Profile

## a) Annual Conference

The MTAA's annual conference MedTech 2012 was held on Thursday 8 November 2012 at Doltone House in Sydney. The theme of the conference was *Medical Technology and Healthcare in 2020*.

MedTech 2012 is the premier industry conference for the medical technology industry in Australia and is MTAA's annual flagship event. It brings industry together with policy makers, stakeholders, and other influencers and decision makers. It provides a platform for robust and engaging debate about industry issues and opportunities.

In 2012 the conference provided an overview of how the delivery of healthcare is changing and what industry needs to do to keep pace with change.

International keynote speaker David Houle presented trends and forces that will shape healthcare delivery in the next 10 years globally. Second international keynote speaker Miles Ayling from the UK Ministry of Health, provided insights into how the UK health system is planning to address challenges that are similar to the ones faced in Australia.

The international speakers were followed by a range of Australian speakers and panelists who presented on the changing nature of the economy, health delivery, compliance and regulatory environments, and on building a sustainable Australian medical technology industry.

The conference was followed by the dinner where the 2012 Kerrin Rennie Award finalists and winner were announced. Dinner speaker, Professor Anthony Burkitt from Bionic Vision Australia, looked towards the future through the vision of the World's first bionic eye.

MTAA wishes to thank the annual supporters DHL and Alleasing, major sponsor Pharmaceutical & Medical Professionals, and sponsors Healthcare Placement Solutions, OnQ Recruitment, Persona Grata and UltraFeedback for their generous support of MTAA and the conference in 2012.



Kerrin Rennie Award

## b) Kerrin Rennie Award

The 2012 Kerrin Rennie Award for Excellence in Medical Technology – *Improving Quality of Life* recognised the innovative and extraordinary contribution of medical technology in improving health outcomes of Australian patients.

*This award is endowed by the family of the late Kerrin Rennie, who was a long standing member of the Australian medical technology community.*

### 2012 Winner

#### **Symplcity Renal Denervation by Medtronic Australasia**

The Medtronic Symplcity renal denervation system is a minimally invasive, one-time procedure to disrupt the renal nerves and produce a reduction of blood pressure levels. It does not involve a permanent implant or invasive surgery. Hypertension is the number one risk factor for premature death worldwide affecting more than 6 million Australians. Currently used to treat resistant hypertension, the Symplcity system has the potential to aid more than 100 million people worldwide.

### 2012 Finalists

#### **1. HEARLab and Aided Cortical Assessment test by HEARworks**

HEARLab is an assessment and rehabilitation tool for clinical audiologists. HEARLab provides a hardware framework, coupled with clinical tests designed as modules implemented in software. Aided Cortical Assessment measures minute electrical potentials originating from the brain's auditory cortex in response to speech sounds, enabling assessment of hearing functions in infants, with or without hearing aids or cochlear implants. It enables accurate fitting of hearing technology to infants at the earliest possible moment to assist in speech and language development within the first 6-12 months of life. The HEARLab system was designed and developed in Australia by the Hearing Cooperative Research Centre.

#### **2. SeQuent Please by B Braun**

SeQuent Please is the first paclitaxel eluting coronary balloon catheter providing cardiologists with an effective way to treat coronary stent restenosis, a side effect of the interventional treatment of coronary artery disease with coronary stents. Cardiologists have been using paclitaxel coated coronary artery stents to reduce the incidents of restenosis but the condition continues to occur and becomes more difficult to treat with each reoccurrence. With SeQuent Please the drug is delivered via a coated balloon catheter removing the need for multiple stent layers and maximizing the lumen of the vessel and blood flow to the cardiac tissue.

#### **3. True Beam and True Beam STx by Varian Medical Systems Australasia**

The True Beam system is an advanced medical linear accelerator used in radiotherapy and radiosurgery treatment. It can deliver cancer treatments with pinpoint sub-millimeter accuracy. By closely targeting tumors True Beam is better able to avoid the surrounding tissue and critical organs; delivering faster, more efficient and effective radiation therapy; contributing to speedier patient recovery and lowering associated care costs. True Beam also gives medical professionals the tools to treat more complex cases like lung and liver cancers with this non-surgical treatment.

