

## Position Statement on Doctors' Relationships with Industry 2010

This document provides guidance for doctors on maintaining ethical relationships with the pharmaceutical industry, medical device and technology industry, and health care product and service suppliers in general (herein, 'industry').

### 1. Introduction

*1.1 Doctors are highly trained health professionals who are trained to think independently, to make decisions, and to discharge their duty of care in the best interests of the patient.*

1.2 The history of health care delivery in Australia has been marked by close collaboration between doctors and industry. This collaboration has extended to research as well as education. There is no doubt that it has contributed beneficially to the quality of health care that Australians have been able to receive.

*1.3 Doctors have a responsibility to ensure that their participation in such collaborative efforts is consistent with their duties towards their patients and towards society at large. Doctors must safeguard their clinical independence and professional integrity from the influence of third parties including industry.*

*1.4 Relationships between doctors and industry are subject to the general constraints of the codes of ethics of the medical profession as well as any relevant legislative and regulatory requirements. Doctors should be aware of increasing public scrutiny of their relationships with industry and that they may be called upon to explain their actions if not consistent with professional codes and legislative and regulatory requirements.*

1.5 There needs to be recognition of the importance of potential conflicts of interest and the development of processes to deal with them.<sup>1</sup>

### 2. Medical education

2.1 Anyone who enters the profession of medicine accepts the responsibility to be guided principally by considerations of patients' interests. Wherever medical education is provided, policies should be established that require formal teaching in this regard so as to inculcate an appropriate ethical outlook in medical students.

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<sup>1</sup> These concepts may be defined in the following terms (from The Royal Australasian College of Physicians *Guidelines for ethical relationships between physicians and industry, 3<sup>rd</sup> edition, 2006*):

- An 'interest' is a commitment, goal or value arising out of a social relationship or practice;
- A 'duality of interest' arises when two or more interests coexist. These interests may or may not conflict, depending on the specific circumstances; and,
- A duality may become a 'conflict of interest' when a particular relationship or practice gives rise to two or more contradictory interests.

The decision about whether a duality constitutes a conflict should not rest with the individual concerned but with the affected community. If a conflict is judged to exist, some action needs to be taken to separate the conflicting duties. Specifically, it is suggested that the following sequence of events may prove helpful:

- Individuals in identified areas of activity declare dualities of interest, whether financial or non-financial;
- These are considered by the relevant community – eg., a committee or council or group of individuals directly affected;
- An assessment is made concerning whether the dualities constitute a potential or actual conflict;
- If it appears that a conflict of interest is present or likely, practical strategies are devised to separate the pursuit of the conflicting interests, in some cases, this may entail withdrawal from or curtailing of a particular activity, while in others, it may be sufficient to delegate functions or roles to an individual, a group of individuals, or a committee; and,
- The decisions and practical outcomes are communicated to the constituency affected.

2.2 Medical curricula, both pre-vocational and vocational, should include formal training referring to ethical relationships with industry.

### **3. Major principles guiding doctors' relationships with industry**

3.1 The major principles guiding doctors' relationships with industry include the following:

- The doctor's primary obligation is to the patient. Considerations involving industry are appropriate only insofar as they do not intrude into or distort that primary obligation;
- The primary objective of relationships between doctors and industry should be the advancement of the health of patients;
- *Doctors must maintain their professional autonomy, clinical independence and integrity. Relationships between doctors and industry must not compromise doctors' professional judgement or ability to act in their patients' best interests;*
- *The patient's health needs should be the primary consideration when utilising products and services;*
- Doctors should manage potential conflicts of interest appropriately so as to maintain the public's trust and confidence in the medical profession. Appropriate management may include, but is not limited to, timely and honest disclosure of relevant relationships with industry to patients, peers, ethics committees, and others in a transparent and accountable manner as well as reducing or eliminating the potential for conflicts of interest to develop.

### **4. Industry sponsored research involving human participants, including participation in post-marketing surveillance studies**

*4.1 Any doctor who participates in medical research involving human participants has a duty to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of the individual research participants. The health and well-being of the individual research participant must take precedence over all other interests.*

4.2 Doctors should participate in industry-sponsored research only if it has genuine merit, is ethically acceptable, socially responsible and scientifically valid. The participation of doctors in research activities sponsored by industry should always be preceded by formal approval from an appropriate review body, including ethical review, following national guidelines of the type promulgated by the National Health and Medical Research Council, the Australian Health Ethics Committee, and similar bodies.

4.3 Any doctor participating in a specific research project must appropriately disclose relevant interests in accordance with relevant guidelines.

4.4 Adequate provision for funding must be made. Any incremental costs directly related to an industry-sponsored research project must be covered by the research sponsor(s), not defrayed by Government or other insurance agencies. The budget for a research project should be held in a specially designated fund that is made available for audit and scrutiny according to institutional guidelines.

*4.5 Patient participation in research should occur only with appropriate consent. The prescribing/treating doctor has an obligation to ensure that:*

- the doctor's continuing concern for the patient's welfare is not contingent on the patient's participation in the study;
- the patient is aware of available alternatives, their comparative advantages and/or disadvantages and other related matters that would establish informed consent under normal circumstances;
- the patient may withdraw from the study at any time. Where it is anticipated that this may not be possible, the patient should be clearly informed of this at the outset; and
- the budget has been scrutinised by an Ethics Committee.

