



Doctors and health related commercial organisations

Patient care can be influenced by a doctor's interaction with a health related commercial organisation. This interaction can result in an unnecessary, inefficient or inappropriate use of health resources and harm to patients. To avoid these outcomes, you are expected to always perform your duties in a professional and ethical manner, to disclose any relevant conflicts of interest and to ensure that financial incentives or other inducements do not impact on decisions, treatment or care. This statement outlines the standards expected of you in your interactions with health related commercial organisations. It may be used by the Health Practitioners Disciplinary Tribunal, the Council and the Health and Disability Commissioner as a standard by which your conduct is measured.

Background

1. Doctors regularly engage with representatives from organisations such as pharmaceutical companies, insurers, private healthcare services and medical equipment manufacturers. Engagement with health related commercial organisations can take a number of different forms, including attendance at industry-sponsored conferences or continuous professional development (CPD) programmes, employment or contractual work, and being offered gifts, grants, samples or promotional material. Doctors can also be paid advisers to, or owners, share-holders, directors or managers of health related commercial organisations.
2. Health related commercial organisations provide products and services that help patients and contribute to the public good. Sometimes they also make significant financial contributions towards CPD, conferences and medical research. The value of this contribution to medicine must be acknowledged because it advances individual standards as well as medical practice. However, it is also important to acknowledge that the objectives of commercial organisations are often very different to those of doctors. The primary concern of a commercial organisation is usually to make a return on shareholder investment. Your primary concern must always be the care of your patient.
3. The following have been identified as methods that health related commercial organisations use to influence your behaviour.
 - Sponsorship of medical conferences
 - Sponsorship of CPD
 - Providing gifts or inducements to doctors
 - Visiting sales representatives
 - Journal advertising
 - Product endorsement by high profile or influential members of the profession
 - Publishing research conducted by sponsored researchers.

¹ The Royal Australasian College of Physicians' *Guidelines for ethical relationships between physicians and industry* includes a comprehensive bibliography of research in these areas.

4. Research demonstrates that if you accept gifts or inducements from a pharmaceutical company, this is likely to have a subconscious influence on your choice of prescription or treatment for a patient. Research also indicates that a doctor who is employed or sponsored by a pharmaceutical company often reflects a positive bias to that company's products.
5. You must recognise that you are susceptible to the influence exerted by health related commercial organisations. You must also be aware that if you fail to manage successfully the inherent conflicts of interest which arise from your interactions with these organisations then best patient care will be compromised.

Good medical practice

6. Integrity – being honest and trustworthy – is at the heart of medical professionalism. Make sure that at all times your conduct justifies your patients' trust in you and the public's trust in the profession².
7. You should not rely on a health related commercial organisation for impartial critical information about the diagnosis or treatment of illness. Instead, you should actively seek unsponsored objective information about treatments, devices, products or services. Engage regularly with your colleagues to ensure that your knowledge and care is consistent with current best practice.
8. You should only accept a fee or reward from a health related commercial organisation where this is a fee for professional services rendered (in accordance with the standards outlined in paragraphs 14-22). There must be a written contractual agreement outlining the nature and duration of the services provided.
9. Medical decision-making must always be free of commercial bias, or the appearance of commercial bias, for or against any organisation, device, product or service.

Learning about new treatments

10. The Council recognises that commercial organisations provide educational opportunities for doctors that may otherwise not be available. However, if you accept educational support from a commercial sponsor it is important to acknowledge and manage the inherent risk of bias.
11. If you are a member of a body that is organising or endorsing an educational activity you must ensure that:
 - The activity is scientifically accurate, objective and complete.
 - Any relationship with a health related commercial organisation is disclosed to participants.
 - The provision of sponsored educational opportunities does not create any obligation, or sense of obligation, to purchase or cause to be purchased any goods or services associated with the sponsoring organisation.
12. On conclusion of any sponsored educational activity, the organisers should make a statement of financial transactions available to sponsors, attendees, and any other interested party. This statement must declare any funds received from health related commercial organisations, and detail what that funding was used for.
13. If you are speaking or presenting at an educational activity, you must:
 - Disclose your relationship with any health related commercial organisation to participants.
 - Ensure that your presentation is unbiased and provides a balanced view of the treatment options.
 - Use generic rather than trade names wherever possible.

² Paragraph 88, *Good medical practice*

Providing care and advice

14. In providing care you are expected to provide advice and treatment based on the best available evidence.
15. Act in your patients' best interests when making referrals and providing or arranging treatment or care. It is never appropriate to accept any inducement, gift or hospitality for referring, treating or arranging care for a patient. Similarly, offering or providing real or perceived incentives to another health or disability service provider for the referral of patients to you or your service is unethical.
16. Be honest and open in any financial dealings with patients, employers, insurers and other organisations or individuals. When making recommendations or referrals, including to a particular facility, declare any relevant financial or commercial interest. If you have a conflict of interest, you should also ensure that the patient is aware of, and has access to, alternate sources of care.
17. Do not sell medicines, medical devices, supplements or other products to patients when the products are not clinically indicated. There are some circumstances where the sale of clinically indicated products is appropriate, but you should limit the benefit you receive from their sale to the cost of the product and any reasonable handling costs. You must advise patients of these costs.
18. Fees must not be made contingent on the successful outcome of medical treatment. Such arrangements are inappropriate because they imply that successful outcomes from treatment are guaranteed and therefore create unrealistic expectations.
19. Some doctors, or members of their immediate family, own or have a financial interest in retirement homes, surgical facilities, pharmacies³ or other institutions where care or treatment is provided. If you are in this situation you should avoid conflicts of interest wherever possible. For example, if you are a general practitioner with an interest in a nursing home, you should not usually provide primary care services to patients in that home. If a conflict of interest is unavoidable, you must advise the patient of the conflict and ensure that it does not adversely affect your clinical judgement. For example, if a family member has an interest in a pharmacy you must not allow that interest to influence your prescribing practice or the advice you give to patients⁴ and should advise patients of this conflict when, because of geographic proximity, they are likely to use that pharmacy to fulfil a prescription you have provided. Similarly, if you have an interest in a private surgical facility you should ensure that this does not affect your judgement when arranging treatment at the facility and advise patients you intend to refer of the conflict.