The winner was announced on Thursday **8 November 2012** as part of the MTAA MedTech conference in Sydney.



### c) Media Activities

A public relations campaign to highlight various aspects of the medical technology industry was conducted in 2012-13. MTAA contracted a PR agency to help with some of the media outreach necessary to place the stories in online, print, radio and TV news services. The PR campaign concentrated on the following topics.

#### Medical technology as an innovative industry

The key messages were based mainly on the MTAA white paper on *Building a sustainable Australian medical technology industry*, released in March 2012. The coverage focused on medtech as a part of the manufacturing sector, job creation and opportunities through Australia's close proximity to Asia, as well as the call for a national policy to support the industry.

#### The benefits of modern wound care devices

The media coverage was based on the MTAA Value of Technology report on wound care and modern wound care devices, and MTAA's policy proposal to establish an Essential Care List scheme. The Value of Technology report presents an analysis of the benefits and cost-effectiveness analysis of devices used to address issues like leg ulcers and other wounds, while the Essential Care List scheme sets out a funding pathway for technologies used in the sub-acute care setting. The media coverage coincided with Wound Awareness Week.

#### Sharps and needlestick injury prevention

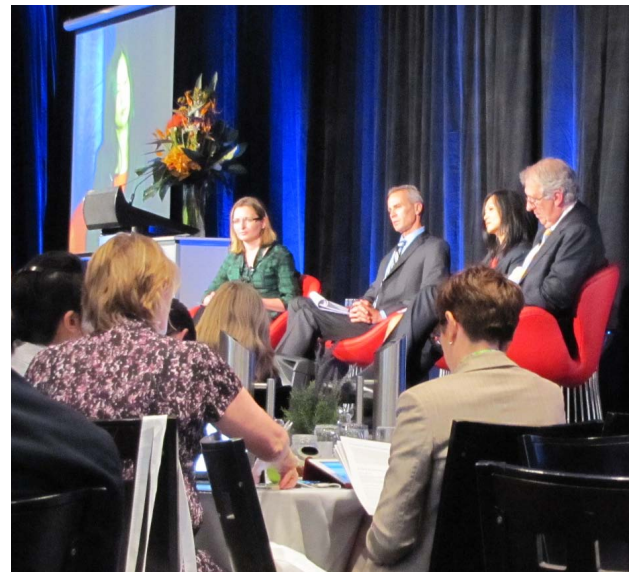
This topic was picked up twice in media coverage over the course of the campaign, firstly coinciding with International Nurses Day and secondly coinciding with a major international nurses conference in Australia. MTAA is founding member of the *Alliance for Sharps Safety and Needlestick Prevention in Healthcare*, an alliance of healthcare professional and other organisations.

#### Remote monitoring

The coverage focused on the benefits of remote monitoring of implantable cardiac devices. The context was provided by the MTAA *Business case for funding of remote monitoring of cardiac implantable electronic devices*. The TV coverage assisted in illustrating how innovative technologies can help keep patients out of hospitals, and calls for improved access to the technologies.

#### Telehealth

MTAA contributed to the health section of News Corp's *Path to Prosperity* series. Coverage included a range of articles and televised panel discussion to highlight the benefits of telehealth technologies. Key messages were based on MTAA's position paper on telehealth highlighting the need for a comprehensive telehealth policy for Australia.



Panel Discussion



Anne Trimmer (MTAA), Andrew Wiltshire (Medtronic), Kevin Barrow (MTAA Chair)



MedTech 2012 Plenary

# Value of Technology Project

The Value of Technology (VOT) project was established to improve the understanding of the impact of advances in medical technology on healthcare expenditure in Australia, and the associated benefits for the Australian healthcare system and community.

