Annual Report 2011-12

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Medical Technology
ASSOCIATION OF AUSTRALIA

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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

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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.

In 2010-11 the Australian medical technology industry:

- was made up of exporters, suppliers or manufacturers of medical technology manufactured in Australia (23%) and importers, third party distributors/wholesalers (77%)
- employed over 17,500 people, the majority working in sales and marketing (50%), or service and support (32%)
- was responsible for 36,000 medical devices listed on the ARTG (2012) (including IVDs and dental) with up to a million different devices linked to them
- was mainly located in NSW (55%) followed by Victoria (21%) and Queensland (11%)
- supplied the Australian market with anaesthetic and respiratory devices (24%), orthopedic devices (22%), cardiovascular/vascular devices (18%), wound care and management devices (16%), infection control (16%) and medical imaging/ultrasound (14%)
- supplied reusable products (38%), single use items (34%) and implantable devices (26%)
- had total annual revenue in the order of $8 billion
- imported goods to the value of $3.3 billion and exported goods to the value of $1.2 billion.

Globally the medical technology market is valued at over US$300 billion per annum and by 2016 will approach US$350 billion.

Message from the Chair

As the Chair of the Board of the Medical Technology Association of Australia (MTAA) it is my pleasure to comment on some of the activities of the Association for the financial year ending 30 June 2012.

The operating environment for the Australian medical technology industry continued to place strain on companies in 2011-12. As globally countries are struggling to manage their economies even a comparatively well performing economy like Australia needs to find ways to balance their (health) budgets. Margin squeeze in public and private health systems, increases in regulatory requirements and delivering more with less are reoccurring themes for most companies in the medical technology sector.

The long-term outlook for the medical technology sector is generally optimistic. An ageing population is driving demand, Australia's proximity to Asian markets and a well developed health system are factors that can positively influence the growth potential for the industry in Australia. MTAA has issued a white paper on *Building a sustainable Australian medical technology industry* in March 2012. It describes the potential for an Australian industry and how to balance the scales to achieve a more export oriented trade.

On the political side, the Board recently held a series of strategic planning sessions to prioritise areas of focus. The main themes identified as key areas to focus for advocacy and PR activities in the next months include broadening the range of products to be reimbursed in the private sector, implementation of health reform and the transition to activity based funding in the public sector, post-market monitoring of devices, support for patients in the community and building a sustainable industry.

The Board is committed to articulating the value of technology message to governments, the opposition parties, other stakeholders and healthcare associations that smarter medical technologies can deliver substantial savings to health systems and improve health outcomes for patients.

For the first time in 2011, the industry in Australia could be more closely statistically defined through detailed data analysis and research. The *Key facts and figures booklet 2011* has been well received and continues to be widely quoted as an authoritative source of information on the medical technology industry.

The value of technology project continues to provide information on the cost-effectiveness of medical technologies that is used in submissions and in PR activities. In 2012, research is ongoing to highlight cost-effective technologies.

MTAA will continue to advocate on behalf of members and the industry to make constructive and positive contributions to public debate and policy, and present a unified voice for the sector.

Since my appointment as Chair in December 2009 it has been reassuring to see that members are willing to participate in a variety of ways to support the work of MTAA in setting industry policy.

Thank you for your support especially through continued membership of the Association, participation in committees and training, attendance at events and the annual conference, and in submitting entries to the Kerrin Rennie Award.

In 2012 MTAA has introduced a changed sponsorship model for events and annual conference. I would like to thank our corporate supporters, Alleasing and DHL, for their support of MTAA and its members.

I would like to thank past and present Board Directors for their contributions and support during 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.

I look forward to growing a sustainable and successful Australian medical technology industry sector in the coming years.

Dr Bronwyn Evans
Chair MTAA

CEO's Report

The reporting period 2011-12 has been a very active period for your association. MTAA has continued to consolidate its place as the 'go to' representative of the medical technology industry in health policy debate and in the development of policies to support a more sustainable industry in Australia.

MTAA has had some significant wins in a tough environment for the healthcare sector. Our wins come about because of the depth and breadth of the relationships we have built with the political parties, the bureaucracy and stakeholder partners in all relevant portfolios – health, industry, trade, and treasury. Following is an outline of some of the key activities in the reporting period.

Private health system

MTAA has played an active role on the Health Technology Assessment Consultative Committee (HTA CC) during the year, ensuring that the new grouping scheme with benchmark benefits operates equitably, and takes account of product utilisation. MTAA was successful in ensuring that benefits were not set below a benchmark benefit of 25% utilisation and has held the Department of Health and Ageing (DoHA) to this benchmark on several occasions.

MTAA has been successful in broadening the terms of reference for the HTA CC to include development of a mechanism to review benefit levels, and to broaden coverage to include additional beneficial technologies that cannot be listed at present on the Prostheses List. These policies remain under active discussion by the HTA CC.

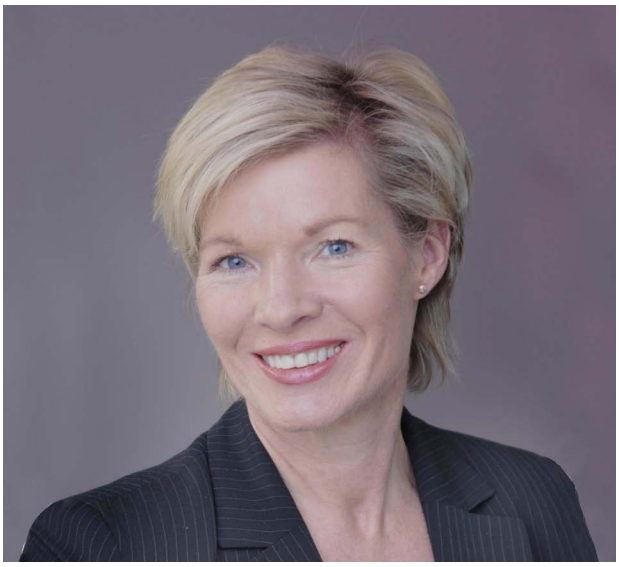
MTAA's participation on an extensive range of healthcare committees translates into provision of up to date information to our members on a broad range of Australian healthcare issues. These include stakeholder committees such as the Home Dialysis Advisory Committee as well as representation on the Prostheses List Advisory Committee and the Clinical Advisory Groups in addition to the HTA CC.

We have ensured that the industry's voice has been heard through the numerous submissions to reviews and inquiries such as the Senate Committee Inquiry into the regulation of high risk medical devices, and the review of the National Joint Replacement Registry, which the Australian Orthopaedic Association has undertaken.

