



ANNUAL REPORT

2015/2016



Medical Technology
ASSOCIATION OF AUSTRALIA

www.mtaa.org.au



MEDICAL TECHNOLOGY FOR A HEALTHIER AUSTRALIA



CONTENTS

| | |
|----------------------------|----|
| About MTAA | 3 |
| Chair Report | 4 |
| CEO Report | 7 |
| Board of Directors | 10 |
| Committees | 12 |
| MTAA Representing Industry | 15 |
| Professional Development | 17 |
| Annual Conference 2015 | 19 |
| 2015 Industry Awards | 21 |
| Our Members | 23 |
| The Secretariat | 24 |

ABOUT MTAA

The Medical Technology Association of Australia (MTAA) is the national association for the medical technology industry. MTAA ensures 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. MTAA members supply the majority of the non-pharmaceutical products used in the treatment of disease and disability in Australia. The range of medical technology is diverse, from familiar items such as syringes and wound dressings through to sophisticated devices such as pacemakers, defibrillators, hip and other prosthetic implants. Products range from 3-D additive manufacturing to robotic surgery equipment and complex hospital installations, in vitro diagnostics, radiation therapy machinery, diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines, and eHealth and remote monitoring devices.

Our members also play a vital role in providing healthcare professionals with essential education and training. Industry sponsored fellowships and funding for research and development in hospitals, universities and research facilities helps ensure safe and effective use, development and commercialisation of medical technology.

Associate members are supporter or partner organisations and individuals who work with MedTech companies along the MedTech value chain all the way from idea to patient. They include legal, logistic, consulting practitioners, compliance agencies, health economists, researchers and universities, as well as industrial designers and product commercialisation specialists. They bring valuable expertise and input to the industry.

Corporate Goals

1. *To be recognised as the national body that represents the medical technology sector with a united voice.*
2. *To ensure the medical technology sector is sustainable.*
3. *To be an influential partner in the healthcare and industry policy debate*
4. *To provide leadership in ethical interactions with the Australian healthcare community*
5. *To deliver indispensable value to members.*



Medical Technology
ASSOCIATION OF AUSTRALIA



CHAIR REPORT

GAVIN FOX-SMITH

Medical Technology plays a significant role in the health and well-being of Australians. The pressure of increasing health care costs, the increasing power of economic stakeholders in purchasing decisions, and consolidation of businesses has added further pressure on our industry to ensure we continue to articulate the value we bring to the healthcare sector, and that we continue to collaborate broadly with all stakeholders. I thank Chief Executive Susi Tegen and her team for their dedication and focus during this time.

“...our solutions make our health system more efficient, and improve the lives of the patients we serve.”

We have been working on many regulatory reviews that will shape the future of our industry including the primary healthcare review, the MBS review and the long awaited private health insurance (PHI) review. We have earned our seat at the table in determining health care in Australia, and our willingness to contribute in a positive way has been acknowledged as constructive to achieving the best health outcomes. With that in mind, it is more important than ever that industry come together and speak with one voice to our stakeholders, including government, patients, and

clinicians. We strongly believe that the Prostheses List allows surgeons to choose the most appropriate medical technologies based on individual patient needs, and therefore is essential to ensuring access to the best treatments available.

In an environment of increased complexity of business models and finite funding models, the Medical Technology sector remains reliant on innovative medical devices and highly trained professionals.

Technologies are often positioned as one of the cost drivers rather than the solutions to the challenges in our healthcare delivery. This is a perception MTAA is working hard to change, to ensure decision makers and policy makers understand that technologies are an asset, a solution, a way to make improvements to healthcare outcomes. We need to demonstrate that our solutions make our health system more efficient, and improve the lives of the patients we serve. They are not simply a cost driver. These challenges have underlined how important MTAA's role is, and how critical our industry is to the nation's healthcare future.

Medical Technology and People

Every day somewhere around Australia and the rest of the world, someone's life is improved by what we do. We relieve pain and discomfort, treat disease and



disability, lengthen lives, improve peoples' quality of life, and we ensure people are able to make a contribution to our society. If a medical technology speeds a person's recovery from illness so they can get back to work more quickly, think about how large that contribution is to our society. Instead of lying in a hospital bed costing the healthcare system money, they are back in the workforce, paying taxes and helping to support the cost of health and other public services for their fellow Australians. The work we do helps Australians live longer, healthier and more productive lives. This has been our constant message to all political stakeholders, and it is one we will continue to deliver as the various reviews of the Australian healthcare system continue.

"...healthcare has become the largest employer in Australia. This sector employs over 1.4 million people, four times as many as agriculture, forestry and fisheries combined; five times more than mining; three times more than financial services; and twice as many as the accommodation and food (tourism) sector."

In articulating the importance of the medical technology sector, it is important that it is understood that healthcare has become the largest employer in Australia. This sector employs over 1.4 million people,

four times as many as agriculture, forestry and fisheries combined; five times more than mining; three times more than financial services; and twice as many as the accommodation and food (tourism) sector. We provide the tools and the talent that deliver innovative and efficient healthcare to all Australians. Our sector spans the range of small, medium sized and large companies which collaborate and innovate with some of the greatest minds across the globe to deliver advanced technology.

