Medical Technology
Association of Australia

MEDICAL TECHNOLOGY
ASSOCIATION OF AUSTRALIA

ANNUAL REPORT 2010-11

MEDICAL TECHNOLOGY FOR
A HEALTHIER AUSTRALIA

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Corporate Overview

Vision

- Medical technology for a healthier Australia

Corporate Goals

- To be recognised as the peak body representing the medical technology industry
- To deliver indispensable value to members
- To be an influential partner in the healthcare environment

Mission

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

Values

- Leadership
- Influence
- Collaboration
- Integrity

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 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 2009-10 the Australian medical technology industry:

- included over 500 medical technology companies
- employed over 17,500 people
- was responsible for over 35,000 medical devices listed on the Australian Register of Therapeutic Goods (ARTG)
- was mainly located in NSW (54%), followed by VIC (24%), QLD (11%) and WA (7%)
- had a total annual revenue in the order of $7.6 billion
- imported products to the value of $3.3 billion and exported products to the value of $1.2 billion
- spent $388 million on R&D (2008-09).

Message from the Chair

On behalf of the Board of the Medical Technology Association of Australia (MTAA) it is my privilege as the Chair to comment on the state of the industry and report some of the activities of the Association for the financial year ending 30 June 2011.

It has been another busy 12 months for the industry and the Association. Not that we would expect quiet years ahead!

Global factors like the financial market volatility, pressures on exporters due to the high Australian dollar and increasing pressures on health budgets combined with national health and regulatory/reimbursement reforms have contributed to at times a challenging operating environment for the industry.

The medical technology industry continues to innovate and develop new and improved devices every 18-24 months on average. The annual growth of the industry is estimated at 4-5% over the next few years. Globally the industry is expected to reach a market value of $312 billion this year.

MTAA has been advocating and positioning medical technologies as smart solutions to enable older Australians to continue living in their homes for longer, help manage chronic disease in the community and allow faster recovery times and earlier hospital discharge. In recent submissions MTAA has outlined considerable savings of up to $3.1 billion per year that can be achieved by improving delivery of healthcare in the home, reducing the premature need for residential care and hospitalisation, and other associated costs.

Thank you for your support especially through continued membership and participation in committees and events. MTAA has been very busy advocating on behalf of members and representing the industry in a multitude of ways. In the year ahead, MTAA will continue this work on your behalf and make constructive and positive contributions to public debate and policy.

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 tireless efforts and work accomplished by Chief Executive Officer, Anne Trimmer, and all the staff of the Association.

I look forward to working with you in another busy year ahead to grow the successful Australian medical technology industry.

Dr Bronwyn Evans
Chair MTAA

CEO's Report

The past year has seen a growing focus on the medical technology industry both in Australia and elsewhere. This interest in our industry has arisen in many different contexts – regulatory reforms; reimbursement developments; industry business practices; relationships with healthcare professionals and ethical codes; healthcare reforms; managed diffusion of new technologies.

In response MTAA has significantly increased its capacity to contribute to debate and policy development in all these areas of interest. Our objective has been to be a partner in the reform process and to be seen as a positive contributor in shaping the agenda as it impacts the industry. In our position papers, advocacy and submissions we have ensured that our arguments are evidence-based and persuasive.

I am pleased to report on some of the key areas of activity in the past year.

Health technology assessment reforms - reimbursement

The continuing implementation of the Federal Government's review of health technology assessment (HTA) has remained a key area of activity for MTAA. During the past year MTAA has:

- Been active in working to shape the new arrangements for grouping and benchmark benefits of products on the Prostheses List, including the acceptance of reasonable utilisation to establish the benchmark benefit
- Pushed for alignment of clinical evidence requirements for regulatory and reimbursement purposes
- Had accepted by the Government an expansion of the policy areas for consideration by the Government's consultative committee, including an extension of Part C of the Prostheses List, scoping of funding arrangements for other beneficial technologies and mechanisms to review benefit levels
- Had two nominees appointed to the new Prostheses List Advisory Committee (PLAC)
- Provided comment to Medical Services Advisory Committee (MSAC) on its proposed new arrangements and intervened where those arrangements have disadvantaged members.

Health technology assessment reforms - regulation

Regulators in all major economies have begun to reassess the requirements for approval of medical technologies. This is also the case in Australia, partly in response to one set of recommendations from the review of health technology assessment which directed the Therapeutic Goods Administration (TGA) to increase its requirements for the regulation of higher risk devices. In response MTAA has:

- Made a detailed submission to TGA proposing transition processes for the orthopaedic devices which are to be upclassified or which will require additional evidence
- Provided costing of the impact on companies of unique requirements such as individual product labeling and advocating alternative solutions such as the US Food and Drug Administration's UDI initiative or Health Canada's e-labeling
- Worked with industry associations in other economies to align policy development in regulatory reforms
- Represented the industry on the review of transparency of TGA.

Supporting patients in the community

A significant focus for MTAA's research and submissions in the past year has been on initiatives to improve healthcare delivery for patients outside the hospital setting. MTAA has become a key contributor to policy development for telehealth solutions. During the past year MTAA has provided:

- Detailed and evidence-based submissions to the Treasury (pre-Budget submission), and to the Productivity Commission (on its references on support for the ageing and on disability services) outlining the cost/benefit of an Essential Care List and MBS funding for telemonitoring of wirelessly-enabled devices, and other products which support patients in the community
- Briefing papers and advocacy with the Opposition parties and the Greens for inclusion of MTAA's policy positions in health policies for the next election.

Procurement reforms

MTAA identified current public health procurement processes as a key impediment to doing business efficiently, with consequential cost to the healthcare system. As a consequence:

- A working party comprised of representatives from several member companies was established to develop a position paper proposing reforms to procurement processes including consistency of tender terms and conditions, and contract terms
- MTAA has promoted the position paper to Ministers for Health, heads of health departments and to heads of the State health procurement groups. The position paper has been well-received and negotiations continue on taking this to the next step of developing standardised processes and documents.