The VOT project focuses on the clinical and economic burden of various disease areas, and the benefit relevant medical technologies have on these diseases. The outcome of the VOT research will support advocacy for funding in, and support for, a range of technologies that might not have strong Australian evidence to date and/or lack funding.

During 2012-13 the VOT project focused on the following research areas.

## Needlestick and sharps injuries and safety-engineered medical devices

Needlestick and sharps injuries (NSIs) are one of the most common causes of physical, pathological and psychological hazards for many healthcare workers. NSIs are associated with substantial cost for the Australian healthcare system and can increase morbidity and/or mortality risk for the injured healthcare worker due to exposure to bloodborne pathogens. Extensive evidence has shown the effectiveness of safety-engineered medical devices (SEMDs) in reducing rates of NSIs in healthcare facilities. Post-implementation of SEMDs can reduce NSIs by over 80% and in conjunction with training and guidelines can reduce injuries by over 90%. SEMDs are also cost-effective interventions, in which substantial cost savings are likely to be gained for the Australian healthcare system through the reduction in the number of injured healthcare workers requiring treatment and management of NSIs and bloodborne pathogens.

In May 2013 MTAA conducted an economic evaluation which showed that implementation of SEMDs in all Australian hospitals would result in an average cost savings of \$18.6 million per year. Furthermore, the estimated cost savings is likely to be higher as it did not include the costs associated with treating chronic hepatitis C virus (HCV) (i.e. cost of HCV only included the costs associated with treating low risk injuries) and the costs associated with human immunodeficiency virus (HIV) treatments.

## Chronic wounds and modern wound care devices

Chronic wounds place a significant economic burden on the Australian healthcare system. Treatment and management of chronic wounds remain under-funded, with costs usually paid by patients and their families.

Extensive clinical evidence shows that MWCDs are more clinically effective for wound healing and protection against secondary infections compared with traditional wound care treatments such as standard gauze dressings. MWCDs offer considerable economic benefits over traditional treatments by reducing the number of dressing changes required, reducing the healing time of the wound, reducing clinician and nursing time for assessment and treatment, reducing cost and frequency of complicating infections, and reducing the number and length of hospital stays.

Access to funding for chronic wound care through various Australian Government programs and schemes remains limited. MTAA has proposed an Essential Care List (ECL) scheme that includes funding for chronic wound care treatment better enabling the use of MWCDs in the community setting, thus avoiding costly hospital treatment.

In June 2013 the VOT research findings on the benefits of MWCDs for the treatment and management of chronic wounds was presented as a poster '*Evidence for funding of treatment and management of chronic wounds in Australia*' at the 10<sup>th</sup> Health Technology Assessment international (HTAi) conference held in Seoul, Korea.

During 2012-13 MTAA worked extensively with Australian Wound Management Association (AWMA) and the Wound Management Innovation CRC on a national wound data initiative project. The primary purpose of the project is to establish a national wound repository that can compile data to be used to advocate for funding of chronic wounds and MWCDs. MTAA is part of the Steering Group that is involved with the development of the plan for the establishment of a national wound registry.

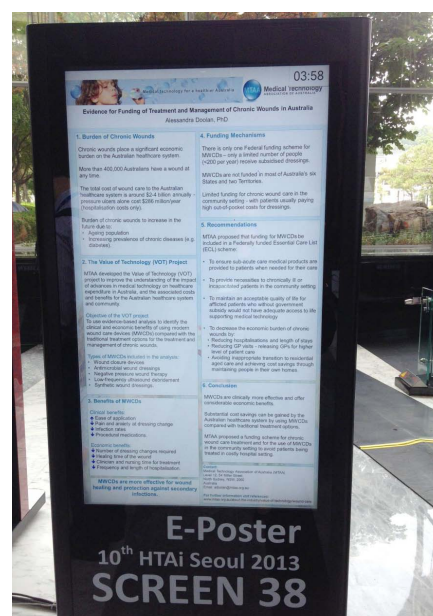
## Insulin pump therapy for patients with type 1 diabetes

Diabetes places a large economic burden on the Australian healthcare system in terms of expenditure on hospitalisations, aged care, medications, diagnostic services and other out-of-hospital medical care. In Australia, the cost of treating diabetes alone is around \$1.5 billion per year.