"Diversity starts with full participation, having the right mix of people from different backgrounds representative of the wider community and who bring different experiences and different perspectives."

Thanks to advances in healthcare, a child born today in Australia can expect to live to almost 95. Yet when we set our retirement age at 65 at the turn of last century, average life expectancy was just 55. We didn't actually expect anyone to live to retirement age! Of course, in many ways, this is a good problem to have and I'm proud of the role my industry has played in giving us that extra 40 years: medicines, technology, better diagnostics, more effective treatments for serious illnesses like cancer - all of these innovations are extending our lives. But as the bell curve of our population skews towards the elderly, there will be fewer and fewer 'young' people in the workforce to support our growing numbers of retirees. Increasingly we will rely on technology to maintain and improve the quality of healthcare delivery.

Promoting diversity in the workplace

We also need to ensure we are tapping into the greatest minds in bringing better health to all Australians, and that means ensuring that we have diversity of thinking, approach and skill sets. This year, through our 'Women in MedTech', MTAA has championed the cause of talented and engaged women. Launched by Sex Discrimination Commissioner, Elizabeth Broderick on behalf of MTAA in July, the initiative included a series of events and educational forums designed to raise the bar on gender diversity by providing insightful, informative

content and networking that supports the industry as a whole. Ultimately, our success as MedTech companies rests on our ability to meet emerging medical needs. To do this, we need to be sure that we are capturing a breadth of capability and opinion to solve the health problems of today, and tomorrow.

That is why we need our people to continue to develop along with the changing market. Diversity starts with full participation, having the right mix of people from different backgrounds representative of the wider community and who bring different experiences and different perspectives. But diversity doesn't really drive innovation until you put that mix of people into an inclusive culture. To really gain competitive advantage, there needs to be a deep belief inside the organisation about the value diversity brings to the way you do business. It needs to be a part of the DNA of an organisation.

Honouring Steadfast Support and Achievement

The MTAA Board firmly believes it is vital for an industry association to have a strong and supportive membership base. We are committed to remaining relevant to all our members. We thank and recognise all of our member companies for their contribution to the industry and their support through membership to further the important activities of MTAA. Each year we say a special thank you and recognise those members who have been continuously committed to MTAA for the last 10, 20, 25 and 30 years.

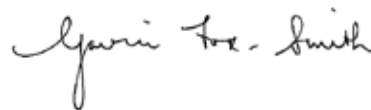
This year we recognised the following:

- For 20 years of continuous membership: Device Technologies.

- For 25 years of continuous membership: Halyard (formerly Kimberly Clark).
- For 30 years of continuous membership: Stryker Australia.
- For 30 years of continuous membership: B Braun Australia.

We also believe it is important to recognise outstanding individuals who have dedicated their careers to the Medical Technology Industry in Australia. We do this by occasionally honoring such people through life membership of MTAA. This year we recognised Peter Ord of Device Technologies Australia which he set up 23 years ago and now employs more than 650 people and represents over 195 companies from all over the world. It is the largest independent medical device company in the southern hemisphere and Peter is a true pioneer in our industry.

Thank you to fellow Board members and Volunteers
In concluding, I would like to say a heartfelt thank you to the MTAA Board and Committee chairs and volunteers for their steadfast support and wise counsel throughout this year. We continue to deliver against an ambitious Strategic Plan and I am confident that we will continue to do so in the year ahead.



Gavin Fox-Smith
MTAA Chair



Fiona Landis, Dharmica Mistry, NSW Young Women of the Year, (awarded March 2016) and Senior Scientist at BCAL Diagnostics, Kathryn Matthews, Partner, Deloitte Access Economics, Hon Jillian Skinner, Minister for Health, The Hon Anthony Roberts MP Minister for Industry Resources and Energy, Susi Tegen and Gavin Fox-Smith.

CE REPORT

SUSI TEGEN



Over the past year MTAA has been at the center of some of the most important health policy debates in modern Australian history. As the Federal Government looks for ways to trim healthcare spending, MTAA has protected members' interests by explaining the role of advanced medical technology in achieving better outcomes for health consumers while reducing the fiscal burden on taxpayers.

“Policy makers have listened to our evidence-based arguments that put patient welfare first, and they now see us as a key part of the solution.”

Facing unfounded claims that the medical device industry could sustain an \$800 million cut, the MTAA bought key stakeholders to the table, to find better ways to fund the growing patient need for new, often life-saving, medical technology. Policy makers have listened to our evidence-based arguments that put patient welfare first, and they now see us as a key part of the solution.

Our success has been due in no small part to the effort that has gone into forging relationships at all levels. We work closely with consumer groups, the medical fraternity, other peak bodies, researchers, academia,

industry and government. By leveraging these relationships we have ensured that your voice is heard.

What is clear is that this effort still has a long way to go, and with six reviews - two of which are major reforms of the health care system - still underway, supply chain costs remain a front and centre public policy issue for the sector.

Private health insurance review

Following consultations with stakeholders in late 2015, MTAA provided submissions to the Department of Health in early December covering possible reforms to Australia's private health insurance arrangements. For many of our members, consideration of the future form and existence of the Prostheses List meant there was a lot at stake. MTAA opposed changes to the PL and made our objections clear in consultations with decision makers and influencers throughout the year.