Evidencing the value of technology

During the past year MTAA has been engaged in a major research project to establish the cost effectiveness of specific technologies. The research will:

- Form the basis of fact sheets to be published on the MTAA website
- Support submissions to government for specific funding arrangements.

In recent months I have been working with HealthPACT (the State and Federal body which examines new technologies and procedures for adoption in the public health system) to devise processes for closer industry engagement. This growing area provides the opportunity for:

- A working relationship where MTAA can act as a conduit to introduce potentially beneficial technologies for consideration by the health departments of the States and Territories
- Establishment of clinical evaluation sites for selected technologies
- More effective diffusion of agreed technologies
- Horizon scanning to identify technologies in research and development pipelines.

Growing a sustainable medtech industry

MTAA is a strong supporter of the need to mark the medical technology industry as potentially a key growth industry in Australia. To support this advocacy MTAA has:

- Established a forum for small and emerging Australian manufacturing companies
- Briefed Minister Carr on policy options to support the industry, in particular through national leadership and commitment to the industry
- Increased training offerings (54 modules in 2011 with over 60% delivered online), and career support offerings that foster industry progression at varying stages of a career and assist in attracting and retaining personnel.

Industry codes of practice

The ethical relationship between the medical technology industry and healthcare professionals continues to come under the spotlight across the globe. In the past year:

- The Federal Government commissioned a review of therapeutic industry codes of practice (which I chaired). The review has recommended the application of a relevant industry code to all companies within that therapeutic sector
- MTAA introduced online training in the Code, supplemented by face-to-face as required (approximately 50% of member companies have completed training on the Code)
- MTAA became a signatory to ethical principles for the industry which have been agreed by associations in nine of the major economies
- MTAA participated in an expert working group to develop ethical principles for adoption across the APEC economies which have been endorsed by APEC SME Ministers.

MTAA secretariat

Over the past year MTAA has continued to invest in the development of an excellent team of people within the secretariat to support members with guidance and through policy development in our committees and forums; to undertake research and contribute to quality submissions; to provide advice and assistance with Code of Practice compliance; to deliver extensive training programs, quality member communications through electronic newsletters and the website, and a first rate conference and seminars.

I would like to thank the staff of the secretariat for their contributions during the year. It has been a very busy but fruitful year for MTAA and for the medical technology industry.

I would also like to thank the Chair of MTAA, Dr Bronwyn Evans, for her support and commitment, and to the Board of MTAA for its strategic contribution to issues.

Anne Trimmer
Chief Executive Officer

MTAA Board Members

David Akeroyd
Managing Director,
Australia and New Zealand,
Baxter Healthcare
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 region. Later regional roles included General Manager for the North Asia group of countries and later India. David took up his current role in 2008.

Kevin Barrow
Managing Director,
Australia and New Zealand,
Becton Dickinson
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.

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

Anthony has over 16 years experience in the medical technology sector with the J&J family of companies. He has worked in marketing, sales and general management roles in Australia, New Zealand, China, Singapore, Scotland and the US. Anthony was appointed General Manager of J&J Medical in New Zealand in 2008, General Manager for Ethicon Endo Surgery in Australia in 2010 and assumed his current role in March 2011.

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 health care 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
BE (Elec), Hons I, PhD (UoW) FIEAust, EngExec, MAICD

Bronwyn has worked with Cochlear for 6 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 25 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 was appointed Chair of MTAA on 8 December 2009.

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

Prior to his appointment with Hospira in 2009, Colin has held senior commercial leadership positions in global healthcare corporations both in the UK, Australia and New Zealand. Colin moved to Australia in 2002 as the Managing Director for Aventis.

Tony Harrington
Managing Director,
Biomet Australia and New Zealand
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. Tony is currently Vice-Chair of the MTAA Board.

Phil Nicholl
Vice President and Managing Director, Stryker South Pacific
Bachelor of Business (Marketing), CSU

Phil has been in the medical devices sector for over 18 years, during which time he has held various senior management positions in Australia, Asia and Europe. Prior to returning to Australia, Phil held the positions of Vice President of Marketing, Stryker Pacific; Managing Director, Stryker Southern Asia and President Asia Pacific, Cochlear Ltd.

Julianne Prowse
General Manager,
Coloplast
MBA (Swinburne)

Julianne has been with Coloplast in Australia and the US for 21 years. Before Julianne's appointment to her current role, she worked with Colopast 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
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 MTAA 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

Mike Daly
Vice President & General Manager Asia & Australia and New Zealand, Bard
BSci/BA Coraopolis (PA, USA) IEP (INSEAD)

Namal Nawana
Managing Director, Johnson & Johnson Medical
BEng (Hons), MMedSc (UoA), MBA (Henley Management College)

Murthy Simhambhatla
General Manager, Australia & New Zealand, Abbott Vascular
PhD, Polymer Science (University of Akron, USA)

Meeting Attendance

1 July 2010 to 30 June 2011

Notes		10-Aug-10	16-Sep-10	7-Dec-10	8-Feb-11	6-Apr-11	15-Jun-11	Eligible to Attend
1	Mr David Akeroyd	Present	Apologies	Apologies	Present	Present	Apologies	3 of 6
2	Mr Kevin Barrow	Present	Apologies	Apologies	Apologies	Present	Present	3 of 6
3	Mr Anthony Bishop	Present	Present	Present	Present	Present	Apologies	5 of 6
4	Ms Carmen Byrne	Present	Apologies	Present	Apologies	Present	Present	4 of 6
5	Mr Mike Daly	Present	Present	Present				3 of 3
6	Dr Bronwyn Evans	Present	Present	Present	Present	Present	Present	6 of 6
7	Mr Colin Hannah					Present	Present	2 of 2
8	Mr Tony Harrington		Apologies	Present	Present	Present	Apologies	3 of 5
9	Mr Namal Nawana							0 of 0
10	Mr Phil Nicholl	Present	Apologies	Present	Present	Present	Present	5 of 6
11	Ms Julianne Prowse	Present			Apologies	Present	Present	3 of 4
12	Dr Murthy Simhambhatla	Present	Apologies	Present				2 of 3
13	Mr Jamie Stanistreet	Present	Present	Apologies	Apologies	Present	Present	4 of 6
14	Mr Mick Trevaskis	Present	Apologies	Present	Present	Present	Present	5 of 6

