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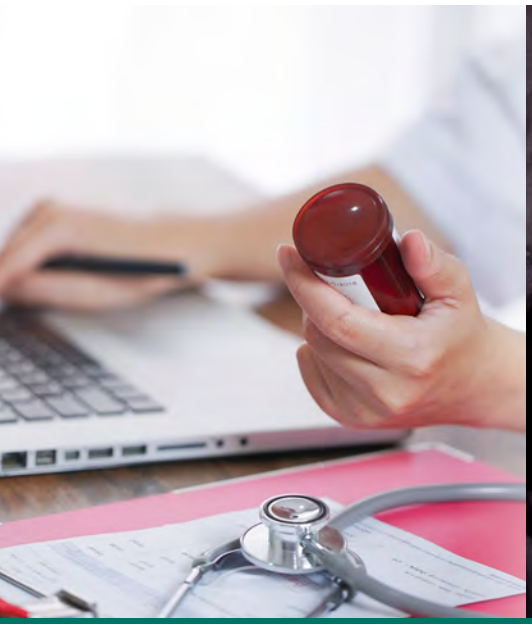
# FAQs



# **Ethical relationships** between **health professionals** and **industry**

# Contents

# 1. Meeting with drug representatives

## I have been asked to meet with drug representatives. How should I manage this?

### Can meeting with drug representatives influence my own practices?

In short, yes. Whilst many doctors and health professionals generally feel that they would not be influenced by meeting with drug representatives or other interactions with industry, evidence shows that such contacts have the potential to impact their diagnosis or treatment in a manner not consistent with the patient's best interest. There is evidence that meeting with drug representatives can influence prescribing choices (both within and between classes of drugs), requests for medications to be placed on hospital formularies, and interpretations of evidence.

### What are the risks and benefits of meeting with drug representatives?

The three key risks of meeting with drug representatives are that such interactions may:

- Inappropriately influence prescribing with negative impacts on quality of care
- Undermine the integrity and assumption of independence of health professionals from industry and therefore the trust on which clinical relationships depend
- Create relationships that, in turn, generate conflicts of interests

There are some potential benefits to meeting with drug representatives. It can be argued that such meetings provide an opportunity to learn about new treatments and products, and initiatives such as compassionate access programs.

### Are there alternative ways in which I can get the benefits of meeting with drug representatives without the risks?

Yes, the best way to keep up-to-date with new treatments and products is to obtain this information from impartial sources such as articles from peer-reviewed medical journals, evidence-based guidelines and educational material from trusted impartial sources.

### How can I minimise the risk of my practice being influenced?

The easiest way to minimise the risk of your practice being influenced by drug representatives is not to meet with them and to only obtain information about new products and treatments from impartial sources.

If you choose to meet with drug representatives, you need to be mindful that their role is to increase the sales of particular products. You therefore need to put in place systematic ways of recognising potential sources of influence and ensuring you are not inappropriately affected by them. This might include not accepting gifts or samples, actively seeking out alternative sources of information about the company's products, and being alert to the possibility of these meetings being used as a basis for establishing other types of interactions.

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Available online: **https://www.racp.edu.au/fellows/ethical-guidelines**

### Should I accept off-prints of journal articles from drug representatives?

There is generally little need for hospital-based physicians to accept off-prints of journals from drug reps because these will generally be accessible through health department, hospital and university databases and journal archives. Off-prints might be more attractive to physicians in private practice who do not have access to such resources. If you do choose to accept an off-print, you need to recognise that it might not be methodologically sound and, even if it is, it would have been carefully selected to present a point of view. As such, you need to critically appraise both the source, methodological rigour and conclusions of off-prints. It is also recommended that should you decide to accept this material, you provide the drug representatives with feedback on any unsubstantiated or unbalanced information you receive.

### Should I accept free samples?

Some argue that there can be benefit to patient care of accepting free samples such as being able to provide patients with treatments at no cost to them. However, you should keep in mind that the provision of samples is primarily a marketing exercise intended to create relationships of reciprocity between clinicians and industry representatives, to accustom clinicians to prescribe particular products and to establish cohorts of patients on long-term treatment with newer and often more expensive drugs.