Insulin pump therapy is currently the only treatment type that replicates normal insulin secretion by a healthy pancreas. This is especially important for individuals with type 1 diabetes, in which insulin therapy is necessary for their survival. However, the proportion of Australians with type 1 diabetes who use insulin pumps remains relatively low - only 10% of individuals with type 1 diabetes.

Insulin pump therapy is recommended as a treatment option for children and adults with type 1 diabetes due to the numerous clinical benefits it provides compared with multiple dosage injection (MDI) therapy. These benefits include reduction in HbA1c levels, decreased glucose variability, fewer episodes of severe hypoglycaemia and improvement in individual's quality of life (QOL). Additionally, insulin pump therapy compared to MDI therapy is cost-effective, where the use of insulin pump therapy is shown to be 'good value for money'.

The VOT research provided evidence-based support for the MTAA submission to PBS on *Post Market Review of Products Used in the Management of Diabetes: Insulin Pump Review*, February 2013.



MTAA Poster at HTAi conference, Seoul, Korea



# Submissions

## 2013

- Comments to IMDRF on WG (PD1)/N4R2 Auditor Competency and Training Requirements for Organisations undertaking Audits of Medical Device Manufacturers - 13 June 2013
- Comments to IMDRF on WG (PD2)/N3R5 Recognition Criteria for Medical Device Auditing Organisations - 13 June 2013
- Comments on TGA's consultation paper: Evaluating the feasibility of a new-to-market risk communication scheme for therapeutic goods - 13 June 2013
- Comments on TGA's Exposure Draft Regulation Impact Statement: Changes to pre-market approval of medical devices - 3 June 2013
- Submission to DoHA on the Home Care Packages Program Guidelines - 17 May 2013
- Comment on IHPA's paper on the Development of a table of standard costs for conducting clinical trials in Australia - 6 May 2013
- Submission to the Senate Community Affairs Committee on Assistive and sub-acute medical technologies to enable older Australians to remain at home - 22 April 2013
- Joint submission with IVDA to the Senate Finance and Public Administration Committee on the Therapeutic Goods Amendment (Pharmaceutical Transparency) Bill 2013 - 18 April 2013
- Submission to the Australian Government Office of the Australian Information Commissioner (OAIC) on the consultation draft: Mobile Privacy – A better practice guide for mobile app developers - 17 April 2013
- Initial feedback on TGA's proposed publically accessible database for adverse event notifications (DAEN) for medical devices - 15 April 2013
- Comments on the Trans-Tasman early warning system: how the process will work in Australia and New Zealand - 5 April 2013

- Submission to TGA in response to the proposal paper on reforms to premarket assessment - 15 March 2013
- Submission on the ANZTPA framework - February 2013
- Submission to the PBS on the Post Market Review of Products Used in the Management of Diabetes - 14 February 2013
- 2013-14 pre-Budget submission - 31 January 2013
- Submission to the Commonwealth Consumer Affairs Advisory Council (CCAAC) in response to an Issues Paper: App purchases by Australian consumers on mobile and handheld devices - 31 January 2013
- Comments on the MSAC draft papers on Fit for purpose pilots and pathways and MSAC application form – January 2013 (member only)

## 2012

- Submission to the National Aboriginal and Torres Strait Islander Health Plan - 20 December 2012
- Position paper: Developing a comprehensive telehealth policy for Australia - December 2012
- Comments on Draft Consultation Paper Strategic Review of Health and Medical Research in Australia - 28 November 2012
- Submission to IHPA on ABF pricing framework 2013-14 - October 2012
- Comments to the Office of the Chief Scientist on Improving the translation of research into innovation leading to national prosperity - 14 September 2012

All submissions and position papers can be accessed on the MTAA website at [www.mtaa.org.au](http://www.mtaa.org.au).





