



Doctors and health-related commercial organisations

Key points

There is a potential for health-related commercial organisations to influence how doctors practise and the clinical decisions they make. It is important that you recognise this potential influence and take appropriate steps to manage any bias or conflicts of interest that may arise from your interactions with health-related commercial organisations.

Health-related commercial organisations and doctors have different objectives and interests. Generating a profit is a principal goal for many commercial organisations. However, your primary concern as a doctor must always be the care of your patients.

Integrity and transparency are vital. Ensure that, at all times, your conduct and decisions justify your patients' trust in you, and the public's trust in the profession.

About this statement

The pharmaceutical and medical device industries, and other health-related commercial organisations, spend significant resources on marketing and promotional activities. These activities may be, in part, designed to influence how you practise and the clinical decisions you make. It is important to recognise that potential influence and take appropriate steps to manage any bias or conflicts of interests, both real and perceived, that may arise from your interactions with health-related commercial organisations. Failure to do so could compromise your clinical objectivity and the care you provide to your patients. It could also lead to unnecessary care and/or inappropriate use of health resources. In addition, it could erode the trust and confidence that patients have in doctors, and how the public perceives the medical profession.

This statement outlines what is expected of you when you interact with health-related commercial organisations. It is intended to guide you to recognise, assess and manage conflicts of interest, or perceived conflicts of interest, that may arise. However, the guidance in this statement is not exhaustive, so you will need to exercise your judgement when applying it to your situation. If you are unsure what to do, you should seek independent advice.

Terms we use in this statement

Bias: Inclination or prejudice for or against one person or group, or a treatment or product, especially in a way considered to be unfair. Perceived bias has the potential to be as damaging as a real bias if it is not recognised and managed.

Conflict(s) of interest: A conflict of interest arises when your own interests are at odds with your professional responsibilities. A conflict of interest is not limited to financial interests and could include non-financial interests such as your status, reputation, close relationships or research interests.

A conflict of interest is not always avoidable, and whether a conflict of interest is acceptable will depend on the circumstances and what steps have been taken to manage or reduce that conflict. A perceived conflict of interest has the potential to be as damaging as a real conflict if it is not recognised and managed.

Duality of interests: A duality of interests exists when two or more sets of goals, values or obligations co-exist in a particular setting. Where those goals, values or obligations are opposing or contradictory, it results in a conflict of interest.

Health-related commercial organisations: include but are not limited to:

- a. the pharmaceutical industry
- b. the biotechnology industry
- c. the medical device industry
- d. private health insurers
- e. commercial providers of services related to clinical practice, research and education.

Products: include, but are not limited to medicines, medical devices, appliances, supplements or items used to diagnose, cure, manage, or prevent a disease, disorder or injury in a patient, or to improve the patient's wellbeing.

Someone you have a close relationship with: includes any individual you have a familial, business and/or a personal relationship with, where that relationship could affect your professional and objective judgement.

How health-related commercial organisations can influence doctors and the medical profession

1. Doctors and health-related commercial organisations share some common goals; they seek to prevent, control, cure and manage diseases, or physical and mental conditions, and conduct research to improve and advance health care.
2. However, they also have different and potentially conflicting goals. For many commercial organisations, generating a profit is a principal goal, whereas your primary concern as a doctor must always be the care of your patients.
3. Health-related commercial organisations, especially the pharmaceutical industry and medical device industry, engage in marketing and promotional activities to influence how doctors practise and the clinical decisions they make. Promotional activities targeted at doctors take many forms including:
 - a. advertising
 - b. providing gifts, merchandise and drug samples to doctors and treatment facilities
 - c. sponsorship of continuing medical education (CME) including conferences, meetings, and talks
 - d. communication and visits from sales representatives
 - e. endorsement of product by high profile or influential doctors or scientists
 - f. providing grants for research, education and conference travel
 - g. publishing updates and summaries on new drugs and treatment methods
 - h. publishing studies conducted by sponsored researchers.
4. Research¹ shows that doctors who accept gifts, inducements or sponsorship from pharmaceutical companies often reflect a positive bias to those companies' products. As a doctor, you need to recognise this influence and take appropriate steps to avoid or manage it to ensure your clinical objectivity and professionalism are not compromised.

Principles to consider when you interact with health-related commercial organisations

5. Medical decision-making must be free of actual or perceived bias towards an organisation, device, product or service. The following principles will help you to identify, assess and manage bias or conflicts of interest that may arise in the course of your interactions with health-related commercial organisations.