Industry Skills

One of our priority projects for the year was our MedTech Industry Skills Study conducted in collaboration with Deloitte. With funding support from the NSW Government through the NSW MedTech Knowledge Hub, we held workshops across Sydney, Brisbane and Melbourne, disseminated an industry survey and held over 30 one-on-one consultations with

a range of member and non-member companies. The report, issued by Deloitte in mid-2016 pointed to significant future shortages in key skills areas. MTAA will be working closely with governments at the Federal and State levels to address these shortages in the interest of driving growth and sustainability of a sector that governments have identified as strategically important to Australia's economic success.

"We welcomed over 20 new corporate and associate members to MTAA during the financial year, swelling our membership ranks to over 100 companies."

A steadily growing membership base

We welcomed over 20 new corporate and associate members to MTAA during the financial year, swelling our membership ranks to over 100 companies. In a time when the industry is under threat, the value proposition has never been stronger. It is gratifying to see companies band together under the MTAA banner to meet the challenges we face. Having a strong membership cohort sends a clear message to government that our sector is united and determined to advance our cause. It bolsters our lobbying position and provides companies with the information and intelligence they need to make informed decisions about their long term corporate strategies.

Better Procurement Terms

We pushed for national alignment of processes for public procurement of medical technology, standardized terms and conditions and removal of duplicative requirements, improved governance arrangements for public procurement to ensure discipline and transparency in the procurement process; and skills development of health procurement officials.

MTAA continued to advocate on behalf of MedTech companies and engage directly with State and Territories' procurement departments to ensure that no electronic system, regardless of who develops it, is mandated as a condition for participation in public healthcare tenders.

National Disability Insurance Scheme and MedTech

Through a series of member information events and consultations, MTAA provided MedTech companies and other interested stakeholders with a better understanding of the processes involved in the selection, sourcing and supply of assistive technology's for people with a disability. As the NDIS rolls out, this major initiative is still in its early phase and MTAA has positioned itself as a key stakeholder in promoting its members' interests.

Stopping the Spread of a Patchwork of Vendor Credentialing

Vendor credentialing is a compliance and risk management system used to manage risk in healthcare facilities, where a third-party provider conducts vendor checks on behalf of an accredited hospital. In many overseas markets the credentialing has been undertaken by third parties and the process has been designed and driven by these third party training organisations causing significant unnecessary cost and additional processes burdened on the medical device companies.

This year, MTAA worked with its members, healthcare facilities and Standards Australia to develop an industry wide Australian Standard for the requirements of vendor credentialing. The focus of the standard is to minimize unnecessary cost and reduce the duplication of credentialing requirements. The first industry wide consultation process is to be held in June and will be hosted by MTAA and Standards Australia.



Susi with Federal Health Minister Susan Ley



We also welcomed the uptake and commitment to the Code by the Australian Orthopaedic Association. This will greatly assist industry engaging with this influential group of healthcare professionals at their conferences and meetings. This was the result of considerable work by the secretariat, Board Director Doug North and the Code Committee and above all a medical group demonstrating commitment to ethical doctor/industry interaction.

The Board's decision to offer Code of Practice training to members free of charge, was warmly greeted with more than 2000 people having completed the online training during the financial year.

Value of Technology

MTAA's paper on "The 'Value' of Safety-Engineered Medical Devices In Reducing Needlestick and Sharps Injuries" was presented at Health Technology Assessment International (HTAI) 2016 Annual Meeting in Tokyo, Japan in May. The research findings on the 'value' of safety-engineered medical devices (SEMDs) in reducing needlestick and sharps injuries (NSIs) recommended the use of SEMDs in Australian healthcare facilities be mandated where implementation of SEMDs will effectively reduce rates of NSIs and occupational exposures to blood-borne pathogens.

Our VoT program turned its attention to the important areas of imaging and oncology. MTAA Chairman Gavin Fox-Smith hosted a series of meetings with senior executives of these companies to discuss issues affecting the sector and strategies for addressing them through MTAA.

Thanks to an outstanding Board and team

The enormous challenges faced this year, and the positive outcomes achieved, could not have happened without the steadfast support of our Board, committee members and Member company CEs. I am genuinely grateful to each and every member for the efforts they have made. In particular, I would like to single out our Chairman, Gavin Fox-Smith who has given generously of his time and expertise. I have valued the counsel he has provided throughout the year.

I would like to thank all the staff who have worked at the MTAA over the last year. It has been an incredibly difficult period, with major changes in industry, government and policy. These changes have required flexibility, stamina and skills like never before. I have really appreciated the talented and resilient staff who have responded exceptionally to the unique demands, the policy support the MTAA has received from Fiona Landis and the internal administrative and business support from Allison Fox. The mention of their name, does not diminish the contribution of other staff who have worked with and supported me to ensure companies are able to have the best outcome possible for patients and industry. David Ross departed in March after 15 years of exceptional and loyal service to the MedTech industry and MTAA. He has provided many years of valuable advice and support to our members and industry as a whole. I valued his opinion, consideration and legacy.