## Members at 30 June 2013

3M Healthcare Pty Ltd  
Abbott Australasia (Vascular) Pty Ltd  
Alcon Laboratories (Australia) Pty Ltd  
Allergan Australia Pty Ltd  
Allied Healthcare Group  
Ambu Australia Pty Ltd  
American Medical Systems (AMS) Pty Ltd  
Analytica Limited  
Applied Physiology Pty Ltd  
ArthroCare (Australasia) Pty Ltd  
Atrium Australia Pacific Rim Pty Ltd  
Australasian Medical & Scientific Ltd  
B Braun Australia Pty Ltd  
Bard Australia Pty Ltd  
Bausch & Lomb (Australia) Pty Ltd  
Baxter Healthcare Pty Ltd  
Becton Dickinson Pty Ltd  
Big Green Surgical Company Pty Ltd  
Biomet Australia Pty Ltd  
Biotronik Australia Pty Ltd  
Boston Scientific Pty Ltd  
Brainlab Australia Pty Ltd  
Cochlear Limited  
ConMed Linvatec Australia Pty Ltd  
Coloplast Pty Ltd  
Corin (Australia) Pty Ltd  
Covidien Pty Ltd  
Culpan Medical Pty Ltd  
Device Technologies Australia Pty Ltd  
Edwards Lifesciences Pty Ltd  
Find-Me Technologies Pty Ltd  
Fresenius Kabi Australia Pty Ltd  
Gambro Pty Ltd  
Gelworks Pty Ltd  
Heraeus Kulzer Australia Pty Ltd  
Hologic (Australia) Pty Ltd  
Horten Medical Pty Ltd  
Hospira Pty Ltd  
Johnson & Johnson Medical Pty Ltd  
Karl Storz Endoscopy Australia Pty Ltd  
Kimberly-Clark Australia Pty Ltd  
Laminar Air Flow Pty Ltd  
LifeHealthcare Pty Ltd  
Link Orthopaedics Australia Pty Ltd  
Mayo Healthcare Pty Ltd  
Medical Specialties Australia Pty Ltd  
Medigroup Australia Pty Ltd  
Medtronic Australasia Pty Ltd  
N Stenning & Co Pty Ltd  
Oceania Orthopaedics Pty Ltd  
Olympus Australia Pty Ltd  
Paragon Therapeutic Technologies

Paul Hartmann Pty Ltd  
Platigo Solutions Pty Ltd  
Prism Surgical Designs Pty Ltd  
Quicksmart Pty Ltd  
REM Systems Pty Ltd  
RITM Australia Pty Ltd  
Signostics Pty Ltd  
Simavita Pty Ltd  
Sirtex Medical Limited  
Smith & Nephew Pty Ltd (Healthcare Division)  
Smith & Nephew Surgical Pty Ltd  
Smiths Medical Australasia Pty Ltd  
Somnomed Limited  
Sorin Group Australia Pty Ltd  
Spectrum Ophthalmics  
St. Jude Medical Australia Pty Ltd  
Stryker Australia Pty Ltd  
Surgical Specialties Pty Ltd  
Synthes Australia Pty Ltd  
Terumo Australia Pty Ltd  
Tornier Pty Ltd  
Tunstall Australasia Pty Ltd  
Varian Medical Systems Australasia Pty Ltd  
Wellspect HealthCare Australia  
W. L. Gore and Associates (Aust) Pty Ltd  
Zimmer Pty Ltd

## Associate members at 30 June 2013

Covance Pty Ltd  
Dassault Systemes Australia Pty Ltd  
Five Corners Pty Ltd  
Healthcare Placement Solutions Pty Ltd  
Open Sesame Consulting  
Pacific Clinical Research Group  
PricewaterhouseCoopers  
Regulatory Concepts Pty Ltd  
Slate Hill Consulting Pty Ltd  
Sue Akeroyd & Associates  
The Bioadvisory Group Pty Ltd  
The SPD Company Pty Ltd  
UltraFeedback Pty Ltd



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