It is important to remember that free samples tend to be for newer and often more expensive drugs which may offer little to no benefit over older and cheaper drugs for the same condition. Consider this before assuming the short-term cost saving is beneficial overall.

### Should I receive patient support resources e.g. drug diaries, educational materials?

It is in everyone's interests to provide patients with resources that improve safety and adherence to treatment. However, if you accept these resources, you should make sure that they are being used to support treatments that are in the patient's best interests and that the use of the resource does not bind the patient to the company

In addition, as with free samples, these patient support resources tend to be for newer and often more expensive drugs which may offer little to no benefit over older and cheaper drugs for the same condition.

### Should I accept a gift from a drug representative?

In general, you should not accept gifts from drug reps. Gifts create an expectation of reciprocity and may create perceived or actual conflicts of interest and introduce (often unconscious) biases that can influence your practice and prescribing behaviour. Importantly, this can occur irrespective of the size of the gift. Because industry codes now require gifts

to be made public in a centralised database, and you might need to declare them in other contexts (e.g. committee memberships), acceptance of gifts might impact on your perceived integrity and trustworthiness. You should also not ask for or accept any money in exchange for seeing industry representatives or recommending their products.

## Should I allow the drug representative to take me out for a meal or provide hospitality?

Offers of hospitality such as meals are a type of gift. As with any other kind of gift, there is little justification for accepting personal invitations of hospitality. This is different to an organisation accepting support for meetings, which might include food or other types of hospitality, where there is no personal provision of hospitality and "firewalls" are in place to prevent bias.

## Can I ask a drug representative about compassionate access programs?

It is reasonable to ask a drug representative about compassionate access programs. However, you should bear in mind that the medicines offered through compassionate access programs might not be supported by high levels of data on safety and efficacy (particularly if the medicine is not yet been registered by the Therapeutic Goods Administration (TGA)[1] in Australia and from Medsafe[2] in Aotearoa New Zealand). Like drug samples, compassionate access schemes can also serve marketing purposes by familiarising clinicians and patients with particular medicines.

## Can I ask a drug representative about off-label use of a drug?

Clinicians are generally expected to adhere to the principles of 'rational prescribing' and 'quality use of medicines', which emphasise prescription of medicines that have been demonstrated to be safe and effective. In this context, a distinction is often made between 'on-label' and 'off-label' prescribing. 'On-label' uses are those that have been approved by regulatory organisations such as the Therapeutic Goods Administration (TGA) following formal assessment of safety and efficacy data from clinical trials, whereas 'off-label' prescribing refers to situations where medications are prescribed outside such approved indications (e.g. for a different indication, patient age range, dose or route).

In Australia and Aotearoa New Zealand, industry promotion of off-label prescribing of its products is prohibited, however such practices are common and known to have significant effects on prescribing behaviour.  It is best to source information about off-label use of a drug from reliable sources of information such as peer reviewed journals and clinical experts.

## Can I get into legal or professional trouble for meeting with drug representatives?

It is not illegal to meet with drug representatives. However, there are clearly ethical and professional issues raised by interactions with the pharmaceutical industry. Your professional reputation might be negatively impacted if you are perceived to be unduly influenced by interactions with drug representatives or not sufficiently transparent about any interactions you have. There might be serious legal and professional consequences if decisions about patient care are deemed to be biased or clinically inappropriate.

## Do I need to declare my meeting with a drug company representative?

There are currently no clear rules in place regarding declarations of meetings with drug representatives. However, it is good practice to alert patients and colleagues to the fact that you interact with the pharmaceutical industry (e.g. to professional bodies, employers, committees, students, on research articles and in relevant clinical situations).