I often reflect on what we have achieved. Someone said to me recently that I should think more about how we have protected the sector from damage that might have occurred for companies and patients, if we had not been advocating or part of the discussions driving better health outcomes.

I look forward to watching the MedTech industry and the MTAA grow and thrive so it can continue to add value to Australians.

Susi Tegen
MTAA Chief Executive

BOARD OF DIRECTORS

Below are the photographs and biographies of the MTAA Board Directors as at 30 June 2015.

We thank the following previous Directors of the board for their service;

David Jolly, St Jude Medical, Graham McLean, Stryker, Philippa Lewis, Simavita.



Paul Braico, Vice President and Managing Director, Boston Scientific

A passionate medical device industry professional and leader with 30 years' experience in the medical technology industry, Paul has worked in diverse organisations. Prior to his current role, Paul held several senior leadership roles in Australia and Japan.

Joined Board in June 2012 and is a member of the Finance and Audit Committee.



Emma Cleary, Chief Operating Officer, Device Technologies Australia Pty Ltd

Emma has over 25 years experience spanning medical devices, managed services, professional accounting and other industries in Australia and overseas. Emma is a Chartered Accountant and joined Device Technologies as CFO in 2005. More recently, Emma developed and launched Device Solutions, the managed services division of the company that focuses on improving patient diagnostics and care through the use of digital technology. Joined Board in October 2013 and is a Vice-Chair of the board and Chair of the Finance Committee.



Rebecca Cortiula, Managing Director, Terumo Australia Pty Ltd

Rebecca has a broad range of experience including in the following specialty areas: laboratory science, cardiovascular surgery, interventional radiology and cardiology, transfusion and general hospital medical devices, both consumables and capital equipment. Rebecca has over 15 years experience at Terumo Australia. Joined Board in November 2015.



Christopher Cowley, Managing Director, Varian Medical Systems Australasia

Chris was appointed Managing Director of Varian Medical Systems Australasia in 2009, having previously worked for Varian in the Middle East as Service and General Manager. Prior to his employment with Varian he studied, trained and worked as a Biomedical Engineer in the UK. Chris has been in the medical device industry as a customer and vendor for 28 years.

Joined Board in October 2014 and is a member of the Code Authority.



Hilary Crilly, Managing Director, Becton Dickinson Australia and New Zealand Pty Ltd

Hilary has 24 years experience in the pharmaceutical and medical device industries, including 14 years as a corporate office holder, Company Secretary or Director, and is currently Director for BD in Australia and New Zealand. She is a member of the Australian Institute of Company Directors and has 30 years experience as a chartered accountant. Joined Board November 2015.



Lyn Davies, Managing Director, Tunstall Australasia Pty Ltd

As Managing Director of Tunstall Healthcare, Lyn Davies is responsible for the strategic direction, business growth and operational services delivery for the Asia Pacific region. Lyn joined Tunstall in 2004 with 20 years experience in customer service and 14 years in contact centre environments. She has worked with well-known organisations such as Logan City Council, Mater Hospitals, CITEC and the Queensland State Government. Joined Board in December 2013.



Steve Flynn, Director Market Access and Healthcare Solutions, Baxter Healthcare

Steve leads a team of 25 strategic sales and government liaison professionals across Australia and New Zealand that work with healthcare professionals, hospital executives, payers and policy makers. He joined Baxter in January 2006 as Regional Business Manager, Healthcare Solutions, ANZ. Prior to joining Baxter, Steve spent 6 years at TNT, a global provider of mail, express and logistics services and 5 years at GM Holden Limited. Joined Board in November 2015.



Gavin Fox-Smith MTA Chair, Managing Director, Johnson & Johnson Medical Pty Ltd

Gavin is one of Asia Pacific's most experienced health sector leader, with nearly three decades in the medical technology and devices sector. He joined J&J Medical ANZ in 1997 as a Regional Business Director, holding diverse leadership roles in sales, marketing and general management across the J&J family, including Ethicon, EES, DePuy and Cordis. Joined Board in April 2012 and Chair.



Doug North, Managing Director, Surgical Specialties Pty Ltd

Doug is the major shareholder and Executive Director of Surgical Specialties. 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 90 staff across Australia and New Zealand. Joined Board in April 2013.



Mark Taffa, Managing Director, Horten Medical Pty Ltd

Mark is the founder and Managing Director of Horten Medical, a company distributing medical devices, established in 2005. At GE Medical, Mark had product responsibility for all of Asia in digital imaging, based in Singapore and consulting to the Brunei government on e-health. Actively involved in the healthcare industry for over 15 years, Mark has experience in running small scale local manufacturing of complex medical equipment for local and export sales. Joined Board December 2013, is a Vice-Chair of the board and Chair of the Access Committee.



Andrew Wiltshire, Senior Director, Corporate Affairs, Medtronic Australasia Pty Ltd

Andrew has over two decades experience in the Australian medical technology and pharmaceutical sectors. As Senior Director, Corporate Affairs, Andrew is actively engaged in efforts to positively promote industry to government, healthcare providers and the community for appropriate access to medical technologies. He oversees Medtronic's government affairs, PR, quality, regulatory and reimbursement initiatives in Australia and New Zealand. Joined Board October 2013 and is Chair of the Government Affairs Committee.