4.6 Clinical trials should be registered in a publicly accessible register before recruitment of participants is undertaken.

4.7 It is acceptable for doctors in clinical practice to participate in appropriately designed, ethically approved post-marketing surveillance studies, the purpose of which is to monitor the performance of a product under conditions of actual use.

4.8 It is ethically acceptable for doctors to receive remuneration for participation in approved surveillance studies when such participation involves a significant amount of professional time and skill over and above that applied directly to patient care. This remuneration should be appropriate to the time expenditure, complexity of the study, and skill required. It may involve reimbursement of opportunity costs.

## **5. Meetings sponsored by industry**

5.1 In this setting, sponsorship refers to the provision of financial and/or material support for meetings. Doctors, in participating, must have in the front of mind there is no automatic obligation to provide a benefit to industry and the specific sponsor *per se*.

5.2 There is a clear and important distinction between education and training, including continuing professional development and industry promotion and marketing.

5.3 It is ethically acceptable for industry to sponsor meetings that contribute to doctors' education and continuing professional development; however, such sponsorship must be transparent and at arms length to the organisation of the meeting and consistent with the following guidance:

5.3.1 Sponsorship of meetings by industry should be provided independently of the meeting's clinical and scientific content;

5.3.2 Whilst the AMA acknowledges the right of industry to sponsor and engage speakers for meetings, an independent organising committee of doctors (and others, as appropriate) should have the ultimate decision regarding the organisation, content, selection of speakers and attendees, and choice of education activities and materials;

5.3.3 Any funds provided by industry to sponsor meetings should be controlled by the independent organising committee that may use the funds to defray the meeting costs, including sponsorship of invited speakers;

5.3.4 Any payments or reimbursements to individual participants who provide a service to the meeting should be commensurate with any services provided and made through the meeting organisers and not the sponsors. It is not appropriate for sponsorship to cover the costs of family or friends who may accompany a participant;

5.3.5 Meeting organisers and their delegates must not be in a position of conflict of interest by virtue of any affiliation with the sponsors(s) of those activities. Speakers should declare any relevant interests, including direct or indirect sponsorship to attend a particular meeting;

5.3.6 The program for such activities may acknowledge the financial and/or other aid received, and may identify but not excessively promote the sponsor's product(s);

5.3.7 Sponsorship for medical students, residents and fellows to attend educational events is appropriate; however, the relevant academic institution must be responsible for selecting the attendees as well as controlling the sponsorship funds.

## **6. Continuing Professional Development**

6.1 It is ethically acceptable for industry to contribute to continuing professional development (CPD); however, such contributions must be transparent and at arms length to the organisation of the meeting and in accordance with the guidance outlined above in Section 5.

6.2 CPD activities should address the educational needs of the targeted medical audience and not the marketing needs of the contributing company.

6.3 Institutions accrediting an educational activity should ensure that the activity is free of biases related to industry sponsorship.

## **7. Product samples**

7.1 Product samples are packages containing pharmaceutical products distributed by pharmaceutical manufacturers or their agents to doctors. Doctors should be aware of the associated risks and benefits before providing product samples to patients.

7.2 Product samples may be considered to be a marketing exercise by industry to accustom a doctor to prescribing a particular product or to influence a patient's preference for a particular product. Product samples may, however, be used to serve patients' interests in certain circumstances. For example, they allow prescribing doctors to evaluate an initial clinical response to a medication and/or permit them to initiate immediate therapy.

*7.3 Distribution of samples, should not involve any form of material gain for the doctor or for the practice with which he or she is associated.*

## **8. Dispensing and related issues**

8.1 Practising doctors who also have a financial interest in dispensing and selling pharmaceuticals or who offer their patients health-care related or other products are in a prima facie position of conflict of interest.

*8.2 Doctors should not dispense pharmaceuticals or other therapeutic products unless there is no reasonable alternative. Where dispensing does occur, it should be undertaken with care and consideration of the patient's circumstances.*

*8.3 Doctors should not knowingly invest in industry manufacturing companies or related undertakings where knowledge about the success of the company or undertaking might be seen to influence inappropriately the manner of their practice or their prescribing behaviour.*

8.4 Doctors in active practice should not be affiliated with industry manufacturers if the nature of their affiliation influences their medical practice in an inappropriate fashion.

## **9. Relationships involving industry representatives**

*9.1 Industry representatives seek out doctors in order to market products; however, the primary way in which doctors inform themselves about new products should be through CPD programs and a judicious study of the appropriate professional literature.*

*9.2 Doctors in practice should not ask for or accept a fee, loans, or equivalent consideration from industry in exchange for seeing them in a promotional or similar capacity.*

9.3 Practising doctors should not ask for, accept, nor allow their prescribing habits to be influenced by, personal gifts from industry.

9.4 Doctors in active practice may accept educational materials appropriate to their areas of practice.

## References

Australian Medical Association. *Code of Ethics 2004. Editorially Revised 2006*

National Health and Medical Research Council. *National Statement on Ethical Conduct in Human Research*. Australian Government 2007

Royal Australasian College of Physicians. *Guidelines for ethical relationships between physicians and industry*. Third edition, 2006.

Royal Australasian College of Physicians. *Ethical aspects of conflicts of interest*. January 2004

World Medical Association. *Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects*. As amended by the WMA General Assembly, Seoul, Korea, October 2008.

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