Notes:

1 Elected from 16 September 2010 to AGM 2012
2 Elected from 16 September 2010 to AGM 2012
3 Elected from 16 September 2010 to AGM 2012
4 Elected from 16 September 2010 to AGM 2012
5 Resigned 9 December 2010
6 Elected from 16 September 2010 to AGM 2012
7 Appointed to fill casual vacancy 6 April 2011. Term expires 25 October 2011
8 Elected from 16 September 2010 to AGM 2012
9 Resigned 6 July 2010 (term of office was expiring on 24 September 2009) Attended meeting on 11 August 2010 at the invitation of the Chair
10 Elected from 24 September 2009 to 25 October 2011
11 Term expired AGM 16 September 2010. Appointed to fill casual vacancy 8 February 2011. Term expires 25 October 2011
12 Resigned 12 January 2011
13 Elected from 24 September 2009 to 25 October 2011
14 Elected from 24 September 2009 to 25 October 2011
Denotes term expiring 25 October 2011.

MTAA Secretariat

Anne Trimmer, Chief Executive Officer
Brett Andrews, Corporate Services Manager
Jane Apfel, Conference Manager
Marion Demann, Corporate Communications Manager
Dr Alessandra Doolan, Health Outcomes Policy Officer
Joanne Franks, Office Coordinator
Alina Hughes, Code of Practice Manager
Fiona Landis, Industry Policy Manager
Dr Kylie Maidment, Research Manager
Warren Mitchell, Commercial Issues Manager
David Ross, Director Healthcare Access
Fiona Shipman, Professional Development Manager
Paula Southcombe, Manager, Accounts & Finance
Cliff Spong, Director of Regulatory and Scientific Affairs

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 a crucial role in industry policy development and the preparation of responses to government reviews. It is one of three strategic committees that report to the Board. The Committee met eight times during the reporting year and prepared industry responses to the TGA *Discussion Paper on Reforms in the Medical Devices Regulatory Framework*, and the *Discussion Paper on Proposed Changes to MSAC Processes for Applications for Public Funding*. The Access Committee continued to monitor and respond to departmental implementation of endorsed recommendations of the HTA review. The Access Committee argued to government the limited nature of the government's authority to legislate benefit levels, and not market price. The result is that companies may negotiate a patient co-payment where supported by the hospital and surgeon.

The Access Committee also successfully argued against the intention to set benchmark benefits for Prostheses List products based on the lowest benefit accepted for a product in a group. The Department of Health and Ageing (DoHA) conceded that utilisation was an important factor in the equation and determined that the benchmark benefit would be set at the lowest benefit in the category with 25% utilisation.

The Access Committee provides a crucial resource for industry responses to strategic healthcare reviews and its members have appreciated the willingness of DoHA to engage on issues of significant importance to the healthcare environment.

Reimbursement Subcommittee

The Reimbursement Subcommittee (RSC) is a sub-committee of the Access Committee and met on eight occasions during the reporting year. The Chair of the RSC is Robyn Chu from Johnson & Johnson Medical.

The focus of the RSC is on Prostheses List reimbursement issues and MSAC processes. The RSC developed a template for the preparation of submissions to the Prostheses secretariat covering problematic grouping issues. The Committee has also addressed issues relating to Prostheses List criteria which will form the basis for future action.

The RSC provides supporting input to the deliberations of the Access Committee.

Regulatory Subcommittee

The Regulatory Subcommittee (RegSC) is a sub-committee of the Access Committee. RegSC has members from a number of member companies and was chaired by George Faithfull from Stryker.

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

- the proposed regulatory reforms released for discussion by the TGA in late 2010
- the impact of the proposed reclassification of implanted hip, knee and shoulder joints
- investigating ways for members to demonstrate and explain the use of medical technology to TGA and DoHA
- providing advice to the Access Committee on regulatory issues connected with the submissions prepared during the year
- the formation of a Loans Kits Interest Group
- the identification of high risk medical devices on the ARTG.

Code of Practice

The Code of Practice is administered by the Code of Practice Committee (CPC) which is responsible to the MTAA Board. It is headed by an independent Chair and includes industry representatives, a representative of the Medical Technology Association of New Zealand (MTANZ) and a consumer representative.

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 of codes of conduct internationally and feedback from members and other stakeholders, CPC has recommended a number of changes to the Code which would form a 7th edition.

Independent External Review of the Code

An independent external review of the Code commenced in June 2011. The review is chaired by Ms Jan McLelland. The review will lead to a revised 8th edition of the Code in 2012.

Submissions and/or comments have been sought from interested parties including the wider healthcare sector, government, consumer groups and the medical technology industry.

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. The two industry members on CMC are drawn from a panel of industry representatives.

In 2010-11 CMC was able to review the activities of most member companies taking a balanced approach to receiving comprehensive information and the administrative and compliance load on companies in compiling their submissions. CMC continues to take an educative approach. CMC finds the overall level of understanding and compliance with the Code reasonable.

Both the Code Complaints Committee and the Code Appeals Committee have been required to meet during the year. These committees 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.

Government Affairs and Policy

The Government Affairs and Policy Committee was formally established by the MTAA Board during 2010-11 as a strategic committee reporting to the Board. It had operated for some years as a policy forum for government affairs managers within member companies but with the increase in diversity of policy considerations, has taken on a more formal structure under the chairmanship of MTAA Board member, Jamie Stanistreet.

The Committee undertook a strategic planning session during the year to identify the priority areas for its work. These include the national health reforms; the strengthening of the private health sector including extension of funding by private health insurance to a range of appropriate technologies to underscore the value of PHI; and the development of an Australian medical technology industry. Prior to the 2010 Federal election the Committee published MTAA's key policy objectives as a briefing paper to assist companies in their discussions with candidates.