COMMITTEES

MTAA relies on the efforts and expertise of members of its various committees and working groups. The Association's aim is to take an evidence-based approach to advocacy, with the result that its views are sought by policy makers and key decision makers. The MTAA would like to thank member companies for enabling their many staff in various areas of their business to participate in this vital work.

Access

The Access Committee met on four occasions this year. Much of its work has been dominated by the policy issues around the reforms of the Prostheses List, the Private Health Insurance Review, the MBS Review and the MSAC review. An informal Working Group was also established for a short period of time to provide Government with timely input on the proposed reforms process and issues.

Access Committee Members

Mark Taffa, Horten Medical (Chair)
Andrea Kunca, MTAA (Secretary)
Andrew Wiltshire, Medtronic
Caroline Fuery, SpeedX
Falko Thiele, Biotronik
George Faithfull, Stryker
Iain Hamilton, Johnson & Johnson
Karen Harrision, B Braun
Libby Day, Baxter
Peggy McBride, St Jude
Peter Yeates, Alcon
Rachel Todd, Liva Nova

Code Authority

The Code Authority met on five occasions this year to discuss policy issues and compliance matters around the Code of Practice, including the development and promotion of educational material to facilitate member compliance with the Code. This includes the development of several FAQs to clarify the provisions of the Code in relation to hospitality, sponsorship of third party conferences and company sponsored educational events. This is up from the previous reporting period where only two meetings were held.

The Authority also considered four complaints. The issues the complaints raised were in relation items provided to healthcare professionals, unprofessional conduct and financial support provided for education and training purposes. Of these complaints, one was found to be beyond the MTAA's jurisdiction. The remaining complaints were resolved through mediation and/or the provision of training and education. No sanctions were applied over this period.

Code Authority Committee Members

Nick Shalley, Independent (Chair)
Andrea Kunca, MTAA (Secretary)
Chris Cowley, Varian
Dawn de Cruz, Allergan
Henry Ko, Consumer Representative
Hugh Cameron, Becton Dickinson
Jessie Yap, Medtronic
John Quinn, RACS
Michelle Wagner, Johnson & Johnson

Code Panel

The Code Panel held five meetings to consider 43 monitoring reports submitted by member companies. Reports related to the following activities:

- Company-sponsored Training and Education and Medical Technology Demonstrations
- Company-sponsored Third Party Educational Conferences
- Items provided by the Company to a Healthcare Professional

There were no serious breaches of the Code. A minor breach that was taken to the Code Authority was an issue regarding an item that was given to healthcare professionals at an event. The material on the item was focused on promotion of the company's products instead of educational content. The issue was dealt with by providing educational training and support to the company.

Code Panel Committee Members

Jason Korke, Independent (Chair)
Alan Limbury, Independent (Chair)
Ken Ramsay, Independent (Chair)
Amanda Hickey, Surgical Specialties
Dean Driscoll, Olympus
Gary Burgess, Sirtex
Glen Mason, Johnson & Johnson
Helen Mikolaj, Consumer Representative
Jacqui Gibson, Consumer Representative
Jennifer Mew-Sum, Medtronic
John Stubbs, Consumer Representative
Michael Goldberg, St Jude Medical
Roderick McRae, AMA
Susan Dean, Alcon
Trent Enright, Terumo
Wayne Lee, Hospira

Government Affairs

The Government Affairs Committee is one of the MTAA's three strategic committees, chaired by a Board member and reporting directly to the Board. It met six times this year. The Committee provides input to the strategic direction of the Association's government policy and advocacy agenda. The Committee focuses on developing industry responses to issues of major importance to industry sustainability. It also develops strategies to ensure effective working relationships with ministers, shadow ministers, MPs, Senators and departmental officials that our business challenges are understood and addressed

Government Affairs Committee Members

Andrew Wiltshire, Medtronic (Chair)
Polo Guilbert-Wright, MTAA (Secretary)
Carolyn Cameron, Allergan
David Cain, Johnson and Johnson Medical
Heather Winslade, Sirtex
Luxin Wang, Alcon
Maurice Ben Mayor, Stryker
Michael Reynolds, Biotronik
Michael Simmonds, Boston Scientific
Philippa Lewis, Simavita
Richard Dowling, Baxter
Robert Izzard, Smith & Nephew

"The Government Affairs Committee is one of the MTAA's three strategic committees, chaired by a Board member and reporting directly to the Board."

Regulatory Affairs

The Regulatory Affairs Committee (RAC) met on eight occasions this year. The RAC is comprised of 19 regulatory professionals and deals with operational matters raised at the TGA's Regulatory and Technical Consultative Forum on a quarterly basis.