1 https://www.tga.gov.au/

2 https://www.medsafe.govt.nz/index.asp

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# 2. Speaking at a pharmaceutical company sponsored event

## I've been asked to speak at a pharmaceutical company sponsored event. How should I manage this?

### What questions should I ask before agreeing to speak?

The decision about whether to accept this invitation will depend on the purpose of the event and the degree of control that the company has over its organisation and delivery. Before agreeing to speak at a company sponsored event, you should consider the following questions:

- Where has the invitation come from? What is the purpose of the meeting and who is organising it?
- What role does the company have in setting the meeting agenda, selecting speakers and determining the content of talks?
- Is there an explicit or implicit link with a single company or product?
- Will there be other forms of industry interaction (e.g., exhibits, trade stalls, gifts, entertainment)? Will the scientific and promotional components of the meeting be sufficiently separated by the organisers?
- Have the criteria used to select invited speakers and delegates been publicly disclosed?
- Will I be paid to speak at the event?
- Will presenting at the event be likely to result in any actual or perceived loss of professional independence?
- Does the sponsoring company's organisational history and practices raise any concerns?

In general, industry support of meetings should be indirect and mediated through independent organisers, untied to the promotion of any commercial product or other industry concern, and appropriately disclosed to relevant organisations and meeting attendees.

### What are the risks and benefits of participating in such events?

Attendance of meetings, industry sponsored or otherwise, provide opportunities for learning, networking and career development. Any event organised or sponsored by a pharmaceutical company could, however, be a marketing opportunity and carries a risk of influencing the capacities of clinical practitioners to make disinterested decisions on behalf of their patients. Another risk is real or perceived conflict of interest stemming from your relationship with the sponsor and their product (even if you do not speak specifically about this product). It might also erode public and professional perception of your objectivity, integrity and professional judgement.

### Could accepting this invitation influence my practice?

The evidence shows that physicians who attend sponsored events are more likely to prescribe the sponsor's product and request its inclusion on hospital formularies.

### Does it matter what perception is created if I accept this invitation?

Yes, this could result in the loss of trust by patients, your peers, government and the wider community and undermine the assumption of independence of health professionals from industry and therefore the trust on which clinical relationships depend.

### Is there some way I could present at this event and not align myself with the drug company?

This depends on the organisation and purpose of the event and your role in it. A degree of real or perceived alignment is inevitable if a meeting is organised by a single company, whether or not you personally speak about the company or its product. You can, however, minimise perceived alignment by, for example, not accepting payment for your travel expenses or participation, basing your presentation on best evidence, using your own slides, referring to therapies by their generic names, and making clear declarations of any other relationships you have with industry.

### Does the purpose of the meeting make a difference (e.g. educational, promotional, etc)?

Any event organised or sponsored by a pharmaceutical company, even if it is labelled as "educational", is also a promotional opportunity and carries a risk of impacting on the capacities of clinical practitioners to make disinterested decisions on behalf of their patients. That said, you should be particularly cautious about meetings that have no or limited educational value and are clearly directed at product promotion or familiarisation.

### Should I accept an offer of payment, funding or reimbursement for the event?

Reimbursement for expenses might be appropriate but you should not accept payment beyond this. If there is more than one sponsoring company, their payments should be pooled and distributed to speakers by the conference organisers. These measures reduce (but do not eliminate) the real or perceived conflict of interest associated with accepting payment from industry.

### Does it make a difference whether there is an explicit or implicit link between the event and the drug company's product?

In general, it is not appropriate for health professionals to be involved in promotional meetings on behalf of industry (i.e., those with an explicit link to the drug company's products). You should also bear in mind that a meeting sponsored by industry may also have an implicit link with its products and may still contain elements of promotion.

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## Should I participate if the content is controlled or influenced by the sponsor?

The information you present should be based on the evidence and not be influenced or controlled by the sponsor.

## Should I agree to use the company's slides?

No. Using the company's slides will create doubt as to your impartiality as a health professional and the unbiased nature of the information you present at the event.

## Would I need to report this activity? If so, where and to whom?

The nature of industry support, and any obligations associated with it, should be declared openly in relevant circumstances (e.g., to professional bodies, employers, committees, students, on research articles and in relevant clinical situations).

You should make sure that any industry support used by the meeting organising committee to pay clinicians for their contributions will be disclosed and placed in the public domain prior to the meeting.

