



**Comments on *Good Medical Practice:*
*A Draft Code of Professional Conduct***

November 2008

1. Background – about MTAA

The Medical Technology Association of Australia (MTAA) represents the manufacturers, distributors and exporters of medical technologies which include products ranging from consumable items such as syringes and wound care products, to complex technologies such as diagnostic imaging equipment, *in vitro diagnostic* products, and implantable orthopaedic and cardiac devices.

The industry has a significant level of interaction with healthcare professionals, a relationship which is essential to product development and to the education and training of clinicians to ensure that products are used optimally for the best patient outcomes.

2. MTAA Code of Practice

The medical technology industry is subject to a well-developed self-regulatory Code of Practice which governs the relationship between the medical technology industry and healthcare professionals. Adherence to the Code is binding on members of MTAA and advisory for non-members although non-members can agree to submit to the complaints process in the Code. MTAA is in the process of introducing a trade mark licence which carries with it the right by a medical technology company to licence a decal to indicate that the company not only adheres to the Code but also has committed to taking additional steps of ensuring that its workforce is educated in the Code and that it actively monitors compliance with the Code.

The Code of Practice sets out guiding principles as well as specific restrictions on the interactions between a company and a healthcare professional. These requirements are more restrictive than those outlined in Appendix 1 to the Draft Code of Professional Practice and are addressed in more detail in section 4 below.

3. Industry Codes of Practice – the broader context

MTAA first introduced a Code of Practice in 2002. The first Code was very broadly-based and was not much more than statements of good intent. As the global environment changed so too did the level of compliance required of industry. The Code was significantly upgraded in 2006 and again (twice) in 2008. The Code now includes provisions that not only specify appropriate behaviour but also includes an enforcement mechanism to address non-compliance, and a monitoring mechanism to enable an independent committee to audit company activities.

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A finding that a company has breached the Code may result not only in a significant financial penalty but also in publication of the information on the MTAA website and in its Annual Report. The Code also provides that the finding of a breach may be reported to the industry regulator, the Therapeutic Goods Administration.

In the United States, several of the larger orthopaedic companies have become subject to a high level of supervision by the Department of Justice, arising from settlements of actions brought against the companies for offering inducements to healthcare professionals. Subsequent to these settlements there has been a series of actions taken in the United States by members of Congress and others to further restrict the interaction between industry and healthcare professionals. Recently two members of Congress have written to leading universities and research bodies asking for full disclosure of financial relationships with specified device companies.

Recently several leading teaching institutions in the United States have implemented policies which sever all relationships with the medical technology industry. These include a ban on all gifts from medical technology and drug companies, and the removal of an entitlement to financial gain for a faculty member. These conflicts of interest rules will have an impact on development of technology products because of the level of collaboration that is involved.

A recent study in the United States, published in *Health Affairs*, showed that physician innovation accounted for almost 20 percent of about 26,000 medical device patents filed in the US during 1990-1996. However, contrary to fears that academic physicians are heavily influenced by industry funding, the study notes that 60 percent of the physician-inventors work in private practice, not in an academic medical setting. The study data also show that physician involvement extended beyond the initial patents. Physician patents received an average of 15.2 citations in subsequent patents compared with 12.7 patents developed by non-physicians. Each citation represents an estimated \$1 million in value for the patent-holding firm.

The challenge for both the healthcare system and the medical technology industry is to ensure ethical and transparent means by which industry can continue to support product research and development, particularly given the funding constraints within the healthcare system.

4. Scope of MTAA Code of Practice

The MTAA Code of Practice (which applies also in New Zealand through the Medical Technology Association of New Zealand) is a fundamental part of the framework by which the Association sets best practice standards of behaviour for the medical technology industry, educating members, monitoring industry activities, providing self-regulation and disciplinary functions and interacting with government, professional bodies and associations, and consumers.

Companies are required to comply with the letter and the spirit of the Code and in dealing with healthcare professionals, companies must undertake ethical business practices and socially responsible conduct. Companies must not use any inappropriate inducement or offer personal benefit or advantage in order to promote or encourage the use of a company's products.

Companies conduct extensive training and education on their products. In doing so the emphasis is on the educative content. The location of training and education must be conducive to learning. It cannot be held at a resort location and where it is 'hands-on' must be provided in an appropriate clinical setting.

The Code also specifies that a company must not:

- Directly fund a healthcare professional to attend a conference. Conference sponsorship may be provided to the professional body organizing the conference but no direct support may be given to the healthcare professional. Support may also be given to a hospital education fund for a travel or education grant but again there can be no direct nexus between the granting company and the healthcare professional who receives it
- Provide hospitality except in the context of product education or in-service training, or by sponsorship of an educational conference. Any hospitality which is given must be subordinate to the primary purpose of the event
- Pay the cost of travel or hospitality for partners or families
- Pay for participation in or attendance at a sporting event or other entertainment
- Provide any gift unless it serves an educational purpose.

An area for further consideration is that of consultancy arrangements with healthcare professionals, particularly where the consulting clinicians are involved in product development which might result in the payment of significant royalties.

The most recent edition of the MTAA Code of Practice require that fellowships be arranged through a body with capacity to accredit the fellowship, such as a professional association or a training hospital. This not only ensures that the fellowship is above conflicts of interest but also supports the professional associations in their quest to ensure appropriate educational standards for fellows. Companies are permitted under the Code to make grants to specified bodies for the purposes of education or medical research where they are set up for this purpose.

5. Comments on the Draft Code of Professional Conduct

MTAA welcomes the decision to develop a national framework for professional conduct. However MTAA is of the view that the provisions dealing with relationships between healthcare professionals and industry could be significantly improved. Both MTAA and Medicines Australia have highly-evolved Codes of Practice which could be referenced in the document as providing a benchmark for industry/clinician relationships. The industry Codes in fact impose a higher level of obligation on the relationship than does the Draft Code.

MTAA has worked closely with many of the professional associations which have members who interact with the medical technology industry. Through these collaborations MTAA has sought to educate healthcare professionals on the appropriate relationships and transparency of arrangements to ensure that the relationships are ethical and open to scrutiny.

The MTAA Code of Practice can be found at <http://mtaa.org.au/pages/images/4th%20Edition%20and%20guidance%20material%20final.pdf>