Public health system

During the year MTAA became the only supplier industry body appointed to the stakeholder reference group of the Independent Hospital Pricing Authority (IHPA). This has ensured that we have been able to provide comment on the pricing framework with proposals to improve the funding for and uptake of new medical technology.

MTAA has proposed several mechanisms to enable more rapid review of Diagnosis Related Groups (DRGs) with funded introduction of new technologies.



Value of technology – improving patient access

Over the past year MTAA has launched its Value of Technology (VOT) project, which utilises research to establish the cost-effectiveness of specific technologies. The research has supported submissions to government for funding (e.g. research conducted for *VOT - Remote monitoring systems for patients with chronic heart failure and implantable cardiac devices* was used extensively in the 2012 submission setting out the business case for public funding of remote monitoring of cardiac implantable electronic devices).

The VOT research has also provided opportunities to work closely with other industry bodies and organisations (e.g. Australian Wound Management Association and Wound Management Innovation CRC for *VOT - Chronic wounds and modern wound care* devices and Pain Australia for *VOT – Chronic pain and infusion pumps*).

The VOT research combined with MTAA policy papers and submissions has been the basis for a series of media activities that highlighted the benefits that medical technology can bring to patients' lives and the healthcare system.

Regulatory affairs

The regulation of medical devices has been the subject of intense scrutiny during the year with two Senate Committees of Inquiry, one into the regulation of high risk medical devices and the other into the circumstances surrounding the PIP breast implant. At the end of the reporting period, the government was considering its response to the reports from these inquiries but the common theme is that there needs to be improved post-market surveillance with increased use of clinical quality registers and better adverse event reporting mechanisms for clinicians and consumers.

MTAA has worked with TGA to ensure that proposed regulatory changes do not impose unreasonable additional burdens on companies. In particular MTAA was successful in TGA drawing back from a proposal that would require a sponsor to identify every product with its ARTG number which would have imposed considerable additional cost and unique Australian requirements for labelling and packaging. MTAA has worked with TGA to ensure that the increased regulation of implantable orthopaedic shoulders, hips and knees is able to draw substantially on assessments previously undertaken for European re-classification rather than requiring new or unique evidence.

Growing a sustainable med tech industry

In the past year MTAA has developed a strategic industry policy agenda to increase government awareness of the industry's economic contribution and to argue for increased support for the development of the Australian medical technology sector.

During the year MTAA released a white paper *Building a sustainable Australian medical technology industry* as a roadmap for government and industry to work together more strategically to develop the policy levers industry needs to achieve growth in the sector.

MTAA has proposed the development of an ecosystem map to assess Australia's capabilities in medical technology and identify a strategy to address the gaps to support development of the industry.

During the year MTAA re-launched the SME forum as the Australian Medical Technology Innovation Group with a list of policy priorities to progress in 2012 such as access to finance, investment in infrastructure, innovative procurement strategies, development of industry clusters, and export strategies. MTAA also made several submissions to reviews of manufacturing capability undertaken by the Federal, NSW and South Australian Governments.

Delivering programs and events that support members

During the past year MTAA has consolidated its education and learning programs for members. In all, six courses are available each with a series of online and/or face-to-face training modules. MTAA has negotiated the introduction of a Health Economics course through University of Technology Sydney which will specifically target the needs of the medical technology industry.

Two half day MedTech Forums were held for the first time. These addressed:

- Access to Medical Technology
- Transition to Activity Based Funding.

MTAA, together with other therapeutic goods industry associations, held the first Sponsor Information and Training Day on 22 June in Canberra. The day was organised so senior staff from the TGA could present to an audience of over 250 industry representatives.

MTAA's flagship conference MedTech 2011 was held in Sydney, attracting a strong audience of delegates from varied backgrounds. The Kerrin Rennie Award was awarded for the fifth time and celebrated excellence in medical technology.

Strengthening industry-wide Code compliance

MTAA has been working with the government to encourage the implementation of policies which will extend Code coverage across the industry, beyond member companies of MTAA. In the 2012 Federal Budget the government approved funding to extend the reach of code compliance beyond the therapeutic industries, to the healthcare professionals. Compliance with the Code has become an industry-wide obligation for companies supplying to some health purchasers, a development MTAA is encouraging.

During the year MTAA undertook its first independent external review of the Code of Practice, the recommendations from which have been incorporated into an 8th edition which will be voted on by members at the 2012 Annual General Meeting, following extensive consultation.

I have given only a brief overview of the work which has been underway on your behalf during 2011-12. Your support for that work is critical to its success, through your participation in the various working groups, committees and forums, and most importantly through your continuing membership of the association.

I look forward to your ongoing involvement with MTAA in 2012-13.

Anne Trimmer
Chief Executive Officer

Corporate Supporters

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DHL SUPPLY CHAIN

Thank you for your support

MTAA Board Members

David Akeroyd

Managing Director, Australia and New Zealand, 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 role 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.

Paul Braico

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

Paul has over 26 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.

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.

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)

Carmen has worked in the healthcare industry for over 20 years in the areas of clinical research, quality management, and sales and marketing. With an interest in wider health policy issues, Carmen has recently 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.

Bronwyn Evans

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

Bronwyn has worked with Cochlear for 7 years with responsibility for the design and implementation of the global QMS Regulatory Compliance programs across jurisdictions including Australia, America, Europe, China and Japan. Bronwyn also has a senior involvement in the operational areas of design control and manufacturing with Cochlear. Prior to joining Cochlear, Bronwyn gained over 29 years experience in a range of industries including power generation and distribution, standards development and engineering education. Bronwyn is on the board of John Holland Group, The Warren Centre for Advanced Engineering and Engineers Australia, Centre for Engineering Leadership and Management. Bronwyn has chaired MTAA since December 2009.

Gavin Fox-Smith

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

Gavin has over 26 years experience in the medical technology 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 as Director of Marketing for Asia. Gavin joined Johnson & Johnson Medical ANZ in 1997 as a Regional Business Director and held diverse leadership roles in sales, marketing and general management across the Johnson & Johnson 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 Pty Ltd
B.Sc. Materials (UTS), MBA (AGSM, UNSW), GAICD

Tony has over 23 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 currently holds the position of Managing Director for Biomet Australia and New Zealand and was appointed to this role in early 2009. In those roles, Tony has been principally focused on organisational change management to realign performance with corporate objectives. He is currently Vice Chair of the MTAA Board.

Phil Nicholl

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

Phil has been in the medical devices sector for over 19 years, during which time he's held various senior management positions in Australia, Asia and Europe including Vice President of Marketing, Stryker Pacific (Hong Kong), Managing Director, Stryker Southern Asia (Singapore) and Vice President and Managing Director, Stryker South Pacific (Sydney) and President Asia Pacific, Cochlear Ltd (Sydney).

