



INTERACTIONS WITH THE MEDICAL INDUSTRY

INTRODUCTION

Interactions between medical practitioners and the medical industry are subject to greater scrutiny by government, the media and society than ever before. Patients rely on the independence and trustworthiness of their surgeon, in particular any advice or treatment they recommend or prescribe.

Certain interactions between qualified Surgeons, Trainees or International Medical Graduates (IMGs) and the medical industry have the potential to become a conflict of interest. A conflict of interest in medical practice arises when a surgeon, entrusted with acting in the interests of a patient, also has a financial, professional or personal interests or relationships with third parties, which may affect their care of the patient¹.

Interactions between surgeons and the medical industry can be beneficial to surgeons, patients and the industry. The interactions facilitate new opportunities for collaboration to develop innovative technology to meet the ever changing needs of patients. Interactions between the medical industry and surgeons have evolved to include conducting of clinical trials, serving on scientific advisory boards and proctoring the introduction of new technology.

KEY WORDS

Medical Industry, interactions, conflicts of interest.

RACS POSITION

It is RACS position that a surgeon must not accept financial remuneration, either by way of money or goods or services, based solely or partly on the use, or expectation of use, of medication, devices or prostheses (subject to considerations of 3b – Specific Scenarios Training sessions). RACS supports the Medical Industry Code of Practice and has developed the following recommendations for Surgeons, Trainees and IMGs:

1. A Surgeon must not approach the medical industry as an individual for payments, either direct or indirect, during the marketing phase of a device or technology.
2. A Surgeon must not enter into any financial arrangement that could influence, or be reasonably perceived to influence, the decisions they make on behalf of their patients (subject to 6.).
3. A Surgeon must declare to the patient or their legal guardian, any arrangement with medical industry that results in benefit, financial or non-financial, before any recommendations or decisions with respect to medication, prostheses, devices or technology on behalf of patients are made.

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4. A Surgeon must disclose to the patient any possible self-interest and must make such issues available for scrutiny - particularly by patients, but also by colleagues, professional bodies and the general public.
5. Except where he or she has been involved in the creation or development of a medical product, a surgeon shall not promote or endorse that product other than (whether or not for remuneration) by demonstrating or training others in the use of that product (subject to considerations of 3b – Specific Scenarios Training sessions).
6. A Surgeon must ensure that any relationship with the medical industry is transparent and publicly acknowledged if a medical product is, either directly or indirectly, endorsed.
7. A Surgeon must distance themselves from financial grants obtained from medical industry e.g., educational grants should be directed to organising bodies, payment for specific fellowship training should be by way of the specialist organisations.
8. Surgical organisations must not accept grants from medical industry if there are any conditions stipulating that the funds be directed towards a specific individual or individuals.
9. A Surgeon shall not permit any member of their family to accept benefits from the medical industry.
10. Potential conflicts of interest, or even the possibility of a perceived conflict of interest that cannot be resolved, should be addressed by consultation with relevant institutional authorities or with RACS.

KEY ISSUES

The community has entrusted medical practitioners with certain rights and privileges; one of these is to recommend medication and devices that best meet the requirements of the patient. Medical practitioners who recommend medications, devices or prosthesis to increase personal financial remuneration either by way of money or goods or services are in breach of the Medical Board of Australia (MBA) Code of Conductⁱⁱ, the Royal Australasian College of Surgeons (RACS) Code of Conductⁱⁱⁱ, Medical Council of New Zealand (MCNZ) Code of Ethics, or the MCNZ Code of Conduct.

Interactions and possible conflict of interests require identification, consideration, appropriate disclosure and accountability. RACS advises that interactions between Surgeons, Trainees and International Medical Graduates (IMGs) with the medical industry be governed by three over-riding principles:

1. That the best interest of the patient(s) is paramount.
2. That surgeons and trainees conduct themselves with transparency and accountability.
3. Acknowledgement of perception of conflict of interest as an issue.

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RACS acknowledges that there are a myriad of scenarios that have the potential to expose Surgeons, Trainees and IMGs to conflicts of interests, and lists a number of examples below to ensure absolute clarity of RACS' expectation of conduct.

Consulting Rooms

Meetings with medical industry representatives are encouraged for the purposes of education and obtaining information. A fee must not be charged for such meetings nor should gifts be accepted.

Operating Theatres

Although the attendance of medical industry representatives during procedures can be useful, the overall responsibility for the treatment of the patient resides with the clinician and decisions regarding the patient must be made by the clinician.