Regulatory Affairs

The Regulatory Affairs Committee (RAC) has approximately 20 members from member companies. The chair of the RAC is Rebecca Smith from Johnson & Johnson Medical.

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 issues and developed papers to be discussed at the regular meetings of the TGA/Industry Regulatory & Technical Consultative Forum.

The Committee also considered:

- ways to improve members' understanding of TGA's requirements
- the supply of procedure packs to meet the TGA's published expectations
- the review of ISO 13485:2003
- the development of regulatory training survey for the medical technology industry
- the TGA's regulatory reform proposals
- the TGA Transparency review
- the review of the Therapeutic Goods Advertising Code.

A number of working groups continued consideration of a number of issues including identifying feasible definitions of Class III and AIMD Unique Product Identifiers and their associated variants, notifying regulatory relevant changes to the TGA, and the development of a suitable program for a sponsor information and training event for the industry. The Committee also provided input to two of the Global Harmonisation Task Force's study groups, Study Groups 1 and 3.

Orthopaedic

The Orthopaedic Committee met quarterly during the reporting year. The Committee considers issues affecting industry's relationship with orthopaedic healthcare providers and informing responses as necessary.

The Committee also provided an industry member to the National Joint Replacement Registry (NJRR) Consultative Committee. After resolution of uncertainties regarding the use of NJRR data following implementation of applicable HTA Review recommendations, the Orthopaedic Committee recommended that companies support the linking of Prostheses List Billing Codes with product catalogue numbers.

Member Forums

Clinical Investigation

During the year a Clinical Investigation Interest Group was established to discuss aspects of conducting studies of medical devices for pre-clinical programs, regulatory approvals as well as the ongoing post marketing requirements. The Group's convenor is Catherine Bourgeois from St Jude Medical.

The Group decided that the two work priorities are the revision of the MTAA clinical investigation agreement templates and developing a training program for clinical investigators.

Commerce

The Commerce/e-Commerce Group provided a forum for members to raise concerns and address issues relating to procurement, including contracts and e-commerce.

Issues discussed and information provided included:

NSW Health

1. HSS organisational chart, contact list and warehouse consolidation
2. End user reports of products from distribution centres

   There had been member concern about the loss of end user data for products that are shipped through the central distribution centres. NSW Health advised a limited trial of end user reports by the last quarter of 2011.
3. SCCB contract price, volume and warehousing

   Members were concerned about multiple suppliers being awarded the contract but the distribution centres only wanting to stock one or two suppliers and the apparent lack of coordination to take advantage of price/volume offers from the contract. NSW HSS advised of the internal processes that should be followed and asked to be advised when this was not effective.

National Health and Hospitals Network agreement

Members were provided with updates on the implementation of statewide Local Health Networks (LHNs) and Local Health District (LHDs) in NSW.

SA tender clauses – costs transparency

MTAA represented member concerns about the costs transparency clauses in SA tenders requesting detailed commercially sensitive information on manufacturing and administrative costs.

Members were also represented on external committees:

Crisis Management

Members were represented on the Health Sector Group of the Trusted Information Sharing Network (TISN), established by the Attorney General's Department to provide an environment where business and government can share vital information on security issues relevant to critical infrastructure resilience.

Standards Australia

MTAA assisted in the successful funding application for the revision of AS/NZS 4187 *Sterilization of Medical Devices* and coordinated the appointment of member representatives to several other committees.

Communication

The Communicators Forum provides a platform to share and discuss issues and opportunities facing the industry and communications practitioners in the medical technology industry. It was set up to undertake initiatives to improve understanding of medical technology in the public and media.

Small & Emerging Companies

The Small and Emerging Companies Forum supports smaller Australian companies, primarily manufacturers and considers priority issues for this part of the membership which now makes up about 18% of total members. The forum is working to develop an industry policy agenda as part of MTAA's strong commitment to supporting and developing the domestic medical technology sector in Australia.

Workforce Forum

During 2010-11 MTAA established a Workforce Forum for discussing key 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.

Alliance for Sharps Safety and Needlestick Injury Prevention in Healthcare

MTAA continues to advocate for the mandated use of safety engineered devices in healthcare settings to protect healthcare workers from injury and disease. Through an Alliance of healthcare professional and other organisations with an interest in the area MTAA continues to address the issue with relevant state and federal departments and bodies. The Alliance is chaired by the MTAA CEO, Anne Trimmer, and has attracted new members in the past year. A new website was launched to present the issue to the public: www.allianceforsharpssafety.org

Committee Membership

Access Committee

Name	Position	Company
Eugene Salole (Chair from April 2011)	Manager, Pricing and Economic Affairs, Patient Access	Pfizer
Robert Kitchen (Chair until December 2010)	Director, Scientific Affairs	Alcon Laboratories (Australia)
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 and Regulatory	Cochlear
Mick Shaddock	Senior Business Manager	Device Technologies Australia
Andrew Wiltshire	Director, Corporate Affairs	Medtronic Australasia

Code of Practice Committee

Name	Position	Company
George Walck (Chair)	Director	George Walck & Associates
Victor Boase	Manager, Corporate Financial Services & Company Secretary	Kimberly-Clark Australia
John Cooper	VP Australia, New Zealand & India	Zimmer
Michael Goldberg	Financial Controller	St. Jude Medical Australia
Patricia Greenway	Consumer Representative	Consumers' Health Forum
MTANZ representative		MTANZ
Robert Kitchen (until December 2010)	Director, Scientific Affairs	Alcon Laboratories (Australia)
Michelle Wagner	Compliance Director	Johnson & Johnson Medical

Government Affairs and Policy Committee

Name	Position	Company
Jamie Stanistreet (Chair)	Managing Director	Medtronic
Stuart Bruce	Regulatory & Corporate Affairs Manager	Boston Scientific
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
Brian Vale	Technologies Advocate	Medtronic
Peter Vicary	Director Government Affairs and Policy	Johnson & Johnson Medical

Professional Development

Professional Development

Medical technology professionals require current 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 2010-11 a wide range of training, education and information sharing opportunities were available through MTAA, 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. In 2010-11 existing face-to-face training courses were reviewed with modules added or removed, according to identified needs.