Integrity is a key aspect of your professionalism as a doctor

6. Integrity is vital to your professionalism as a doctor. Because of the inherent power and knowledge imbalance in a doctor-patient relationship, patients and the public are inclined to trust you. Ensure that, at all times, your conduct and the decisions you make justify your patients' trust in you and the public's trust in the profession.²

¹ There is extensive literature on how health related commercial organisations can influence doctors and the clinical decisions they make. See for example the Royal Australasian College of Physicians' *Guidelines for ethical relationships between health professionals and industry* for a comprehensive list of references.

² See also *Good Medical Practice*.

Prioritise your patient's interests ahead of your own

7. Interactions with health-related commercial organisations can create a duality of interests. This can lead to a conflict of interest between your obligations to your patients and your obligations to the commercial organisation(s) you are associated with. The interests and welfare of patients must be your primary concern and take priority over any commercial, personal or other interests you may have.
8. If you are unsure whether your interactions with a health-related commercial organisation create or result in a conflict of interest, you should err on the side of caution and act as though a conflict exists.

Be open and transparent about your relationships and interactions with health-related commercial organisations

9. Managing conflicting interests effectively includes being open and transparent, and having appropriate processes in place to identify and address specific issues and conflicts. While disclosure alone may not necessarily resolve the conflict of interest, open communication is a vital part of managing that conflict.
10. Your patients must be able to trust that you will be open and transparent with them. Ensure that you fully disclose any financial or personal interests you may have with a health-related commercial organisation where that affects (or could be perceived to affect) your actions as a doctor. You should also document those disclosures.

Critically appraise information from health-related commercial organisations

11. Health-related commercial organisations are often selective about what information they share and who they share that information with. For example, promotional materials from a pharmaceutical company about a new drug could be biased or skewed in that they may emphasise the benefits of that drug but downplay or omit certain adverse findings. For that reason, it is vital that you critically appraise the information that health-related commercial organisations publish about new drugs, devices, and treatments. This is particularly important if you provide patients with any materials issued by health-related commercial organisations.
12. Where possible, avoid relying on health-related commercial organisations for key information about the investigation 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.

Any payment or benefit you receive from a health-related commercial organisation must be documented and disclosed

13. You should only accept a fee or payment from a health-related commercial organisation where that reflects the services you provide. Ensure that there is a written agreement that outlines:
 - a. the nature and scope of the services you provide
 - b. the disclosures you may need to make to relevant parties such as your patients, your employer/institution, or a research ethics committee.

Beware of the potential to overtreat

14. Health-related commercial organisations aim to influence your clinical practice by changing your prescribing behaviours and the tests and interventions you choose and recommend to your patients. This could lead you to preferentially prescribe medication, request investigations or make referrals which are not in keeping with best practice. This could also increase the cost of care and negatively impact other patients who may require care more urgently.
15. To reduce the risk of poor care or overtreatment, you must ensure that you act in your patient's best interests, and that there is a clinical basis for the treatments you prescribe, investigations you request, and the referrals you make.

Areas where you may have to manage conflicts of interest

16. Conflicts of interest may arise in the following interactions with health-related commercial organisations and you may have to take appropriate steps to manage those conflicts. These areas are not exhaustive as it is not possible to cover every situation.
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When providing care and advice to patients

17. You must put your patients' interests ahead of your own. This includes any referrals you make and any investigations you request. You must disclose to your patients and your employer (if applicable) any relevant interest (financial and non-financial) where a conflict of interest could arise or be seen to arise. If you have a conflict of interest, you must ensure that your patient is aware of, and has access to, other sources of care.
18. Other than the fees for care provided, it is unethical to accept any gift, reward or inducement for referring, or arranging care for a patient. Similarly, it is inappropriate to offer or provide any gift, reward or inducement to another doctor or health care professional for referring their patients to you or your practice.³
19. Your fees should be communicated clearly. You must not charge a higher fee because, for example, you believe there is a high chance of success in the proposed treatment. Such an arrangement creates unrealistic expectations in patients and is inappropriate and unethical.