You should also be aware that, in Australia, the Medicines Australia Code of Conduct requires companies to publicly report when a company pays a healthcare professional for their service or provides financial support for them.

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# 3. Funding from a pharmaceutical company to attend a conference

## I have been offered funding from a pharmaceutical company to attend a conference. Should I accept this?

### What are the risks and benefits of accepting such funding?

Attendance at meetings, industry sponsored or otherwise, provides opportunities for learning, networking and career development. Any event organised or sponsored by a pharmaceutical company could, however, be a marketing opportunity and carries a risk of influencing the capacities of clinical practitioners to make disinterested decisions on behalf of their patients. This risk is potentially exacerbated by the receipt of funding to attend the conference. It might also erode public and professional perception of your objectivity, integrity and professional judgement.

### Would I need to report this activity? If so, where and to whom?

The nature of industry support, and any obligations associated with it, should be declared openly in relevant circumstances (e.g., to professional bodies, employers, committees, students, on research articles and in relevant clinical situations). You should also be aware that, in Australia, the Medicines Australia Code of Conduct requires companies to publicly report when a company pays a healthcare professional for their service or provides financial support for them.

### Should I accept support for my partner or family to travel with me?

Sponsorship (either direct or indirect) to cover the cost of travel, attendance or meals for family or friends is never acceptable.

### Should I accept funding for accommodation, meals and other travel-related expenses?

The more support you accept, the more likely you are to feel the need (conscious or unconscious) to reciprocate by, for example, recommending the company's products or agreeing to further contact. It also makes it more likely that your judgment will be influenced by the relationship with industry and that there will be a real or perceived conflict of interest.

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# 4. Pharmaceutical company sponsorship for clinical meeting or grand round

## I've been offered pharmaceutical company sponsorship for my clinical meeting or my grand round. How should I manage this?

### What are the risks and benefits of accepting such funding?

Medical grand rounds and clinical meetings are important for medical training and ongoing professional development. Being able to invite speakers and provide food can enhance both meeting quality and attendance. Ideally, financial support for grand rounds should be sought from the clinical institution or from alternative unbiased sources (e.g., from attendees or philanthropic sources).

Any event sponsored by a pharmaceutical company could, however, be a marketing opportunity and carries a risk of influencing the capacities of practitioners to make disinterested decisions on behalf of their patients. Even where sponsors are prohibited from offering promotional material (e.g., offprints) or from having contact with attendees, sponsorship can still erode public and professional perception of your objectivity, integrity and professional judgement. These are particularly salient in teaching institutions because of the powerful effect that normalising industry interactions might have on students and trainees and on the culture of institutions.

### Should the value of the drug company sponsorship influence my decision?

In general, any sponsorship raises questions of inappropriate influence and conflict of interest and may shape the institutional culture. At the same time, if a decision is made to accept industry sponsorship, you should limit this as much as possible. Food should not be excessive and there should be no other promotional materials offered to meeting attendees.

### Should I accept the offer if it comes with conditions or expectations?

No. All industry support should be untied. The industry supporter should have no part in determining the speaker, subject or content for the meeting.

### What strategies can I use to accept sponsorship in a manner that is ethically and professionally justifiable?

If it is decided that there is no alternative to industry sponsorship, there are several steps that can be taken to mitigate undue influence:

- ensuring that all industry support is untied and does not come with any conditions
- ensuring that the industry supporter has no part in determining the speaker, subject matter or content of the grand round or meeting
- ensuring that all content presented is in accordance with the accepted norms of scientific practice and that it is communicated in an unbiased and balanced manner, especially if any products are mentioned
- Where there is an industry sponsored speaker, ensuring that alternative viewpoints are also represented (e.g., by specifically inviting another speaker who has an alternative viewpoint)
- ensuring that food is not excessive and that attendees do not receive any other gifts
- ensuring that displays of industry materials and interactions with industry personnel are prohibited or kept to a minimum
- ensuring that any promotional material is displayed in an area separate from the one in which the event is taking place
- ensuring that attendees are alerted to the fact that the meeting is sponsored
- ensuring that all speaker dualities of interest are declared to the audience.