Julianne Prowse

General Manager, Coloplast Pty Ltd
MBA (Swinburne)

Julianne has been with Coloplast in Australia and the US for 22 years. Before Julianne's appointment to her current role, she worked with Coloplast in the US for four years as General Manager, Breast Care, and then Vice President, Ostomy Care. Prior to joining Coloplast, Julianne worked in a number of industries including travel, recruitment and pharmaceutical sales.

Jamie Stanistreet

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

Jamie joined Medtronic in 1999 following their acquisition of AVE Inc and was appointed to the MD 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. He is currently Vice Chair of the Board.

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 oversighting 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

Anthony Bishop

Area Vice President Australia & New Zealand, Johnson & Johnson Medical
B.Bus Hons (QUT), MMgt (MGSM)

Colin Hannah

Vice President Australia and New Zealand, Hospira
B.Ed, (Physical Education/Biomechanics) University of Lancaster, UK

Mark Wallwork

Managing Director, Boston Scientific Pty Ltd
B.Econ (UWA)

MTAA Secretariat

Anne Trimmer, Chief Executive Officer
Brett Andrews, Manager Corporate Services
Marion Demann, Corporate Communications Manager
Alessandra Doolan PhD, Health Outcomes Policy Officer
Joanne Ince, Office Coordinator
Alina Hughes, Code of Practice Manager
Fiona Landis, Industry Policy Manager
Fee Koch, Public Health Policy Officer
Michelle Mars PhD, Research Manager
Kylie Maidment PhD, Research Manager
Warren Mitchell, Manager Commercial Issues
David Ross, Director Healthcare Access
Fiona Shipman, Professional Development Manager
Cliff Spong, Director Regulatory and Scientific Affairs

Meeting Attendance

1 July 2011 - 30 June 2012

Notes		23-Aug-11	25-Oct-2011 (1)	25-Oct-2011 (2)	6-Dec-11	21-Feb-12	17-Apr-12	19-Jun-12	Eligible to Attend	Appointed	Departed
		Melbourne	Sydney	Sydney	Sydney	Brisbane	Sydney	Canberra			
1	Mr David Akeroyd	Present	Present	Present	Apology	Present	Present	Apology	5 of 7	16-Sep-10	
2	Mr Kevin Barrow	Present	Present	Present	Present	Present	Present	Present	7 of 7	16-Sep-10	
3	Mr Anthony Bishop	Present	Present	Present	Present	Apology			4 of 5	16-Sep-10	1-Mar-12
4	Mr Paul Braico							Apologies	0 of 1	19-Jun-12	
5	Ms Carmen Byrne	Present	Present	Present	Apology	Present	Present	Present	6 of 7	16-Sep-10	
6	Dr Bronwyn Evans	Present	Present	Present	Present	Present	Present	Present	7 of 7	16-Sep-10	
7	Mr Gavin Fox - Smith						Apology	Present	1 of 2	17-Apr-12	
8	Mr Colin Hannah	Present	Apology						1 of 2	6-Apr-11	25-Oct-11
9	Mr Tony Harrington	Present	Present	Present	Present	Present	Apology	Present	6 of 7	16-Sep-10	
10	Mr Phil Nicholl	Present	Apology	Apology	Present	Apologies	Apology	Present	3 of 7	25-Oct-11	
11	Ms Julianne Prowse	Present	Apology	Apology	Present	Present	Apology	Present	4 of 7	25-Oct-11	
12	Mr Jamie Stanistreet	Present	Present	Present	Present	Present	Present	Present	7 of 7	25-Oct-11	
13	Mr Mick Trevaskis	Present	Present	Present	Apology	Present	Apology	Present	6 of 7	25-Oct-11	
14	Mr Mark Wallwork			Present	Present	Present	Apology		3 of 4	25-Oct-11	22-May-11

Notes

1 - Elected from 16 September 2010 to AGM 23 October 2012
2 - Elected from 16 September 2010 to AGM 23 October 2012
3 - Elected from 16 September 2010 to AGM 2012 - resigned 1 March 2012
4 - Appointed to fill casual vacancy 19 June 2012
5 - Elected from 16 September 2010 to AGM 23 October 2012
6 - Elected from 16 September 2010 to AGM 23 October 2012
7 - Appointed to fill casual vacancy 17 April 2012
8 - Term expired AGM 25 October 2011
9 - Elected from 16 September 2010 to AGM 23 October 2012
10 - Elected from 25 October 2011 to AGM 2013
11 - Elected from 25 October 2011 to AGM 2013
12 - Elected from 25 October 2011 to AGM 2013
13 - Elected from 25 October 2011 to AGM 2013
14 - Elected from 25 October 2011 to AGM 2013 - resigned 22 May 2012

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 and valuable role in industry policy development and the preparation of responses to government reviews. The Access Committee is one of three strategic committees reporting to the Board. The Committee met on three occasions during the reporting period and also considered issues outside of these meetings.

The Access Committee considered issues raised by the Senate Community Affairs References Committee Inquiry into regulatory standards for approval of medical devices in Australia, researched and reviewed members submissions and were instrumental in the preparation of the industry submission to the inquiry. As of the end of the reporting period, Government had not provided its response to the inquiry.

The Access Committee has monitored DoHA's actions in attempting to streamline processes of the Medical Services Advisory Committee (MSAC). The Committee has been representing industry concerns regarding the effectiveness of MSAC changes in a submission to DoHA identifying shortfalls in process. The submission was sympathetically received and was followed by a meeting of stakeholders under DoHA auspices to identify a consensus.

Reimbursement Subcommittee

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

The Committee managed industry involvement and comments on the Prostheses List Advisory Committee's draft of a new clinical evidence paper laying out the rationale and requirements for the provision of clinical evidence with listing applications. Drawing on industry feedback, the Committee prepared a draft which formed the basis of the MTAA submission to the Prostheses List Advisory Committee (PLAC) on the paper.

The Committee has established as a priority to improve the quality of communications with the Private Health Insurance Branch of DoHA. A successful first meeting between the Committee and DoHA at senior executive level was held where a range of operational issues have been addressed.

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 MTAA's Access Committee.

During the year the RegSC considered a number of issues of strategic importance to the medical technology sector including:

- an MTAA position paper on regulatory reforms
- the reclassification of implanted total and partial load bearing implanted hip, knee and shoulder joints from Class IIb to Class III which came into effect on 1 July 2012
- the reforms proposed by TGA and published in the document, *TGA reforms: a blueprint for TGA's future*
- Senate inquiries into aspects of the operation and role of the TGA
- the proposed work program for the newly formed International Medical Device Regulators Forum (IMDRF)
- providing advice to the Access Committee on regulatory issues connected with the submissions prepared during the year.