Regulatory Affairs Committee Members

Mahesh Datar, Medtronic (Chair)
Val Theisz, MTAA (Secretary)
Cletus Pinto, Hospira
David Le Cheminant, Life Healthcare
Delwyne Lauten, Abbott Vascular
Diane Compton, St Jude Medical
Fleur Winslade, Terumo
Heather Winslade, Sirtex
Juliana William, Baxter Healthcare
Kevin Samuels, ConMed Linvatec
Lachlan McKenzie, Stryker
Laleetha Devi, Halyard
Leanne Etherington, Device Technologies
Lopeti Lavulo, Speedx
Meryl Musson, Edwards Lifesciences
Michelle Nguyen-Lee, Boston Scientific
Naeema Mohamed, Covidien
Natasha Kshetrapal, Smiths Medical
Sue Winter, Johnson & Johnson Medical
Yih-Fye Freeman, BBraun

Regulatory Sub-Committee Members

George Faithfull, Stryker (Chair)
Val Theisz, MTAA (Secretary)
Christine Cuthbertson, Paragon Technologies
Darren Forrest, Medtronic
Elizabeth Van Den Akker, Abbott Vascular
Gary Burgess, Sirtex
Hugh Cameron, Becton Dickinson
Jenny Bennell, St Jude Medical
Leanne Etherington, Device Technologies
Mary Kennel, Bard Australia
Rebecca Gaudin, Johnson & Johnson
Renee Hardley, Boston Scientific
Ruth Shennan, Device Technologies
Samantha Tham, Smith & Nephew

Reimbursement

The Reimbursement Subcommittee met on two occasions this year. The key issues covered related to issues and consultations on the reforms of the Prostheses List, the Private Health Insurance Review, the MBS Review, the MSAC review and the IHPA reviews. Several engagement events between the Subcommittee members and Departmental stakeholders were also facilitated over that time.

Reimbursement Sub-Committee Members

Michael Simmonds, Boston Scientific (Chair)
Andrea Kunca, MTAA (Secretary)
Brett Spence, Prism Surgical
Craig Stamp, Device Technologies
Karen O’Keeffe, Stryker
Kevin Guinee, Bard
Michelle Costa, Johnson & Johnson Medical
Michelle Frost, Allergan
Neroli Manning, Sirtex
Sheryl Dunlop, Zimmer
Sue John, Open Sesame Consulting
Tracey Doman, St Jude Medical
Vanessa Xavier, Smith & Nephew

The Legal Counsel and Compliance Forum provides a platform for members to network, receive updates and discuss the Medical Technology Industry Code of Practice

Legal Counsel and Compliance Forum

The Legal Counsel and Compliance Forum met three times this year. The Forum provides a platform for members to network, receive updates and discuss matters in relation to the Medical Technology Industry Code of Practice. Some of the issues discussed included:

- Code Monitoring process
- HPV tender requirement
- Melbourne Health Tender
- Procurement survey
- Publication of additional FAQs on the MTAA website
- APEC Business Ethics Forum
- MTAA Code logo and Review of Medicines and Medical Devices Regulation – Stakeholder Forum on Advertising

Engagement with other Professional Associations

MTAA continued to work with the Australian Orthopaedics Association (AOA) to promote their understanding of the Code to enable MTAA members to continue to support the AOA’s educational activities without compromising their compliance with the Code.





MTAA REPRESENTING INDUSTRY

Submissions

- MTAA Budget summary 2016/17 - April 2016
- MTAA Submission to the Australian Competition and Consumer Commission (ACCC) - April 2016
- MTAA response to the ACSQHC on the Prioritisation of Clinical Quality Registries - April 2016
- MTAA Submission on the 2016 Review of the Radiation Oncology Health Program Grants (ROHPG) Scheme - March 2016
- MTAA Submission to the MSAC Reform Consultation - February 2016
- MTAA SPARK Australia Pre-budget submission 2016-17 - February 2016
- MTAA 2016-17 Pre budget submission - February 2016
- MTAA Submission to the MBS Review on Obsolete MBS Items - Tranche #1 - February 2016
- MTAA Submission to the Private Health Insurance Consultation - December 2015
- MTAA Submission to the TGA Consultation - Revised Uniform Recall Procedure for Therapeutic Goods (URPTG) - November 2015
- MTAA Submission to the Medicare Benefits Schedule Review Taskforce Consultation Paper - 9 November 2015
- MTAA Submission to Discussion Paper on 'Better Outcomes for People with Chronic and Complex Health Conditions through Primary Healthcare' - September 2015
- MTAA Submission to Issues Paper on 'Review of Research Policy and Funding Arrangements' - September 2015
- MTAA Submission to the Medicines and Medical Devices Review Taskforce - September 2015
- MTAA Submission to discussion paper on 'Victorian Health and Medical Research Strategy' - August 2015
- MTAA Submission to Public Consultation Paper on IPHA Pricing Framework 2016-17 - July 2015

External Representation

MTAA with its members, represents industry in a range of different committees, stakeholder forums and groups. Some of the key representations this year were:

- RegTech – TGA Regulatory & Technical Consultative Forum (regulations & regulatory framework)
- TICC – TGA Industry Consultative Committee (regulations & regulatory framework)
- State Health Procurement Departments (procurement issues)
- NHMRC – National Health & Medical Research Council (clinical trials framework)
- IHPA – Independent Hospital Pricing Authority (clinical trials framework)
- NSW Health, Office for Health and Medical Research (clinical trials framework)
- TGACC – Therapeutic Goods Advertising Code Council (compliance with Advertising Code)
- Standards Australia Council, SA Chairman's Advisory Group (industry sector representation)
- TISN HSG – Trusted Information Sharing Network, Health Sector Group (industry sector representation)

Representation on Standards Australia standards committees

- HE-003 Medical electrical equipment
- HE-009 Hypodermic equipment – general medical
- HE-012 Surgical implants
- HE-019 Anaesthetic and Breathing Equipment
- HE-030 Biological and clinical evaluation of medical devices
- HE-033 Vendor credentialing
- HE-011 Safe disposal of sharps and clinical wastes



PROFESSIONAL DEVELOPMENT

Ongoing professional development is essential for developing and maintaining a knowledgeable and sustainable medical technology workforce. Medical technology professionals require up to date knowledge, skills and understanding to deliver positive outcomes in the ever complex and changing healthcare environment.