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# 5. Funding from a pharmaceutical company to conduct or participate in research

## I have been offered funding from a pharmaceutical company to conduct or participate in research. Should I accept the funding?

### What are the risks and benefits of accepting such funding?

A large proportion of research—particularly clinical research—is industry sponsored. This is in part because there is limited public and philanthropic funding available. In some cases, therefore, interactions between industry and health professionals in the research space may be unavoidable and likely to have benefits for patients and the community.

The reality, however, is that industry funds research in part because this enables it to control the research agenda, including the questions asked, methods used and dissemination and translation of results (e.g., into disease taxonomies, diagnostic and therapeutic algorithms, clinical guidelines). This, in turn, creates and expands the market for their products. Accepting industry funding for research therefore creates the risk that you will simply be contributing to the sponsor's commercial interests. Other risks associated with accepting industry funding for research is that it could impact on your clinical judgment and patient care (e.g., enrolling patients in trials where this is counter to their best interests) and erode public and professional perception of your objectivity, integrity and professional judgement.

### Does it matter if the funding is tied to the sponsor's product or research questions?

While industry sponsorship is sometimes untied to particular products or projects, most often, industry will conduct or sponsor research into their own products in line with their own commercial interests. This does not mean that the research is of poor quality (indeed, industry sponsored research is often of very high quality) or that you should not accept funding to conduct or participate in it. You should, however, be aware of the risk that you might be contributing to the sponsor's commercial interests.

### Should I accept the offer if it comes with conditions or expectations?

All industry funding comes with some conditions (e.g., regarding timelines, research questions, conduct, outcome measures, sponsors' access to data and authorship). The processes for creating research contracts are established by research and industry peak bodies such as the Australian National Health and Medical Research Council, Medicines Australia and Medicines New Zealand. It is important to ensure that conditions imposed by the sponsor do not impact on the scientific merit and validity, integrity critical evaluation and open dissemination of the research.

### Should the sponsor be involved in the design or conduct of the research?

Most industry sponsored research is designed by the sponsor in collaboration with key clinical experts, and industry plays a key role in overseeing research conduct and quality control. From an ethical perspective, the key issue here is that industry involvement does not negatively impact the integrity or scientific merit of the research.

### Should the sponsor be involved in or have a say in the interpretation or publication of the research results?

Decisions regarding the analysis, interpretation and publication of research results should be made without influence from the sponsoring company and should rest with investigators (lead investigators in the case of multi-centre studies). In doing so, however, researchers should provide sponsors with the opportunity to review and comment on draft publication, and to request removal of information that might be commercial-in-confidence. Publication of research results, whether positive or negative, is expected, ideally in a refereed journal.

### Should company representatives be included as authors on manuscripts?

Any individual who has contributed to a manuscript should be included as an author or acknowledged, even if they are company representatives. The integrity of the scientific literature depends on the ability of readers to understand who has contributed to the research and what affiliations and interests they may have.

### Should I accept authorship of manuscripts that I have not contributed to (as a writer)?

No. Only individuals who have a warrant for authorship should be named as authors. So called "guest authorship" is contrary to good publication practice because it misleads readers into thinking that particular—often high status—individuals have participated in writing the article. It also potentially undermines the integrity of the research team and its efforts.

### Should the company be acknowledged in manuscripts?

Different journals may ask for different information to be declared, however in general manuscripts (and submissions for publication) should acknowledge:

- all sources of revenue obtained by the authors in relation both to the study and to other studies over the period specified by the journal
- all financial relationships outside the work in question, including grants, consulting fees, honoraria, support for travel, payment for writing or reviewing manuscripts, medicines, equipment and administrative support, board memberships, consultancies, employment, expert testimony, patents, royalties and other benefits unrelated to the reported study.
- any other relationships or activities that may have influenced the work.

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## Do I need to declare the funding and if so, in what circumstances and to whom?