Engaging in research

20. If you engage in research, be aware that unless conflicts of interest are managed properly then the results of your research may be seen as unreliable or biased.
21. When designing, organising or carrying out research act with honesty and integrity. You, and any person with whom you have a personal or financial relationship, must not enter into a financial relationship with a sponsor of research except where payment is based solely on your time, expenses and effort. There must be a written contractual agreement outlining the nature and duration of the services provided. Do not:
 - Allow such payments to influence your conduct.
 - Participate in research where a sponsoring health related commercial organisation controls the interpretation, dissemination or publication of the results.
 - Engage in an arrangement whereby the value of the compensation (monetary or otherwise) paid in respect of the performance of the clinical trial may be influenced by the outcome.
 - Hold any propriety interest in any product being tested unless expressly approved by the relevant ethics committee.
 - Receive any payment, compensation, gifts or hospitality that is not explicitly declared in a conflict of interest statement. Such a statement must be included in any publication of the research, results or findings.

³ Note that under s.42c of the Medicines Act 1981 authorised prescribers are not permitted to hold an interest in a pharmacy.

⁴ Council's statement on *Good prescribing practice* outlines additional standards that apply in this situation.

22. When submitting articles to medical journals or for public consumption, you should clearly state any relationship you have to organisations providing funding or other support for the studies or that make the products that are the subject of the study whether or not the journals require such disclosure.

Doctors involved in the governance, management, operation or promotion of a health related commercial organisation

23. If you are involved in the ownership, governance, shareholding, management, operation or promotion of a health related commercial organisation, you have a duty to the wider community, the organisation and your colleagues. However, your first consideration must always be the interests and safety of patients.
24. Do not, either directly or through an agent, offer inducements, gifts, or hospitality that may affect, or be thought to affect, the way other health practitioners assess, prescribe for, treat or refer patients.
25. Ensure that information provided to practitioners, patients and regulators is up-to-date, timely, clear, accurate and appropriately referenced and includes full information about the options available, expected risks, side effects, benefits and costs of treatments.
26. You must declare your relationship with the health related commercial organisation in all circumstances where a conflict of interest might arise or be perceived to arise.
27. If you believe that a decision made by the organisation is putting or will put patients at risk of harm, you must make your objections known. You must adhere to internal procedures for reporting information about serious wrongdoing. If this does not result in a satisfactory outcome within reasonable time you have the option of raising the matter with the Director General of Health, the Health and Disability Commissioner, or Council. You may also consider resigning from the position or making your objections known in accordance with the Protected Disclosures Act 2000.

Other relevant standards

The New Zealand Medical Association's Code of Ethics

Clause 37 of the New Zealand Code of Ethics published by the New Zealand Medical Association (NZMA) states:

Before initiating or participating in any clinical research, doctors must assure themselves that the particular investigation is justified in the light of previous research and knowledge. Any proposed study should reasonably be expected to provide the answers to the questions raised. All studies involving patients should be subject to the scrutiny of an Ethics Committee before initiation. It is often appropriate to establish a committee independent of the primary investigators, initiators and funders of a trial to oversee ongoing ethical issues, including the evaluation of emerging results according to stated clinical, ethical and scientific criteria.

The NZMA's Code of Ethics has several other clauses relevant to the relationship between a doctor and the pharmaceutical industry. It is available on the NZMA's website, www.nzma.org.nz

The Royal Australasian College of Physicians

The Royal Australasian College of Physicians has developed *Guidelines for ethical relationships between physicians and industry* that addresses the ethical obligations of physicians in their interaction with the pharmaceutical industry. First published in 1994 and then revised in 2000 and 2006 it discusses the following issues:

- Clinical trials, including commissioned research projects
 - Pharmaceutical industry sponsored travel and attendance at meetings
 - Support for meetings and other educational activities
 - Gifts and entertainment provided to physicians
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- Drug samples
- Remuneration for services
- Duality of Interest

The booklet also includes a comprehensive bibliography outlining the research in this area.

Cole's Medical practice in New Zealand

Council's publication *Cole's Medical practice in New Zealand* contains a chapter with further discussion of the influence of pharmaceutical industry on the medical profession.

National Ethics Advisory Committee ethical guidelines

The National Ethics Advisory Committee has published ethical guidelines that are intended to ensure best practice when conducting research.

The Health Research Council's Guidelines on Ethics in Health Research

The Health Research Council has developed guidelines to assist Ethics Committees in the interpretation of operational standards published by the Ministry of Health. These guidelines provide clear direction to Ethics Committee members and researchers on the standards expected during research. They include advice on a range of topics, such as informed consent and conflicts of interest.

Medicines New Zealand Code of Practice

Medicines New Zealand has developed an extensive Code of Practice that lays down the principles of ethical behaviour for pharmaceutical companies in New Zealand.

The Council's statement on *Safe practice in an environment of resource limitation*

The Council's statement on *Unprofessional behaviour and the healthcare team*

The Council's statement on *Responsibilities of doctors in management and governance*

The Council's statement on *Non-treating doctors performing medical assessments of patients for third parties*

The Code of Health and Disability Services Consumers' Rights

This statement is scheduled for review by July 2017. Legislative changes may make this statement obsolete before this review date.