Code of Practice

The Code of Practice is administered by the Code of Practice Committee (CPC) which is responsible to the Board of MTAA. It is headed by an independent Chair, and is made up of industry members, MTANZ 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.

Considering developments on codes of conduct internationally and also feedback from members and other stakeholders, CPC has recommended a number of changes to the Code as part of the independent external review.

Independent External Review of the MTAA Code of Practice

The MTAA Code of Practice is required to be externally reviewed by an independent person or panel every three years. An external review of the Code was conducted in 2011. The MTAA Board approved terms of reference for the review, which was conducted by an independent panel.

The Code Review Panel members were:

- Ms Jan McClelland, Chair
- Dr Roderick McRae, healthcare professional representative nominated by the Australian Medical Association
- Dr Robert Kitchen, person with medical technology industry experience
- Dr Henry Ko, consumer representative nominated by the Consumers Health Forum of Australia.

The Code Review Panel called for submissions from industry members and other key stakeholders (such as consumers and healthcare professionals). 22 submissions were

received and the Code Review Panel held three meetings to consider submissions and prepare a report containing various recommendations.

The Code Review Panel's report was considered by the Code of Practice Committee and the MTAA Board and will lead to an 8th edition of the Code in 2012.

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 industry members required on CMC.

Throughout 2011-12, CMC was able to review the activities of most member companies. CMC continues to take an educative approach. CMC finds the overall level of understanding and compliance with the Code reasonable.

The inaugural Chair of CMC, Ken Ramsay, stepped down from his role on 30 June 2012 to be replaced by Jan McClelland. The CMC had initiated a review of the processes it uses to collect information from members. This was later taken up by the independent external Code review. The Legal Counsel/Compliance Forum then developed the new process, which came into effect 1 July 2012. It is anticipated this approach will streamline both CMC review activities and member returns.

The Code Complaints Committee (CCC) was required to meet during the year. Both the CCC and the Code Appeals Committee (CAC) are independent, chaired by legally qualified individuals and formed from a panel made up representatives of 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 CAC was not required to meet during the year.

Government Affairs and Policy

The Government Affairs and Policy Committee is one of MTAA's three strategic committees, reporting to the MTAA Board under the chairmanship of MTAA Board Director, Jamie Stanistreet.

The members of the Committee are the government affairs managers within member companies. The focus of the Committee's work is on strategies to raise awareness of, and embed, MTAA's policies with relevant stakeholders including decision-makers such as politicians and bureaucrats, as well as partners in the healthcare sector. The key policies considered by the Committee during 2011-12 include the expansion of coverage of the Prostheses List to include other beneficial technologies that do not meet the current listing requirements, the development of a manufacturing policy for the industry, and national health reform including the introduction of activity based funding.

The Committee reviewed the terms of reference for the Senate Committee's inquiry into the regulation of medical devices and considered the strategic response of MTAA in its submissions and appearance before the Committee.

Regulatory Affairs

The Regulatory Affairs Committee (RAC) has approximately 20 members from member companies. The main role of the RAC is to consider operational issues relating to interactions of member companies with the TGA.

During the year the RAC discussed various operational issues affecting MTAA members during their interactions with the TGA and then developed papers to be discussed at the regular meetings of the TGA/Industry Regulatory & Technical Consultative Forum.

The most significant outcome from the Consultative Forum during the year was the staging of the first Sponsor Information and Training event for sponsors and manufacturers of medical devices and IVD products. The planning and management of the event was undertaken by MTAA. There were 250 delegates and the speakers were senior TGA staff.

The Committee also considered:

- the supply of systems and procedure packs and the TGA's review of surgical procedure packs
- guidance documents prepared by Study Group 1 of the Global Harmonisation Task Force (GHTF)
- assisting the TGA develop review criteria for Class I auto-inclusion applications
- the TGA's regulatory reform proposals.

A working group of MTAA members developed definitions of Class III Unique Product Identifiers and their associated variants for the reclassified hip, knee and shoulder joints which were provided to the TGA. MTAA also chaired and provided secretariat assistance to working groups with members from the TGA, MTAA and other industry associations, as well as representatives from industry which considered better definitions of what constitutes a notifiable change relating to a TGA issued conformity assessment certificate and a better explanation of custom made medical devices.

Orthopaedic

The Orthopaedic Committee met quarterly during the reporting year. The Committee considered issues affecting industry's relationship with orthopaedic healthcare providers and informed industry responses as necessary. The Committee provided an industry member to the National Joint Replacement Registry (NJRR) Consultative Committee. The Orthopaedic Committee Chair, John Cooper, and the industry member of the NJRR Consultative Committee, Phil Nicholl, participated in an interview with Henry Bosch in November 2011 to discuss the Australian Orthopaedic Association Review of the NJRR.

Member Forums

Clinical Investigation

During the year the Clinical Investigation Interest Group met regularly to discuss topics affecting clinical investigations and prepared a paper about the importance of using the correct Standard when undertaking clinical investigations. The paper was presented at the ARCS conference in Sydney.

Commerce/eCommerce

The Commerce/eCommerce Forum provided a platform for members to raise concerns and address issues relating to procurement, including contracts and eCommerce. The Forum provided input into a MTAA submission to NEHTA on the recommendations from members to reduce the number of fields in the National Product Catalogue (NPC).

The Forum represented members on the variations in the format of the NPC browser template used in tenders and requests from some states to modify the way the information was presented. These variations and requests compromised the intention of suppliers to populate a standardised catalogue.

Members had expressed concern about the loss of end user data for products that are shipped through NSW Health central distribution centres. MTAA has been pursuing this issue for an extended period and most recently with the new director for Procurement at NSW Healthshare.

Members were kept informed of the eligibility of small businesses to claim interest on outstanding NSW Health debts. The ongoing issue of late payments was taken up with the Health Minister and resulted in significant improvements for those companies that provided data to MTAA.

Communicators

Throughout 2011-12 the Communicators Forum provided a platform to share and discuss issues and opportunities facing the industry and communications practitioners in the medical technology industry. Topics discussed included media reporting on industry issues and barriers for social media uptake by medical technology companies. The Forum participants also provided feedback on MTAA PR activities, re-branding and new corporate designs, and donations of medical products.