Yes. Financial compensation or payment to clinician-researchers should be declared to:

- the ethics committee approving the research
- research participants
- journal editors and readers of articles (including articles not directly related to the research)
- audiences of presentations (including presentations not directly related to the research)
- students
- any committees or decision-making bodies of which you are a member—both when becoming a member as part of a "standing" declaration and on a case-by-case basis in relation to specific items under considerations
- employers (e.g., as part of an "external earnings" declaration).

## What strategies can I use to accept funding in a manner that is ethically and professionally justifiable?

The following measures should be followed to ensure the research you are conducting with industry support is undertaken ethically and professionally:

- While sponsors can be involved in the planning of the research, all research must have social benefit, scientific merit and validity and be ethically sound.
- Any research project conducted or sponsored by a company should include an investigator with a non-commercial institutional affiliation and be assessed by an ethics committee associated with that institution.
- Financial compensation or payment to clinician-researchers should be approved by a responsible ethics committee.
- Payments from industry should be made to the institution and not to individuals.
- All studies should be registered on an appropriate registry.
- Researchers should not be subject to any contractual agreements that negatively affect the integrity or scientific merit of the research, or the likelihood that its results (positive or negative) will be published and openly disseminated.
- It should be a condition of both agreement to participate by researchers and approval by Human Research Ethics Committees that there is a commitment to make all results (both positive and negative) publicly available.
- Final responsibility for decisions concerning publication of results should be taken by investigators.
- Researchers should not agree to be authors on 'ghost-written' manuscripts.
- Researchers should not agree to be "guest authors" on manuscripts to which they have not contributed according to accepted warrants for authorship.
- Industry funding should be disclosed to ethics committees, research participants, collaborators, committee chairs and acknowledged in publications and presentations.

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# 6. Invitation to be a member of a pharmaceutical company advisory board

## I have been invited to be a member of a pharmaceutical company advisory board. Should I accept the offer?

### What are the risks and benefits of taking on such as role?

The main benefit of advisory board membership is that it provides the opportunity to use your clinical knowledge to increase the likelihood that the company's research, therapeutic and other practices meet the needs of patients and communities.

At the same time, however, membership of an advisory board may encourage feelings of commitment to the organisation, its employees and its products and lead to (conscious or unconscious) privileging of the company's interests over those of patients. Other risks associated with accepting membership of an advisory board is that it could impact on your clinical judgment and patient care and erode public and professional perception of your objectivity, integrity and professional judgement.

### Does it make a difference if the role is unpaid?

While payment might exacerbate the sense of reciprocity, this sense exists whether or not the role is paid. Judgment and decision-making might, therefore, be affected irrespective of whether the advisory role is paid or unpaid. Similarly, while colleagues and the public are likely to attach more significance to a paid role, they might also be suspicious of doctors who have unpaid roles in pharmaceutical companies.

### Can I accept funding (e.g., for research) from a company for which I am an advisory board member?

This is permissible, however, you should be alert to the heightened risk that you will be influenced by the company and will have to manage competing loyalties stemming from your advisory board membership and the relationships it has created. You will need to ensure that robust strategies are put in place to ensure the transparency and probity of any activities that are funded by the company.

### What strategies can I use to accept membership of a pharmaceutical company advisory board in a manner that is ethically and professionally justifiable?

Prior to your appointment, you can ensure that the company adheres to industry-wide governance standards (e.g., Medicines Australia Code of Conduct and Medicines New Zealand Code of Practice). You should also ensure that advisory board procedures are satisfactory, this includes making sure there are formal, defined terms of reference, agendas for each meeting, procedures for declaring and managing conflicts of interest, and that minutes are recorded and approved in accordance with usual practices. You should also be satisfied that your involvement is meaningful, rather than purely symbolic.

### Do I need to declare the membership and if so, in what circumstances and to whom?

You should openly declare your membership on a pharmaceutical company's advisory board as it poses questions of dualities of interest. This may be especially appropriate when making presentations at meetings relevant to a company or its products, when teaching and training, when consulting with patients, in meetings and discussions in institutions, when prescribing in circumstances where questions might be raised about the independence of clinical decisions, and when submitting proposals for approval to a Human Research Ethics Committee when company products are involved.

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