Women-in-MedTech #WiMT

In July, an initiative to improve gender diversity within the medical technology industry was launched by Sex Discrimination Commissioner, Elizabeth Broderick on behalf of MTAA. The “Women in MedTech” initiative included a series of four events and educational forums designed to raise the bar on gender diversity by



Susi Tegen, Gavin Fox-Smith and Elizabeth Broderick at the inaugural WiMT event in July 2015

providing insightful, informative content and networking that supports the industry as a whole. A series of breakfast and luncheon events on the theme occurred throughout the year, hosted and strongly supported by our Chairman, Gavin Fox-Smith.

Our [MedTech Forum](#), Health Technology Assessment: MSAC Update, was held at the Australian Technology Park in Sydney in August. The forum updated the medical technology industry on the role of the Department of Health in providing policy advice to the

government that impacts on the medical technology industry and the Medical Services Advisory Committee (MSAC) Reform.

Other events this past financial year included:

- MedTech Skills Audit Workshops, in various states, Deloitte Workforce Study
- PHI Review Member Consultations
- MedTech Forum: Medical Device Regulatory Round-up
- National Disability Insurance Scheme Update.
- Members have been able to meet the MTAA Board at networking dinners in capital cities held in conjunction with board meetings.

Code Training

Nearly 2,000 people have completed Code of Practice Edition 9 training since its release early in 2015. The participant feedback on the online Code training indicates that the functionality of the modules rated highly (4 out of 5). Informal educational events were also conducted through the year to companies to increase their awareness of, and the need to comply, with the Code.



WiMT panel in November 2015. Hilary Crilly the CEO of BD, Andrew Stevens the former CEO IBM Australia NZ, Kevin Barrow the Managing Director of Philips Australia and NZ, Kirsten Garwood the Government and Health Leader, IBM Australia and NZ and Gavin Fox-Smith MTAA Chair.



1075

People completed Code of Practice Ed9 training

412

Women in MedTech event attendees

1634

People completed MTAA training



ANNUAL CONFERENCE 2015

MTAA's flagship annual conference MedTech 2015 was held in Sydney at Australian Technology Park, attracting a strong audience of Australian and international delegates.

The conference theme was "Shaping the future for a healthier Australia." Among the keynote speakers were Professor Henry Cutler from Macquarie University discussing the important role of medical technology in improving Australia's welfare, Mark Fitzgibbon the CEO of NIB presenting on managing healthcare in a digital age and Mark Pesce discussing the future – connected, related and empowered.

Excellent panel sessions covered highly relevant topics such as the future of procurement and tendering, the value proposition of MedTech, the future of wearables, social media in clinical trials, how the future of medical devices will be shaped by changes in materials, advanced manufacturing and business models.

International guests from AdvaMed, MTANZ, Eucomed and APACMed were informative and accessible during the breaks.

We had Hearts4hear CEO, Tanya Hall speak about atrial fibrillation costs and how early detection and patient access to treatment pathways are crucial for improving quality of life.

Tanya spoke about the important issue of what happened when a treatment does not fit within a current prostheses list definition that is not covered by health insurance. So where does the consumer stand?

Many companies have innovative solutions that drive costs in a different direction.







2015 INDUSTRY AWARDS

MTAA's eighth annual awards with a record attendance of 220 people who gathered to recognise peers for excellence in Medical Technology and outstanding individual achievement.

Kerrin Rennie Award

Kerrin Rennie was a long standing member of the Australian medical technology community. This is the ninth year that MTAA has acknowledged a company's extraordinary contribution to the Australian medical technology industry in her memory. The 2015 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. This is the eighth year of the Kerrin Rennie Award.

A company can enter a product used in the diagnosis, prevention, treatment or management of disease and disability. The product must demonstrate evidence of significant contribution to improving patient outcomes by enhancing quality of life, technical excellence, and innovation.

The award was presented, for the first time, to two shared winners at the MTAA Annual Awards Dinner during the MedTech 2015 Conference in Sydney. The joint winners were Boston Scientific and MediGroup EBI.

The Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) System, developed by Boston Scientific, was chosen for innovation in monitoring and treating potentially fatal heart rhythms. It is the first subcutaneous ICD to be implanted beneath the skin with no wires touching the heart. It therefore avoids several risks associated with implanting, using and removing these electrodes.