Using a blended learning approach, new self-paced online learning modules, webinars and face-to-face modules were developed. Learning is delivered across six courses, with each consisting of a series of modules. Face-to-face training is delivered following expressions of interest, scheduled or in-house when requested by a company. Of the 54 training modules offered by MTAA, over 35% are VET accredited and 60% 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: 20 modules offered online (15) with two of these free, or face-to-face (5)
- 4.0 Reimbursement of Medical Technology: four modules offered online (1) or face-to-face (3)
- 5.0 Workforce Development: 15 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

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

1. VET institutions
2. Universities (undergraduate and post-graduate courses)
3. Ongoing professional development.

During 2010-11 MTAA continued to offer resources that support the education of future, newly qualified and current medical technology industry personnel. The *Workplace Learning Directory* provides secondary and tertiary students with opportunities to learn about the work of the medical technology industry. *Planning for Workplace Learning: Guidelines for MTAA members* assists member companies in providing meaningful work placements to students including identifying requirements for those under the age of 18 years. The online *Undergraduate and Post-graduate Course Directories* list over 2300 university courses relevant to the medical technology industry.

Information Sharing

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

- CEO Forums attended by member company senior executives to discuss key issues of relevance to the medical technology industry
- a MedTech Forum on access to medical technology to explore topical issues significant to the medical technology industry in more detail
- MedTech Seminars to discuss key operational issues
- Member only free online Webytes accessed live or via a recording from the member website
- Live online e-briefings presented by MTAA on a range of relevant topics, submissions and issues without the need to take members away from their workplaces.

Career Support

During 2010-11 a new section of the MTAA website was established to highlight the career choices available in the medical technology industry. MTAA career support opportunities foster industry progression at varying stages of a career. Information provided included:

- General information about the medical technology industry
- Business types that make up the medical technology industry
- Career benefits including:
  - Innovative health growth industry
  - Industry Code of Practice
  - Access to the industry professional association
  - Well regulated
  - Supportive lifestyle choices
  - Financial rewards
  - Culturally diverse
  - Varied career opportunities
  - Career pathways
  - Professional development opportunities
- The faces of industry section describing the day-to-day experiences of members working in the industry
- The joining the industry page detailing employment entry points at the emerging, intermediate or advanced levels during a person's career
- Finding the right job hints and tips
- Careers corner assists job seekers identify positions in the medical technology industry
- Keeping ahead through post-graduate education, industry specific networking opportunities and online information
- Mentoring for MTAA members that encourages and supports organisational talent and improves retention
- Paid parental leave scheme information.

Industry Profile

Annual Conference

The annual conference ***MedTech 2010: A history of innovation - looking forward, looking back*** was held on Wednesday 15 - Thursday 16 September 2010 at Star City in Sydney.

Some of the highlights of the program were international keynote speakers, Dr Tom Fogarty and via video link, Dr Devi Shetty, who brought their unique style and insights. They were joined by Bernard Salt whose entertaining insights into the demographic developments in Australia were a favourite with delegates and proved thought provoking once again.

The panel discussion on *Innovative medical technologies for a sustainable healthcare system* explored the barriers and enablers to creating a sustainable healthcare system that values innovative medical technologies.

The plenary program was concluded by Dr Rohan Hammett, National Manager TGA, and Anne Trimmer, CEO MTAA.

Dr Kelvin Kong presented at the conference dinner on Wednesday night that also hosted the **2010 Kerrin Rennie Award for Excellence in Medical Technology**. During the dinner delegates could reflect on some of the milestones of the Association's 30 year history.

The workshop program on day two of the conference provided an opportunity to get into the detail of some industry issues. In 2010 the workshop program had grown in diversity of topics and numbers of presenters.

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.

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 2010 Kerrin Rennie Award was:

SynCardia – Device Technologies

SynCardia is a temporary total artificial heart enabling patients with end-stage heart disease to survive until a replacement heart becomes available. The device temporarily replaces both failing heart ventricles and heart valves. Its high volume blood flow helps patients recover to become better transplant candidates.

The other finalists were:

Nucleus 5 System – Cochlear

The Nucleus 5 System consists of four components: Cochlear implant, sound processor, remote assistant and software. It restores hearing to individuals with severe to profound hearing loss. The Nucleus 5 includes the world's thinnest implant and dual omni directional microphones simplifying phone use. It has increased impact, water and sweat resistance.

SureScan Pacing System – Medtronic

The SureScan Pacing system is an MRI compatible pacemaker. It is designed to overcome complications associated with MRI scans allowing previously restricted pacemaker patients to undergo less invasive and more effective diagnosis.

Synvisc One - Genzyme

Synvisc One is a gel like fluid that treats the cause of pain and decrease in joint mobility associated with osteoarthritis. The gel simulates healthy synovial fluid in affected joints. Synvisc One requires fewer injections lasting up to six months.

Value of Technology

The Value of Technology 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 this research will support our advocacy for funding in, and support for, a range of medical technologies that might not have strong Australian evidence to date.

During 2010-11 the Value of Technology project researched the following key clinical areas, with a strong focus on the clinical and economic impact of medical technologies on patients and on the Australian healthcare system:

- **Hearing impairment and cochlear implants**
  The Cochlear implant is the most effective device in the treatment of people with severe to profound hearing loss. The cochlear implant is extremely cost-effective, generating important health benefits in children and adults at reasonable direct costs and providing net savings to society especially when benefits translate into reduced educational costs and increased earnings.

- **Patients with type 1 diabetes and insulin pump therapy**
  Insulin pump therapy is recommended for children and adults with type 1 diabetes, if treatment with multiple daily injections is not practical, is not considered appropriate or results in unstable average blood glucose levels. Insulin pump therapy is shown to be cost-effective compared to multiple daily injections therapy due to the numerous clinical advantages such as better control of blood glucose levels, fewer problems with hypoglycaemic episodes, and reduction in insulin dose per day.