Australian Medical Technology Innovation Group

The Australian Medical Technology Innovation Group (formerly the Small and Emerging Companies Forum) was established in 2010 to provide a member forum for SMEs who manufacture or conduct research and development activities in Australia to canvass priority issues. The purpose of the Forum is to identify barriers to growth and incentives for investment with the aim of establishing a more sustainable domestic medical technology industry in Australia. Over the past year the Forum has considered strategies to address Australia's medical technology trade deficit including procurement programs that drive innovation and growth in the SME sector and offer solutions to public sector challenges. The Forum has also reviewed strategies to improve access to finance and new export markets in emerging economies as well as ways to improve collaboration between industry and the research community. This group has been central to progressing MTAA's industry policy agenda which is about developing an effective business environment for the industry through its contributions to the NSW Manufacturing Action Plan, the South Australian Manufacturing Green Paper and the Prime Minister's Taskforce on Manufacturing. The group meets every eight weeks by online meeting room and via teleconference.

Workforce

During 2011-12 the Workforce Forum met both face-to-face and online. The key purpose is to discuss issues relevant to human resources and professional development within the medical technology industry. The Workforce Forum provides feedback to assist MTAA achieve its objectives in ensuring a skilled and sustainable medical technology workforce through education, training, information sharing, workforce planning and related issues. Workforce Forum meetings are held online, so members can join from anywhere in Australia.

Overseas Technology Aid Group

The first meeting of the new Overseas Technology Aid Group (OTAG) was held on 24 April 2012. The Group was set up to better coordinate and improve the donation of medical goods for surgical mission. In working with the international team at the Royal Australasian College of Surgeons two donations could be facilitated.

Legal Counsel/Compliance

The new Legal Counsel/Compliance Forum was formed in 2012 for personnel from member companies with responsibility for the MTAA Code, compliance and ethics. This includes staff in positions such as legal counsel and compliance.

The Forum is intended to provide an informal opportunity for participants to network, receive updates and provide feedback on a range of Code and ethics issues such as proposed amendments to the Code and associated processes.

Independent Distributors

The first meeting of the Independent Distributors Forum was held in April 2012. The Forum members discussed the increasing TGA application processing times, which present a disincentive to list new products. The issue of public visibility of processing times is being pursued.

Regulatory Discussion Group

The Regulatory Discussion Group met on numerous occasions during the year. Nominated discussion topics included issues such as the impacts of the reclassification of implanted hip, knee and shoulder joints, TGA assessment and auditing procedures and processing times, TGA fees and charges, and the TGA/Industry Sponsor Information and Training event. Participants in the meetings also raised and discussed other regulatory issues of interest with their colleagues from other MTAA companies.

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), Manager, Pricing and Economic Affairs Patient Access, Pfizer

Stuart Bruce, Regulatory & Corporate Affairs Manager, Boston Scientific Corporation

Robyn Chu, Health Outcomes Director, Johnson & Johnson Medical

George Faithfull, Clinical Research & Regulatory Affairs, Stryker

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

Georgina Sanderson, Director Reimbursement, Quality, Regulatory, Cochlear

Mick Shaddock, Senior Business Manager, Device Technologies Australia

Andrew Wiltshire, Senior Director, Government Affairs, Medtronic Australasia

Code of Practice Committee

George Walck (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 Australasia

Alasdair Godfrey, Health Economics Consultant, Hospira

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

Kristin King, Manager, Government Affairs & Public Policy ANZ, Baxter

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

David Pullar, Market Access/Government Relations Manager, Genzyme

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

Andrew Wiltshire, Senior Director, Corporate Affairs, Medtronic Australasia

External Committee Representation

MTAA is representing members on a range of external committees and stakeholder groups. As at 30 June 2012 the following were MTAA representatives.

- Alliance for Sharps Safety and Needlestick Injury Prevention in Healthcare: Anne Trimmer (Chair), Marion Demann (Secretariat), Susan Martland
- Cardiac and Cardio-thoracic CAGs: Warwick Kitt (industry adviser)
- Complaints Resolution Panel: MTAA staff
- Hip, Knee, Spinal and Specialist Orthopaedic Clinical Advisory Groups (CAGs): Bernard O'Connor (industry adviser)
- HTA Consultative Committee: Anne Trimmer, David Ross (observer)
- National Joint Replacement Registry Consultative Committee: Phil Nicholl
- 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 has appointed representatives for Forensic Products, Devices for Contraception and Prevention of Sexually Transmitted Infections, Surgical Implants, Medical Gloves, Anaesthetic and Breathing Equipment, Quality Management for Medical Devices, Telehealth and Controlled Environments. Representatives have contributed to Standards for Technical Management Programs for Medical Devices (AS/NZS 3551), Electrical Installations in Patient Areas (AS/NZS 3003), Sterilization of Medical Devices (AS/NZS 4187) and Controlled Environments – Biological Safety Cabinets (AS/NZS 2252)
- Therapeutic Goods Advertising Code Council: Alina Hughes
- TGA-Industry Consultative Committee: Anne Trimmer, Bronwyn Evans
- TGA/Industry Regulatory & Technical Consultative Forum: Cliff Spong
- Trusted Information Sharing Network (Health Sector Group): Warren Mitchell
- Urogenital and Vascular CAGs: Nick Shalley (industry adviser).

Industry Profile

a) Annual Conference

MTAA conference MedTech 2011: *Medical technology – building sustainable healthcare*

MTAA MedTech is the annual conference for the medical technology industry in Australia focusing on the big policy issues. On 8 November the MTAA MedTech 2011 conference brought together senior industry representatives and key healthcare leaders for a lively debate about key issues and opportunities for the medical technology industry.

In 2011 the theme of the conference was a reflection on the contribution that medical technologies can make towards building a sustainable healthcare system for Australia into the future. Presentations touched on some of the levers in the current environment which impact on sustainability, how new technologies are introduced and assessed, how innovation can be encouraged and rewarded, and on the management of safety and quality of technologies in use in the market.

A CEO Forum explored some of the challenges industry faces involving company leaders from a range of member companies. This session was facilitated by AFR journalist, Peter Roberts.

International keynote speaker Stephen Ubl, President and CEO of AdvaMed, gave delegates an insight into the broader global environment for the industry, the beneficial impact of medical technology and the impact of the US health reforms on the medical technology industry.

The Kerrin Rennie Award has been an integral part of the conference for the past several years and was presented at the conference dinner. Professor Christopher Semsarian from the Centenary Institute in Sydney was the guest speaker.

MTAA wishes to thank the major sponsor Pharmaceutical & Medical Professionals and sponsors Healthcare Placement Solutions and Persona Grata for their generous support of the conference in 2011.

b) Kerrin Rennie Award

Medical technology saves and improves lives by detecting diseases earlier and by providing more effective treatment options for patients and the healthcare system. The Kerrin Rennie Award for Excellence in Medical Technology – Improving Quality of Life recognises the innovative and extraordinary contribution of medical technology in improving health outcomes of Australian patients.