ExAblate Neuro by MediGroup EBI was the shared winner of the award for the exciting therapy treatment opportunities that it presents to patients. ExAblate Neuro offers neurosurgeons a non-invasive alternative for deep brain procedures such as treating Parkinson's disease. It offers minimal hospitalisation, no need for implanted hardware or an operating room, making it an economic alternative for hospitals and clinics. The treatment combines two technologies – focused ultrasound and magnetic resonance imaging with real-time feedback.

Other finalists this year include:

CardioMEMS™ HF System, St Jude Medical
Nanostim Leadless Pacemaker, St Jude Medical
GEMini, Clinical Genomics Technologies
Flex HD Pliable, Johnson & Johnson Medical
Nevisense, Australian Dermatology Equipment

Outstanding Achievement Award

Nominations for the Outstanding Achievement Award are open to individuals who have contributed in a significantly to the health of the population and the development of the medical technology industry. The winner was announced at the MTAA Annual Awards Dinner at the MedTech 2015 Conference in Sydney. This is the third year of awarding and industry Outstanding Achiever.

And the winner is.....

Tanya Hall, CEO and founder of Hearts4heart, was awarded the 2015 Outstanding Achievement Award. As founder of the national not-for-profit organisation, Hearts4heart, a service that supports adults with heart disease, Tanya Hall is recognised for her extraordinary effort to raise awareness for heart disease, the leading cause of death in Australia.

MTAA Chief Executive Susi Tegen commended Tanya. "We are very proud to present this award to Ms Tanya Hall, she is exceptional in her work and an outstanding example of the talent within this industry."

Finalists also included:

Peter Ord
Professor Timothy Jones
Dr Susanne Pedersen

MTAA would like to thank all judges for their time and effort in judging the entries.

The judging panel included:

- Prof. Anne Simmons, Head of School, School of Mechanical & Manufacturing Engineering, UNSW
- Prof. Guy Maddern, RP Jepson Professor of Surgery, University of Adelaide and Surgical Director of ASERNIP-S
- Nick Shalley, Managing Director of Beanick Consulting
- Mr Chris Russell, Technical Director, Australia Harvestore Produces Pty Ltd and former judge, ABC TV, New Inventors.

Peter Ord, awarded MTAA Life Membership

Peter Ord, an Australian Medical Technology Industry pioneer was honoured by the MTAA board and welcomed to life membership of MTAA at the MTAA Annual Awards Dinner at the MedTech 2015 Conference in Sydney.



Chris Russell and Tanya Hall.



Chris Russell, Chris Selwa from MediGroup EBI and Allison Fox.



Chris Russell, Paul Braico and David Walker from Boston Scientific and Allison Fox.



Gavin Fox-Smith, Peter Ord and Susi Tegen.

OUR MEMBERS

Members

3D Medical
3M Healthcare Pty Ltd
Abbott Medical Optics AMO Australia Pty Ltd
Abbott Vascular
Admedus Pty Ltd
Alcon Laboratories (Australia) Pty Ltd
Allergan Australia Pty Ltd
American Medical Systems (AMS) Pty Ltd
Analytica Ltd
Astora Womens Health
Australasian Medical & Scientific Ltd
B Braun Australia Pty Ltd
Bard Australia Pty Ltd
Baxter Healthcare Pty Ltd
Becton Dickinson Pty Ltd
Bionic Products Pty Ltd
Biotronik Australia Pty Ltd
Boston Scientific Pty Ltd
Brainlab Australia Pty Ltd
ConMed Linvatec Australia Pty Ltd
Corin (Australia) Pty Ltd
Culpan Medical Pty Ltd
Device Technologies Australia
Edwards Lifesciences Pty Ltd
Fresenius Kabi Australia Pty Ltd
GLIA Diagnostics
Global Orthopaedic
Globus Medical Australia Pty Ltd
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N Stenning & Co Pty Ltd
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Olympus Australia Pty Ltd
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Simavita (Aust) Pty Ltd
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Spectrum Surgical
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Insight Strategy
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Open Sesame Consulting
Regulatory Concepts Pty Ltd
SJ Alder Pty Ltd
Slate Hill Consulting Pty Ltd
Sue Akeroyd & Associates
The SPD Company Pty Ltd
VAMED AG
VR Consulting

MTAA SECRETARIAT

MTAA Secretariat* at 30th June

Susi Tegen, Chief Executive
Allison Fox, Director of Business Operations
Andrea Kunca, Director of Policy and Access
Val Theisz, Director of Regulatory Affairs
Avril Douglass, Events Coordinator (part-time)
Joanne Ince, Events Coordinator (part-time)
Kerri Lukas, Executive Assistant
Kiran Sandhu, Code of Practice Coordinator
Fiona Shipman, Professional Development Manager
Melinda Padovan, Receptionist and Office Administrator
Michael Osborne, Marketing Coordinator
Paul Suebwongpat, Health Economist
Polo Guilbert-Wright, Government Relations and Communications Manager
Roslyn Mitchelson, Industry Policy Manager (part-time)
Sandy Gokani, Bookkeeper (part-time)
Scott McClennan, Business Development Manager

MTAA also acknowledges the work of past employees:
David Ross, Fiona Landis, Jane Wurth, Prema Thavaneswaran, Kara Young and Alessandra Doolan.



MTAA Staff, November 2015







Medical Technology
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