- **Obesity management and bariatric surgery**
  Bariatric surgery has proven to be a successful method in treating individuals who are morbidly obese. There are several surgical treatment options available and the type of procedure performed depends largely on the patient's clinical needs. So far all surgical treatment options have allowed patients to achieve and maintain significant weight loss, improve their health, and enhance their quality of life. Bariatric surgery has been shown to be cost-effective when compared to conventional and non-surgical treatments, where the cost of undergoing surgery is offset by avoidance of ongoing costs of managing obesity (e.g. cost of medication) due to the dramatic reduction or resolvement of many comorbidities such as type 2 diabetes and hypertension.

- **Remote monitoring systems for patients with chronic heart failure and implantable cardiac devices**
  Chronic heart failure patients with an implanted cardiac device (e.g. implantable cardioverter defibrillator or pacemaker) require constant clinical monitoring. Numerous positive health outcomes are associated with remote monitoring of cardiac devices, such as lowering mortality rates, improving quality of life and avoiding cardiac events such as strokes. Remote monitoring can also result in cost savings for the patient and the Australian health system, mainly achieved as a result of reducing the number of clinical visits and distance travelled by healthcare professionals, and early detection of symptom exacerbations and early intervention.

The Value of Technology project was presented for the first time as a series of posters at the 2010 MTAA annual conference. These posters and additional information can be viewed at MTAA's website.

Research Activities

The core research activities in 2010-11 were associated with MTAA policy submissions and analysis of trends in Australian healthcare. Examples include:

- **Industry Statistics**

  Medical Technology in Australia: Key Facts and Figures 2011 has been developed to provide a snapshot of our industry and the healthcare environment in Australia within which it operates. This publication will be available soon. In addition, MTAA is about to commence an industry wide survey targeting 500 Australian medical technology companies. The survey will cover market size/composition, turnover, value of imports/exports and employment.

- **Provision of an Essential Care List**

  Research has continued on the cost savings and benefits of providing patients with access to medical consumables that are currently funded in an ad hoc way. These data were included in two submissions to the Productivity Commission (*Caring for Older Australians, Disability Care and Support*) and the 2011-12 pre-Budget submission to Treasury.

- **Blood Management**

  The medical technology industry manufactures a range of items that assist with patient blood management. These include microwave scalpels, items for minimally invasive surgery, ultra filtration devices, transfusion systems and salvage devices that wash and save red blood cells. MTAA made a detailed submission in response to the *National Blood Authority, Patient Blood Management Guidelines: Module 2 – Perioperative*, calling for the inclusion of research-based evidence on the use of medical devices to enhance patient blood management.

- **Electronic Health Records**

  In response to the *Draft Concept of Operations: Relating to the introduction of a personally controlled electronic health record (PCEHR) system*, MTAA made specific recommendations that early consideration be given to the future use of data from electronic records for the development of high quality clinical registries.

- **Achieving Health Outcomes**

  In response to the *New Inquiry into the National Broadband Network (NBN)*, MTAA outlined ways in which the NBN could help with achieving health outcomes. Research covered telehealth, access to electronic health records, rapid delivery of results/medical data, smart medical homes and delivery of healthcare in the home.

- **Telehealth**

  Australia has ageing population and there is an increased demand for technologies that enable patients with chronic conditions to remain in their own homes. The key research focus has been determining how medical devices that enable remote patient monitoring should be reimbursed. MTAA has made detailed submissions to the Productivity Commission and DoHA recommending that Medicare Benefits Schedule (MBS) item numbers for telehealth include reimbursement for the assessment and monitoring of medical data collected from a patient's home. MTAA estimates that cost savings of $3.1 billion can be achieved with telehealth and has presented research on the benefits of assistive technologies for home medical monitoring to Government and at a range of Australian conferences.

Submissions

Submissions in 2011

- Submission to DoHA in response to its draft Concept of Operations for a Personally Controlled Electronic Health Record (PCEHR) - 31 May 2011
- Response to Productivity Commission's draft report on Disability Care and Support - 28 April 2011
- Submission to the National Blood Authority on patient blood management guidelines - 1 April 2011
- Submission in response to the release in January 2011 of the Productivity Commission draft report Caring for Older Australians - 21 March 2011
- Submission to TGA transparency review - 11 March 2011
- Response to the House of Representatives Standing Committee on Infrastructure and Communications on its inquiry into the NBN - 24 February 2011
- Response to MSAC changes - 18 February 2011
- Response to Australian Government paper on Connecting health services with the future: Modernising Medicare by providing rebates for online consultations - 27 January 2011
- Submission to the DoHA review of the Stoma Appliance Scheme - 21 January 2011.

Submissions in 2010

- Pre-Budget submission to Treasury 2011-12 - 24 December 2010
- Submission to DoHA on Draft Information Requests for Assessing a Pair of Co-dependent Technologies - 22 December 2010
- Submission to TGA on its response to the HTA review - 17 December 2010
- Position Paper on Reforming Public Health Procurement of Medical Technology - 14 December 2010
- Response to the Community Skills and Health Industry Skills Council on E-Scan 2011 - 5 November 2010
- Submission to ACSQHC in response to the National Safety and Quality Health Service Standards released in August 2010 - 7 October 2010
- Submission to ACSQHC in response to its discussion paper on Patient Safety in Primary Healthcare - 1 October 2010
- Submission to the TGA review of advertising of therapeutic goods in Australia - 27 August 2010
- Submission to the Productivity Commission's Issues Paper Disability Care and Support - 16 August 2010
- Submission to the Productivity Commission in response to its Issues Paper on Caring for Older Australians - 30 July 2010
- MTAA Federal Election policies - 8 July 2010.

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

Code Committee Reports

Code Complaints Committee

The Code Complaints Committee (CCC) considered a Complaint by Abbott Australasia Pty Ltd (Abbott) against Johnson & Johnson Medical Pty Ltd (J&JM).

The matter concerned marketing claims made by J&JM about their OneTouch Verio product range with respect to the Abbott FreeStyle Lite range of products across a range of materials. OneTouch Verio and FreeStyle Lite are blood glucose monitoring devices marketed to healthcare professionals and consumers.