A company could enter a product launched in Australia between 1 January 2010 and 1 August 2011 and used in the diagnosis, prevention, treatment or management of disease and disability. The product must demonstrate the following criteria:

- evidence of significant contribution to improving patient outcomes by enhancing quality of life
- evidence of technical excellence
- evidence of innovation.

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

The winner of the 2011 Kerrin Rennie Award was **Latitude Heart Failure External Sensor (Boston Scientific)**.

Latitude Heart Failure External Sensor (Boston Scientific) is a remote patient management system used to monitor the status of a patient's implanted cardiac device providing regular device measurements and medical alerts. The addition of weight scales and blood pressure monitors allows for greater monitoring capabilities. Data is wirelessly transmitted from the patient's home and gives physicians up to date information allowing for early intervention.

The other finalist was:

Restore Sensor (Medtronic Australasia)

Restore Sensor is a neurostimulator with motion-sensing technology used in pain management especially for chronic back and leg pain. The device senses a change in body activity to deliver a targeted amount of pain relief dependent on the movements of the patient. Neurostimulation is also known as spinal cord stimulation. It uses a device similar to a pacemaker that delivers mild electrical signals to mask the body's pain signals.

In addition four commendations were awarded:

Somation Definition Flash (Siemens)

The technology is used in the areas of diagnosis and prevention, the Somation is a whole body scanner. Its innovation lies in the significantly reduced speed for scans and lower radiation dose.

BonAlive Bioactive Glass (Device Technologies)

This bone graft substitute is used for filling bone voids especially in the treatment for chronically infected bones. The innovation means that the infected bone can be treated in a single operation rather than multiple procedures.

Vial-Mate Reconstitution Device (Baxter Healthcare)

Vial-Mate is an intravenous medication delivery device that is closed to airborne contaminants thus preventing bloodstream infections in patients. Vial-Mate is reducing the number of steps required in administering IVs and is a ready-to-mix, flexible and needleless device reducing medication error and needle stick injuries.

Symplicity Catheter System (Medtronic Australasia)

Is used to perform renal denervation, a catheter based, endovascular procedure to treat hypertension. The system is the first of its kind and a new treatment option to reduce blood pressure in treatment resistant patient populations.

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 2011-12, 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 MTAA training program is based on future national and global directions of the industry, and feedback gained from the medical technology workforce. Existing face-to-face training courses were reviewed with modules added or removed, pending identified learning needs. Several face-to-face modules were re-issued as online learning.

Utilising a blended learning approach new self-paced online learning modules, webinars and face-to-face modules were developed. This learning is delivered across six courses, with each hosting a series of modules. Face-to-face training is delivered following expressions of interest, pre-scheduled, or in-house when requested by a company. Of the 55 training modules offered by MTAA, 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 MTAA 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, and face-to-face (1)
- **6.0 Commercial Practice:** two modules offered online (1) and face-to-face (1).

Education

During 2011-12, MTAA continued to offer resources that support the education of future, newly qualified and current medical technology industry personnel. The MTAA *Workplace Learning Directory* assists secondary and tertiary students in being exposed to the work of the medical technology industry.

In 2011, MTAA partnered with McCarthy Mentoring to offer a new mentoring program for member companies, the *Emerging Leaders Development Program*. This initiative aims to connect MTAA member company high potential aspiring leaders within the medical technology industry with the expertise, insights and networks of leaders from business, government and not-for-profit sectors.

A member company leader registered for the program. Over the 12 months program the mentor provided a professional sounding board with no vested interest in the medical technology industry. The matching process conducted by McCarthy Mentoring was robust, providing an excellent mentor/mentee match.

Information Sharing

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

- MedTech Seminars to discuss key operational issues
- Member only free online Webytes accessed live or via a recording

MedTech Forums are a new half day event. Forums are designed to explore topical issues significant to the medical technology industry. Experts in the field address different aspects of a topic, provide premium insight and areas for consideration. Delegates are invited to participate during the panel discussion.

The first MedTech Forum, *Access to Medical Technology*, was held on 28 July 2011 with 55 delegates in attendance. The second, *Activity Based Funding*, was held 28 March 2012 with over 60 delegates.

Career Support

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

Value of Technology

The Value of Technology (VOT) project was developed to improve the understanding of the impact of advances in medical technology on healthcare expenditure in Australia, and the associated costs and benefits for the Australian healthcare system and community. The outcome of the VOT research supports advocacy for funding and support for a range of medical technologies that might not have strong Australian evidence to date.

During 2011-12, the VOT project focused on the following research.

Chronic wounds and modern wound care devices

Chronic wounds place a significant economic burden on the Australian healthcare system and cause devastating effects on patients and their quality of life. Modern wound care devices (MWCDs) are shown to be more effective than the traditional 'wet or dry' gauze for wound healing and protect against secondary infections. MWCDs compared with traditional treatments also offer considerable economic benefits by reducing the number of dressing changes required, healing time of the wound, clinician and nursing time for assessment and treatment of the wound, and cost and frequency of complicating infections. The treatment of chronic wounds and patient access to MWCDs are currently not well funded and the cost of wound care devices is usually paid by patients and their families. MTAA has proposed to the Australian Government to include funding for an Essential Care List (ECL) scheme, which will include funding for essential sub-acute medical products such as MWCDs. The scheme will also assist Australians to stay in their homes, which will result in considerable cost savings for the Australian Government and healthcare system.

Chronic pain and infusion pumps

Infusion pumps are effective means of drug delivery for chronic pain therapy and used in a wide range of clinical conditions such as cancer therapy. Infusion pumps are either external or implantable. Infusion pumps are the preferred treatment option where conventional drug delivery systems have failed to provide sufficient pain relief or cause intolerable adverse events. Postoperative use of infusion pumps have been demonstrated to be cost-effective by reducing overall treatment costs such as reducing the need for analgesics (where long term use is associated with several side effects such as nausea, vomiting and constipation), reducing the risk of surgical site infections and significantly reducing length of hospital stay (reduction on average of 1-3 days). Furthermore, the use of infusion pumps in long-term homecare setting therapies such as chemotherapy and antibiotic treatments may also generate substantial cost savings for the Australian healthcare system and community.

Remote monitoring systems for patients with chronic heart failure and implantable cardiac devices

The VOT research on *Remote monitoring systems for patients with chronic heart failure and implantable cardiac devices* highlights the positive health outcomes and cost savings associated with remote monitoring of cardiac implantable devices compared to in-clinic monitoring. The research has also provided evidence-based support for MTAA's submission to government for funding 2012-13, *Business case for public funding of remote monitoring of cardiac implantable electronic devices*.