Education

Educational development should, whenever possible, be through third parties such as specialist groups/ training boards that are accountable to the profession. Education should be free of commercial bias for or against any company, device, product or service. If an activity contains reference to commercial products and/or services, objective information based on generally accepted scientific methods must be presented. The educational content, faculty, venue and format should be determined by the convening body and not compromised or necessarily constrained by an industry's brand or product.

If medical industry has convened an educational meeting, the venue should not be excessive or extravagant Surgeons, Trainees and IMGs should enter into a written agreement with the company/supplier that sets out the nature of the program and the services to be provided by or on behalf of the company^{iv}.

Training Sessions for New Technology

Learning new techniques or becoming familiar with new technology may require training. Such training may require travel and accommodation. Reimbursement for reasonable expenses is appropriate but compensation for lost income is not. A surgeon must not accept any financial support, direct or indirect, in excess of reasonable travel and accommodation expenses from medical industry for such sessions.

a) Attending Educational Meetings

Surgeons, Trainee and IMGs must not accept any financial support, direct or indirect, from medical industry for attending educational meetings. Any such support from industry must be directed to the organisers of the meeting to defray or disseminate payments as deemed appropriate.

b) Presenting at Educational Meetings

Any payment for presenting at surgical meetings should be made to individuals by the organising committee of the meeting, not directly by industry. If organisers accept a grant from

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industry for payment of a speaker, this must not be dependent upon a specified speaker. The organising committee must retain autonomy for the arrangements of the meeting.

Any travel or accommodation expenses met by industry should be declared at the beginning of any presentation or demonstration. Any such expenses or reimbursement should be reasonable and not excessive.

Intermittently, a surgeon is paid by a medical industry company to attend a meeting in order to represent that company. In this situation, a surgeon must disclose that he or she is a paid consultant or advisor to, or an employee of, the company during any discussions involving that company or its products, formal or informal. Subsequently, a surgeon must disclose to a patient or their legal guardian that he or she is or has been a paid representative of the company before making any recommendation about the use of that company's products for the patient.

c) Arranging Meetings

A surgeon must not approach industry directly as an individual for educational support for meetings. Any approach should be clearly understood to be on behalf of the organising committee. A Surgeon acting on behalf of, or as a representative of RACS, should have the expressed permission to do so.

Sponsorship of educational meetings and events (preferably directed through the relevant specialty organisation/ training board) should be appropriate, in accordance with professional and community standards and expectations. Venues and hospitality should be appropriate and not excessive or extravagant.

Funding Fellows

Industry funded fellowships should be organised through, and approved by, the relevant surgical specialty board rather than directly through individual surgeons. A surgeon must not accept financial support directly from medical industry for the purpose of funding their own personal fellow.

Publications

Any industry arrangement or involvement pertaining to a submitted paper for consideration for publication should be accompanied by an appropriate declaration of interest. In addition, any reviewer for a journal should declare any potential conflict of interest with respect to a paper to the editor of the journal. A surgeon may publish (or present) their experience with a device or technique in a peer reviewed journal (or meeting).

Demonstrations

A Surgeon undertaking to demonstrate a technique or the use of prosthesis to colleagues must be aware that they are in fact endorsing the technique or prosthesis. Any direct or indirect payment from medical industry indicates that the surgeon is a paid consultant, advisor or an employee of the company involved. This must be disclosed prior to the demonstration and subsequently to patients prior to recommending that company's devices and prostheses.

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Direct Remuneration

Surgeons may have direct financial relationships with industry for a number of reasons. These include involvement with the creation or development of a device or prosthesis, undertaking evaluations and serving on advisory boards. These involvements must not prejudice decisions regarding individual patients and must be transparent to patients, hospitals and colleagues. They must be able to withstand public and professional scrutiny and conform to professional and community standards, ethics and expectations.

Research

Any funding arrangements, direct or indirect, for research must be transparent and fully declared in all reports, papers or outcomes arising from the research, for genuine research purposes, not inhibit or restrict publication or dissemination of reports, papers or outcomes arising from the research, and; be reasonable, having regard to the nature of the research.

Approver: PDSB

Authoriser: Director, Fellowship and Standards

REFERENCES

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- ⁱ Medical Board of Australia, Good Medical Practice: A code of conduct for doctors in Australia, pg. 21.
 - ⁱⁱ Medical Board of Australia, Good Medical Practice: A code of conduct for doctors in Australia, pg. 21. Medical Council of New Zealand, Good Medical Practice, 2016 section 56-58.
 - ⁱⁱⁱ Royal Australasian College of Surgeons Code of Conduct, 2016, pg. 11.
 - ^{iv} Medical Technology Industry Code of Practice, 2015, pg. 13.

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