Abbott alleged the following breaches of the Code by J&JM:

- 5.1 (a) and (b) that the comparative and clinical claims made by J&JM about its OneTouch Verio product range with respect to the Abbott FreeStyle Lite range breach section 52 of the Trade Practices Act (TPA);
- 5.1 (a) and (b) that comparative and clinical claims made by J&JM about its OneTouch Verio product range with respect to the Abbott FreeStyle Lite range breach section 53 of the TPA;
- 5.1 (c) that the claims made by J&JM about its OneTouch Verio range do not reflect a high standard of social responsibility or conform to generally accepted standards of good taste;
- 5.1 (e) that J&JM claimed the OneTouch Verio range has special and unique qualities
- 5.1 (f) that J&M used the term 'safe' in relation to its OneTouch Verio range without appropriate qualification;
- 5.2 (a) (i) that the claims by J&JM about its OneTouch Verio range are not substantiated;
- 5.2 (a) (iii) that J&JM did not provide substantiating material to Abbott within twenty days;
- 5.2 (a) (iv) that J&JM did not identify unpublished data as 'data on file' when cited in a claim;
- 5.3 (e) that J&JM published advertising material that contained expressly or by implication, exaggerated or unqualified superlative claims;
- 6.3.5 (b) that J&JM displayed advertising and used trade displays at a third party educational conference that did not comply with clause 5 of the Code.

Outcome

CCC had the benefit of comprehensive submissions from both parties in its deliberations.

CCC dismissed the alleged breaches of sections 5.1 (f); 5.2 (a) (i); 5.2 (a) (iii) and 5.2 (a) (iv).

CCC upheld the substance of the complaint finding breaches of sections 5.1 (a) and (b); 5.1 (c); 5.1 (e); 5.3 (e) and 6.3.5 (b).

Sanctions

CCC classified the breaches as moderate (noting there are no patient safety implications).

For the breaches of clauses 5.1 (a) and (b), CCC imposed a penalty of $20,000 (collectively).

For the breaches of clauses 5.1 (c) and (e), CCC imposed a penalty of $20,000 (collectively).

For the breach of 5.3 (e), CCC imposed a penalty of $20,000.

For the breach of 6.3.5 (b), CCC imposed no financial penalty taking the view that this breach flowed out of the breaches of 5.1 (a) and (b), and 5.1 (c) and (e).

The total of fines is $60,000.

CCC made no orders for the recall of the material as J&JM had already done this for other reasons.

J&JM is also required to pay CCC costs.

Code Appeals Committee

The Code Appeals Committee (CAC) considered an appeal by Medtronic Australasia Pty Ltd (Medtronic) against decisions of the Code Complaints Committee (CCC) arising from a referral by the Code Monitoring Committee (CMC).

The matters of complaint and appeal were heard under the edition of the Code applicable at the time of the alleged breach. The CCC and CAC were convened and proceeded under the 4th edition of the Code.

CMC referred five alleged breaches to CCC, consisting of:

- Alleged breach 1: EuroPCR 2008 Barcelona (13-16 May 2008)
- Alleged breach 2: Visit to Medtronic manufacturing facility in Galway (16-19 May 2008)
- Alleged breach 3: Primary percutaneous coronary intervention (14 May 2008)
- Alleged breach 4: New Product Launches (24/6, 25/6 and 27/6 2008)
- Alleged breach 5: Sprinter Legend Brochure
- Alleged breach of section 10.2 (d) of the 4th edition (complaints 1 – 5).

For each of the items above, CMC alleged breaches of:

1. **Section 4.4 (in 5th, 4th and 3rd editions and equivalent to sections 3.5 and 3.6 in the 2nd edition)**
2. **Section 10.2c (in 5th and 4th editions and 10.2b in the 3rd edition)**
3. **Section 10.2 d (in 5th and 4th editions and 10.2b in the 3rd edition).**

CCC did not proceed on points 1 and 2 above. In relation to alleged breaches of section 10.2 d (in 5th and 4th editions and 10.2b in the 3rd edition), CCC agreed to consider this as a single overarching breach as it was common across all matters raised by CMC.

1. EuroPCR 2008 Barcelona (13-16 May 2008)

This matter concerned the direct support of healthcare professionals (HCP) to attend the EuroPCR 2008 conference in Barcelona, Spain in 2008. CCC found the following:

- Minor breach of 5.3.2 (a), 2nd edition
- Minor breach of 5.3.2 (b), 2nd edition
- Minor breach of 5.3.2 (e), 2nd edition.

2. Visit to Medtronic manufacturing facility in Galway (16-19 May 2008)

This matter concerned the appropriateness of a training and education venue and the reasonableness of hospitality, travel and lodging costs around a visit by HCP to a Medtronic manufacturing facility in Galway, Ireland. CCC found the following:

- Minor breach of 5.2 (a), 2nd edition
- Minor breach of 5.2 (c), 2nd edition
- Minor breach of 5.2 (d), 2nd edition
- Dismissed an alleged breach of 5.2 (f), 2nd edition.

3. Primary percutaneous coronary intervention (14 May 2008)

This matter concerned the selection and support of HCP to attend a training and education event associated with the EuroPCR 2008 conference in Barcelona, Spain in 2008. CCC found the following:

- Dismissed an alleged breach of 5.3.(a) (ii), 2nd edition
- Minor breach of 5.3.2 (a), 2nd edition
- Minor breach of 5.3.2 (b), 2nd edition.

4. New Product Launches (24 June, 25 June and 27 June 2008)

These matters concerned new product launches held in Sydney, Newcastle and Brisbane.

CCC found the following:

- Dismissed the alleged breach 6.2 (a), 3rd edition with respect to the event held at the Medtronic facility in North Ryde, Sydney on 24 June 2008
- Minor breach 6.2 (a), 3rd edition, with respect to the new product launches held at Restaurant II, Newcastle and Sono, Brisbane on 25 and 27 June 2008 respectively
- Dismissed an alleged breach of 6.2 (c), 3rd edition
- Moderate breach of 6.2 (c), 3rd edition. CAC imposed a fine of $10,000 after agreeing to treat the two launches as a single moderate breach for the purposes of imposing a sanction.