When referring patients to a facility you own or have a financial interest in

20. You may need to refer your patient to a facility you (or someone you have a close relationship with) own or have a financial interest in.⁴ Be very cautious about such an arrangement. You should only do so if you have explored other options with your patient, and there is no suitable alternative that meets your patient's needs. In those instances, you must manage the conflict of interest by:
 - a. taking care to avoid real or perceived situations where the patient feels pressured into receiving care at the facility you own or have a financial interest in
 - b. fully disclosing to the patient the nature of the financial interest in the facility, and making a note of the disclosure in the patient's medical record including why there is no suitable alternative that meets the patient's needs
 - c. providing accurate information about that facility such as fees, incidental costs and wait times so that the patient can make a fully informed decision about whether to proceed with treatment at the referred facility
 - d. assuring the patient that if they decline care at that facility, their decision will not have an adverse effect on the care you provide.

When selling products to patients

21. Ethical issues can arise when you promote and sell products to patients. For example, your integrity could be compromised if you have a preference for certain products, or if you have sales targets to meet. Where possible, you should avoid selling products to patients, and only do so if there is a clinical basis for that product. In situations where you sell a product to a patient:
 - a. you must be transparent and disclose any financial interests you (or someone you have a close relationship with) may have with the manufacturer and/or supplier and any other benefits you receive from each sale that occurs
 - b. you must be satisfied that the product is in the patient's best interests
 - c. you must provide accurate information about the product to help the patient make an informed decision about whether to buy the product
 - d. the sale price should be limited to the cost of the product and any reasonable handling costs, and you must advise the patient of these costs.
22. If you offer products for sale to patients, you must create and maintain records that detail:
 - a. the actual cost of the product to you, including any rebate, discount or incentives you receive from the manufacturer or supplier
 - b. the manufacturer and supplier's names
 - c. the date manufactured and supplied to you
 - d. the expiry or best before date (if any)
 - e. any additional costs you incurred in sourcing the product, including any formula or calculation you use to set the sale price for the patient.

Meetings and educational events supported or sponsored by health-related commercial organisations

23. Health-related commercial organisations support medical education and continuing professional development in several ways. These include providing grants and donations to medical schools and hospitals, and sponsoring CME events. While these initiatives provide educational opportunities, they also aim to increase the profile of the sponsor and influence how you practise.

³ See also our statement on *Advertising*.

⁴ Note that under section 42c of the Medicines Act 1981, authorised prescribers are not permitted to hold an interest in a pharmacy.

24. If you are organising, endorsing or presenting at an educational event, you must ensure:
- there is a clinical/scientific basis for the event
 - the purpose of the event is educational rather than commercial
 - information is presented in a balanced and unbiased manner, especially where there are references to a commercial organisation's products or to the support and funding provided by a commercial organisation
 - if presenting, include a statement that your presentation is not an endorsement or promotion of any products referred to
 - that you use generic rather than trade names wherever possible
 - that you disclose any relationship with a health-related commercial organisation
 - there is no obligation, or sense of obligation, to buy or prescribe any goods, services or medications associated with any sponsoring organisation.

If funding is offered for you to run or attend an educational event

25. Sponsoring or funding attendance at an educational event can lead to a positive bias for that organisation's products. You should be aware of the risk of being unduly influenced.
26. If you are organising any sponsored educational activity, you should issue a statement declaring support and funds received from health-related commercial organisations, and how those funds were used. That statement should be available to sponsors, participants, the public, and any other interested parties.
27. If you are attending an educational event, only accept payment (including an honorarium) or reimbursement for expenses where that amount will not be perceived as influencing the content of your presentation or your practice as a doctor.
28. You must not accept sponsorship from a health-related commercial organisation to cover the cost of travel, attendance or meals for someone you have a close relationship with.

When working for, or providing consultancy services to, a health-related commercial organisation

29. If you act as a consultant or adviser to any health-related commercial organisation, this should be disclosed to your patients, your employer, and to any committees or boards you are part of. Your employer should be involved in assessing whether your dual role creates a conflict of interest, and if so, what actions should be taken to avoid compromising your clinical objectivity, and your primary responsibility to your patients.⁵