Research Activities

The core research activities in 2011-12 were associated with policy submissions and analysis of trends in Australian healthcare. Examples include:

Industry statistics

MTAA commissioned an industry wide survey targeting Australian medical technology companies. The survey covers market size/composition, turnover, value of imports/exports, employment and opinions on the future of the industry. This information will be published in the 2012 edition of the booklet, *Medical Technology in Australia: Key Facts and Figures*.

Regulation of online contact lens purchase in Australia

MTAA prepared a background paper on the need for changes to the regulation of online contact lens purchase in Australia. Population growth and aging combined with innovation both within and outside the vision correction market mean that the incidence of contact lens wear and the likelihood of contact lens related complication will increase. MTAA proposes that policy responses encompass regulation and education emphasising the role of eye care professionals in the online purchasing process.

The business case for public funding of remote monitoring of cardiac implantable electronic devices

Remote monitoring of cardiac implantable electronic devices (CIED) is efficient, effective and preferred by both patient and doctor. As the Australian population ages, telehealth options such as remote monitoring, will become an increasingly significant aspect of healthcare provision. MTAA prepared a white paper for Treasury and DoHA outlining cost neutral and cost saving business models for remote monitoring of CIED.

The future of medical technology

MTAA is undertaking research on the future of the global and domestic medical technology industry. Research includes environmental scans, database searches and survey research. MTAA contributed to a scenario planning exercise to produce a report on *Alternative Futures for Community Care Scenarios in Australia to the year 2030*.

Number of people in the Australian population with implantable devices

With medical technology becoming increasingly effective and affordable the number of people who have Class III or Active Implantable Medical Devices (AIMD) is steadily rising. Using data from the NJRR, the Australian Institute of Health and Welfare (AIHW), hospital data cubes, industry reports and published research results, MTAA has researched the number of Australians who have implantable devices.

Submissions

2011

- Submission to the review of NJRR - 16 December 2011
- Issues paper on reforms to the MSAC process - December 2011
- Response to CS&HISC Environmental Scan 2012 - 1 December 2011
- Response to draft NSW Manufacturing Industry Action Plan - 25 November 2011
- Response to the discussion paper on *NSW Health and Medical Research Strategic Review* - 16 November 2011
- Response to the *NSW Health and Medical Research Strategic Review Issues Paper* - 26 September 2011
- Response to the exposure draft of the *2011 Strategic Roadmap for Australian Research Infrastructure* from the Department of Innovation, Industry, Science and Research - 22 July 2011

2012

- Comments on the Victorian Government's approach to International Engagement - 3 May 2012
- Response to South Australian Government's green paper on manufacturing - May 2012
- Submission to the Australian Senate Community Affairs Reference Committee Inquiry into the role of the Government and the TGA regarding medical devices, particularly PIP breast implants - April 2012
- Submission to *Australia in the Asian Century* - 5 April 2012
- Submission to the Strategic Review of Health and Medical Research (McKeon Review) - 30 March 2012
- Submission on draft PLAC clinical evidence paper - 23 March 2012
- White Paper: Building a sustainable Australian medical technology industry - March 2012
- MTAA Submission on NSW Government Procurement discussion paper - 2 March 2012
- Submission 2012-13: Business case for funding of remote monitoring of cardiac implantable electronic devices - 1 March 2012
- Submission to IHPA on ABF pricing framework - 21 February 2012

All submissions and policy papers can be accessed from the MTAA website at www.mtaa.org.au.

International Engagement

MTAA represents the Australian medical technology industry internationally in a range of forums to share information on national developments in regulation, reimbursement and market conditions, and to advance harmonisation across many of these areas.

The shared objective of all industry associations represented in international forums is to ensure good health outcomes for patients with timely access to technology which is safe and effective.

International Medical Device Regulators Forum

The International Medical Device Regulators Forum (IMDRF) is the global regulatory body established on 1 January 2012 to replace the Global Harmonisation Task Force (GHTF). GHTF developed the framework under which the regulation of medical devices has been implemented in Australia by TGA. Unlike the GHTF, the IMDRF is a regulator-only body which interacts with the medical technology industry and other interested bodies through an open session during its meetings.

Industry welcomed the establishment of the IMDRF with the inclusion of a broader representation of regulators to improve alignment of the regulation of medical technology post-GHTF.

Global Medical Technology Alliance

The Global Medical Technology Alliance (GMTA) represents more than 20 national and regional medical technology associations from around the world. Membership is open to those associations which are the national representative of the medical technology industry, or segment of the industry (such as IVDs). GMTA is a loosely-established international body which is moving towards incorporation and formalisation. It works closely with international agencies such as the World Health Organization.

APEC codes of business ethics

In late 2011 the leaders of the APEC economies agreed to a proposal from the Ministers for Small and Medium Enterprises to support the development of a code of business ethics for the medical device industry in the APEC region. The purpose of this initiative is to reduce the disadvantage which SME companies can experience when competing in an unlevel market place. A code of business ethics is seen as one way to address the issue.

The agreement of the leaders followed work undertaken in early 2011 when representatives of the medical technology sector met in Kuala Lumpur to develop the framework for the code. This became known as the KL Principles. The KL Principles will provide strong guidance in the APEC region in the way in which companies and healthcare professionals and other customers can operate ethically in their dealings with each other. Separate codes are now in development in each of the APEC economies based on the KL Principles.

Code Committee Reports

Code Complaints Committee

The Code Complaints Committee (CCC) considered a Complaint by Bausch & Lomb (Australia) Pty Ltd (B&L) against Alcon Laboratories (Australia) Pty Ltd (Alcon) on 7 July 2011.

The matter concerned claims made by Alcon about their OPTI-FREE EverMoist contact lens cleaning solution product with respect to B&L (and other) comparable products. The subject of the complaint is an advertisement by Alcon for their OPTI-FREE EverMoist product which features the headlining statement "Now there's a better way to give today's contact lenses 16 hours of moisture". Under the headline is an image of two women, one of whom is wearing a fishbowl on her head. Below the image of the two women is promotional copy introducing OPTI-FREE EverMoist and an image of the OPTI-FREE EverMoist pack. Alcon references “data on file” in the advertisment.