5. Sprinter Legend Brochure

This matter concerned a product brochure and the use of the term 'safe.'

CCC found the following:

- Dismissed an alleged breach of 5.1 (a), 3rd edition on the grounds that this was insufficiently canvassed with Medtronic by CMC
- Severe Breach of 5.1 (f), 3rd edition. CCC imposed the maximum fine of $20,000.

Alleged Breach of section 10.2 (d) of the 4th edition (complaints 1 – 5)

This overarching matter concerned the provision of information under the Code. CCC found the following:

- Moderate breach of 10.2 (d), 4th edition. CCC imposed a fine $15,000.

Medtronic appealed in relation to the following matters:

- New Product launches in Brisbane and Newcastle (6.2 (c), 3rd edition)

Having regard to further information provided by Medtronic, CAC found no breach in relation to either event. Appeal upheld.

- Sprinter Legend Brochure (5.1 (f), 3rd edition)

Having regard to further information provided by Medtronic, CAC found no breach. Appeal upheld.

- Section 10.2 (d) of the 4th edition (complaints 1 – 5)

CAC dismissed this appeal. However, the fine was reduced from $15,000 to $10,000.

Costs

Costs were awarded against Medtronic. Based on unclear Code provisions regarding conflicts of interest and confidentiality, CAC directed that a 10% discount be applied and that the Code be reviewed to clarify these issues.

The Code Appeals Committee (CAC) considered an appeal by Smith & Nephew Pty Ltd (S&N) against decisions of the Code Complaints Committee (CCC) arising from a Complaint by Convatec Australia Pty Ltd (Convatec).

The matter concerned marketing claims made by S&N about their Durafiber range of wound care products and made comparisons with Convatec's Aquacel range of wound care products.

In November 2010 CCC upheld Convatec's complaints as follows:

- 5.1 (a) and (b) that the Durafiber brochure contains misrepresentations in breach section 52 of the TPA
- 5.1 (e) that the S&N Durafiber range has special qualities
- 5.2 (a) (i) that the claims by S&N about its Durafiber range are not substantiated
- 5.3 (b) (iii) and (e) that the comparative testing is not reported in a fair and balanced way, and that S&N Durafiber advertising material makes exaggerated or unqualified superlative claims.

CCC determined the breaches were in the Moderate range and imposed a sanction of $40,000 on S&N. In addition, S&N was required to pay CCC costs.

S&N were also required to recall and destroy the marketing material subject to Complaint and issue an explanatory notice to Healthcare Professionals in receipt of this material. S&N carried out this requirement to the satisfaction of the Chair of CCC.

S&N subsequently appealed against the decision of the CCC.

After consideration of comprehensive written and oral submissions, CAC dismissed all aspects of the appeal.

CAC determined that CCC was correct in classifying the breaches as moderate. CAC found that the sanctions imposed by CCC were reasonable and that they should stand. CAC dismissed submissions as to a reduction in CCC costs.

Noting that the Durafiber product is no longer on sale (for reasons other than action under the Code), CAC made no orders with regard to corrective notices or recall of any marketing material.

CAC also required S&N to pay the CAC costs.

MTAA Members at 30 June 2011

3M Healthcare Pty Ltd
Abbott Medical Optics Australia & New Zealand
Abbott Vascular
Alcon Laboratories (Australia) Pty Ltd
Allergan Australia 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
bioMD Limited
Biomet Australia Pty Ltd
Biotronik Australia Pty Ltd
Boston Scientific Pty Ltd
CareFusion Australia 316 Pty Ltd
Chelsea Medical Pty Ltd
Cochlear Ltd
Coloplast Pty Ltd
ConMed Linvatec Australia Pty Ltd
Corin (Australia) Pty Ltd
Covidien
Device Technologies Australia
Edwards Lifesciences Pty Ltd
Fresenius Kabi Australia Pty Ltd
Gambro Pty Ltd
Gel Works Pty Ltd
Genzyme Australasia Pty Ltd
Hologic (Australia) Pty Ltd
Hospira Pty Ltd
Johnson & Johnson Medical Pty Ltd
Karl Storz Endoscopy Australia Pty Ltd
Kimberly-Clark Australia Pty Limited
Life Healthcare Pty Ltd
Ligamed Australasia Pty Ltd
Link Orthopaedics Australia Pty Ltd
MAC Surgical
Mathys Orthopaedics Pty Ltd
Med-Chem Surgical Pty Ltd
Medical Device Research Australia
Medical Specialties Australia Pty Ltd
Medigard Ltd
Medigroup Australia Pty Ltd
Medtronic Australasia Pty Ltd
N Stenning & Co Pty Ltd
Nanosonics Ltd
Olympus Australia Pty Ltd
Paragon Therapeutic Technologies
Paul Hartmann Pty Ltd
Qlicksmark Pty Ltd
REM Systems
RITM Australia Pty Ltd
Signostics Pty Ltd
Simavita
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
St. Jude Medical Australia Pty Ltd
Stryker
Surgical House
Surgical Specialties Pty Ltd
Synthes Australia Pty Ltd
Terumo Corporation
Tornier Pty Ltd
Varian Medical Systems Australasia
W. L. Gore and Associates (Aust) Pty Ltd
Zimmer Pty Ltd

Associate members at 30 June 2011

Archer Emery & Associate Pty Ltd
Biomed Consulting
Covance Pty Ltd
Five Corners Pty Ltd
Healthcare Placement Solutions Pty Ltd
Intative Medical Marketing
Kelly Speech Communication Pty Ltd
Lesley Pink, Regulatory Affairs Consultant
McKenzie Healthcare
Minerva Medica Pty Ltd
Open Sesame Consulting
Phillips Ormonde Fitzpatrick
Regulatory Concepts Pty Ltd
Sue Akeroyd & Associates
The Amplio Group
The Mentor Management Group
Ultrafeedback Pty Ltd

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