When engaging in research

30. Advances in medical care depend on sound clinical research. However, support provided by health-related commercial organisations can influence the design, conduct, outcomes, and findings from the research and how those findings are interpreted and published. For example, a doctor whose research is funded by a pharmaceutical company may report results in a more favourable manner to facilitate future research opportunities.
31. If you engage in research, you must manage conflicts of interests appropriately. Failure to do so could compromise the integrity of your study and affect public confidence in medical research. To manage and reduce conflict of interest in research, you must:
- act with honesty and integrity when designing, organising, conducting, and reporting findings from the research
 - ensure there is a written agreement that outlines your level of involvement, what services you will provide, and the nature and duration of the research
 - obtain approval from a research ethics committee before conducting the research, and additional approval for any material changes to the scope once the research is underway.
32. Any compensation or payment from a health-related commercial organisation should be a fair and accurate reflection of the time, expenses and effort you spend on the research. You must not:
- allow any payments, funds or gifts from sponsors to influence your conduct and your research findings
 - participate in research where the sponsor or funder restricts the reporting of an adverse event, or controls how the results are interpreted, distributed and published
 - enrol patients in the research unless they (or their authorised representative) have provided full, informed and voluntary consent
 - enter an arrangement where the amount of compensation (monetary or otherwise) is tied to or influenced by the outcome of the study

⁵ For example, it may be appropriate to refer your patients to another doctor or health professional, and to restrict the information you disclose to the health-related commercial organisation you provide consultancy or advisory services for.

- e. hold any proprietary or commercial interest in any product being developed or tested unless that arrangement has been approved in writing by the relevant ethics review committee
- f. accept any payment, compensation, gifts or hospitality that is not explicitly declared in a conflict of interest statement. You must include that statement when you publish the findings from your research.

Enrolling patients in research you conduct or are involved with

33. Studies involving a doctor's own patients can raise significant conflict between the doctor's research interests, and the need to act in the patients' best interests. If you enrol your own patients in your research:
- a. you must explain the nature of your role and involvement in the study
 - b. you must disclose the risks and benefits of participating in the research, and your links and relationship with any sponsors and health-related commercial organisations
 - c. you must provide your patients with the opportunity to seek independent advice about your research
 - d. you should provide other options for the patient's ongoing care which may include transferring the patient to another doctor or health provider
 - e. you must not pressure your patients to participate. Where possible, you should arrange for someone else to obtain consent from your patient to participate in the research.
34. If your patient declines to be involved or withdraws their consent to participate part-way through your research, the patient's decision must not have an adverse effect on the ongoing care that you or another doctor provide.

Publication and dissemination of research results

35. The reliability and integrity of scientific literature is affected by research findings and conclusions, the identity of the authors, their affiliations, and any support or funding they receive. When submitting articles to an academic journal or a public forum, you must:
- a. only be listed as an author if you have contributed substantially to the study and to writing the article, have approved it for publication, and retain accountability for the accuracy of the work
 - b. decline to be named as an author where that article was written in whole or in part by an employee or agent of a health-related commercial organisation and the contribution of the employee or agent is not acknowledged
 - c. publish findings in an accurate and balanced manner by including both negative and positive results from the research
 - d. disclose all sources of funding received, and any financial and non-financial interests and associations that influenced the research.

When you are in a governance or leadership role with a health-related commercial organisation

36. If you are part of a clinical advisory board, or have a governance or leadership role with a health-related commercial organisation:
- a. the interests and safety of patients must be your primary concern despite any obligations you may have towards the health-related commercial organisation
 - b. you should ensure that there are formal and defined terms of reference setting out the degree and level of your involvement
 - c. you must declare your relationship with the health-related commercial organisation in all circumstances where a conflict of interest might arise or be seen to arise.
37. If you provide care to patients, you should also seek approval from your employer (if applicable) before you accept any governance or leadership role with a health-related commercial organisation.

Managing conflicts of interests when you are in a governance or leadership role with a health-related commercial organisation

Provide accurate and balanced information

38. Ensure that any information your organisation provides to practitioners, patients and the public is clear, accurate, up-to-date, and balanced.
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Do not offer any inducements, gifts and hospitality to influence clinical practice

39. Do not, either directly or through an agent, offer any inducements, gifts, or hospitality to influence, or be seen to influence, how other doctors and health practitioners assess, prescribe for, treat or refer their patients.

Do not use your position or standing as a doctor to promote commercial interests contrary to the interests of patients

40. Patients and the public expect doctors to act in their best interests. To uphold that trust, you must not use your position or standing as a doctor to promote any commercial or other interests where that is contrary to the best interests of patients, and where it compromises public health and safety.

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In revising this draft statement, we gratefully acknowledge the Royal Australasian College of Physicians' *Guidelines for ethical relationships between health professionals and industry* (Fourth edition, August 2018) as a key source.

DRAFT