B&L alleged the following breaches of the Code by Alcon:

- Section 5.1(a) of the Code
- Section 5.1(b) of the Code being prohibition of misleading or deceptive advertising or advertising likely to mislead or deceive
- Section 5.1(c) of the Code being a requirement to reflect a higher standard of social responsibility and conform with generally accepted standards of good taste
- Section 5.1(e) not claim that a product is unique or has some special merit or quality or property unless the claim can be substantiated
- Section 5.2(a)(i) being substantiation of all claims in an advertisement by reliable technical, scientific or other support
- Section 5.3(a) being the prohibition on unfairly denigrating a competitor's product
- Section 5.3(b)(i) and (ii) and in particular the requirement that the outcomes of comparative testing are reported in fair and balanced manner
- Section 5.3(d) the prohibition on a company using an Advertisement claims that describe or show a competitor product as broken or defaced, inoperative or ineffective unless based upon the outcome of comparative testing
- Section 5.3(e) being a prohibition of Advertisements which contain or expressly by implication exaggerated or unqualified superlative claims.

Outcome

CCC dismissed the B&L Complaint in its entirety.

Costs

CCC required B&L to pay 100% of the costs associated with this matter.

The Code Complaints Committee (CCC) considered a Complaint by St Jude Medical Pty Ltd (SJM) about Medtronic Australasia Pty Ltd (Medtronic) on 20 October 2011.

The matter concerned Medtronic’s RestoreULTRA brochure (Advertisment) published in 2008 and distributed to at least one healthcare professional in April 2011. SJM alleged certain statements contained in the RestoreULTRA brochure breached the Code. Medtronic informed the Committee that the brochure was never intended for distribution in Australia and was not now in circulation.

SJM alleged eleven statements or assertions made either singularly or collectively in the RestoreULTRA brochure breached clauses 5.1 (b), 5.1 (c), 5.1 (e), 5.2 (a) (i), 5.2 (a) (ii), 5.3 (a), 5.3 (b), 5.3 (b) (i), 5.3 (b) (ii), 5.3 (d) and 5.3 (e)

The Committee recognised that it was the introduction of certain SJM products post 2008 and the effluxion of time that had caused many of the issues with the accuracy of the brochure but believed that the Code required it to consider the effect of the Advertisement at the time it was distributed.

CCC found the following:

5.1 (b)	Upheld in part
5.1 (c)	Upheld in part
5.1 (e)	Upheld in part
5.2 (a) (i)	Upheld in part
5.2 (a) (ii)	Upheld in part
5.3 (a)	Upheld in part
5.3 (b)	Upheld
5.3 (b) (i)	Upheld
5.3 (b) (ii)	Upheld
5.3 (d)	Upheld in part
5.3 €	Upheld in part

CCC noted that the breach of the Code found did not result in any patient safety implications but, if a healthcare professional were to read the brochure in 2011 there would be an adverse effect on how the healthcare professional viewed the SJM and other competitor products to the Medtronic products. Taking all things into consideration, CCC classified the breach as a moderate breach.

In coming to this view, CCC also considered that the breaches of the Code, set out in some detail by SJM, had arisen from a single event, that is the apparent inadvertent distribution of a brochure in breach of the Code to a single healthcare professional that subsequently came to contain errors with respect to a comparator product from SJM which was on the market in January 2009 after the brochure was published in 2008.

Having classified the breaches as being in the moderate range, CCC treated the alleged breaches as a single breach. On that basis, CCC determined to impose an overall financial sanction of $5,000. CCC also requires Medtronic to pay CCC costs as calculated by the Secretary normally in the range of $5,000 to $7,000.

Medtronic was also required to confirm with the Chair under section 12.2 that the brochure is not in circulation and give an undertaking that the brochure will not be circulated in Australia in the future. Further, the CCC directed that Medtronic issue a retraction to any healthcare professional who to its knowledge may have received the brochure, by informing them in writing that the brochure in question was not intended to be circulated in Australia, was out of date and contained inaccuracies and misstatements in breach of the Code of Practice.

Medtronic has undertaken the above actions to the satisfaction of the Chair.

Members at 30 June 2012

3M Healthcare Pty Ltd
Abbott Vascular Pty Ltd
Alcon Laboratories (Australia) Pty Ltd
Allergan Australia Pty Ltd
Allied Healthcare Group Pty Ltd
Ambu Australia Pty Ltd
American Medical Systems (AMS) Australia Pty Ltd
Analytica Ltd
Applied Physiology Pty Ltd
ArthroCare (Australasia) Pty Ltd
Astra Tech 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
CareFusion Australia 316 Pty Ltd
Cochlear Ltd
Coloplast Pty Ltd
ConMed Linvatec Australia Pty Ltd
Corin (Australia) Pty Ltd
Covidien Pty Ltd
Device Technologies Australia Pty Ltd
Edwards Lifesciences Pty Ltd
EV3 Australia Pty Ltd
Fresenius Kabi Australia Pty Ltd
Gambro Pty Ltd
Gel Works Pty Ltd
Genzyme Australasia 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 Limited
Laminar Air Flow Pty Ltd
Life Healthcare Pty Ltd
Link Orthopaedics Australia Pty Ltd
Med-Chem Surgical Pty Ltd
Medical Specialties Australia Pty Ltd
Medigard Ltd
Medigroup Australia Pty Ltd
Medtronic Australasia Pty Ltd
Methadose Pty Ltd
N Stenning & Co Pty Ltd
Nanosonics Ltd
Oceania Orthopaedics Pty Ltd
Olympus Australia Pty Ltd
Orthopaedic Solutions Pty Ltd
Paragon Therapeutic Technologies
Paul Hartmann Pty Ltd
Qlicksmart 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
Sorin Group Australia Pty Ltd
Spectrum Ophthalmics Pty Ltd
St. Jude Medical Australia Pty Ltd
Stryker Australia Pty Ltd
Surgical Specialties Pty Ltd
Synthes Australia Pty Ltd
Terumo Australia Pty Limited
Tornier Pty Ltd
Tunstall Australasia Pty Ltd
Varian Medical Systems Australasia
W. L. Gore and Associates (Australia) Pty Ltd
Zimmer Pty Ltd

Associate members at 30 June 2012

Brandwood Biomedical Pty Ltd
Covance Pty Ltd
Five Corners Pty Ltd
Healthcare Placement Solutions Pty Ltd
Kelly Speech Communication
Open Sesame Consulting Pty Ltd
Phillips Ormonde Fitzpatrick Pty Ltd
Regulatory Concepts Pty Ltd
Sue Akeroyd & Associates
Ultrafeedback Pty Ltd
Waterfall Commercialisation Group Pty Ltd

www.mtaa.org.au

Street Address
Level 12, 54 Miller St, North Sydney
NSW 2060 Australia

Postal Address
PO Box 2016 North Sydney
NSW 2059 Australia

P (+612) 9900 0650
F (+612) 9900 0655
E reception@mtaa.org.au