

Authorising Body:	Practice, Policy, and Partnerships Committee
Responsible Committee(s):	Committee for Ethical & Professional Practice
Responsible Department:	Policy and Advocacy
Document Code:	EG5 Appendix

Purpose

This appendix has been developed by the Royal Australian and New Zealand College of Psychiatrists (RANZCP) to provide common examples and guidance while dealing with commercial organisations within the health care industry. This is intended to support Ethical Guideline 5: The relationship between psychiatrists and commercial organisations within the health care industry.

Industry-sponsored travel and attendance at meetings

The health care industry provides sponsorship and support for psychiatrists to attend educational meetings. Psychiatrists are advised to consider the context, potential implications and available alternatives before deciding on their personal courses of action in accepting such support. In circumstances where an individual is funded, the main ethical implications that need to be considered by a psychiatrist are that:

- The sponsorship is clearly linked to education, with the overall aim of enhancing medical knowledge.
- Any expert presenting is recognised as such and presents their own teaching materials or materials to which they have substantially contributed.
- There should be no loss of professional independence through accepting the sponsorship offered.

Industry-sponsored travel and attendance at an independently-organised scientific meeting or conference program

The healthcare industry provides sponsorship to independently organised scientific meetings or conferences. This sponsorship may be used to defray the costs of bringing invited speakers or attendees to the meeting. As a guide:

- When financial support is offered in return for a formal contribution to a scientific meeting it is recommended that the contractual relationship is between the pharmaceutical company and the meeting organisers, rather than with individual speakers. Support should be ideally provided indirectly through an independent organising committee, and not tied to promotion of any commercial product or other industry concern. Organisers of the meeting should independently determine the content of the meeting and choose the speakers for their clinical and scientific relevance.
- Financial support should be fully disclosed with the nature of industry support and any obligations associated with them declared openly to those who may have an interest in knowing, including the public.

- Acceptance of additional sponsorship for family and friends, either directly from industry or indirectly through an organising committee, to cover their cost of travel, attendance, and meals is not acceptable.
- The acceptance of travel upgrades and other incentives should not be beyond that which is normally expected. For example sponsored travel may only be provided for the purpose of enabling the psychiatrist to effectively participate in the educational meeting.
- Psychiatrists who are invited speakers should take care that their presentation is supported by the scientific data, is not unjustifiably influenced by the interests of the sponsor, and should disclose the extent to which material has been provided to them.
- Accepting sponsorship from industry for travel and attendance at a meeting at which the psychiatrist is not making a formal contribution will inevitably raise the possibility of an actual or perceived conflict of interest which could influence, or could reasonably be seen to influence or affect their decision making or advice in subsequent decisions about products of the sponsoring company. Psychiatrists should be careful at all times to avoid this imputation and be as transparent as possible in all circumstances. Non-presenters who accept industry support to attend conferences should be aware of the potential for such acceptance to influence their practice, make the necessary public declarations and, wherever possible, seek agreement from an appropriate institutional committee. Remuneration for attendance or other payments of 'gifts in kind' of equivalent value (e.g. gift certificates) should not be accepted. The acceptance of any other gifts or tokens of appreciation should be carefully considered before acceptance and always declared.
- The psychiatrist should consider whether the sponsorship could damage the public standing or reputation for independence of the profession, and make their decision accordingly.
- Psychiatrists may need to seek approval from organisations that employ them or that they have an affiliation with (e.g. university, hospital, or other relevant body).

Industry-organised meetings

In some cases an industry body selects and sponsors both the speaker(s) and the meeting. Under these circumstances the industry body should send out invitations in its own name, provide the venue for the meeting, support the speaker and meet other costs. Such meetings should not be or purport to be under the auspices of independent practitioners or clinical organisations, and should be organised in line with relevant industry codes of conduct.

Where psychiatrists are considering acceptance of funding for travel and attendance at an industry-organised meeting, the guidance above for 'industry-sponsored travel and attendance at an independently-organised scientific meeting or conference program' would equally apply. In addition the following should be considered:

- A meeting organised directly by industry should be recognised as primarily promotional, critically scrutinised by attendees in relation to the possibility of bias or incomplete information.
- If a company selects and provides speakers it should take full responsibility for the organisation and promotion of the meeting.
- Psychiatrists should be aware that acceptance of support to cover travel and attendance costs at industry-organised meetings may lead to perceived or actual conflicts of interest in subsequent decisions regarding the sponsor's products.

Organising industry-sponsored meetings

In addition to support for clinical and scientific meetings organised by independent organising committees, industry can also provide sponsorship to psychiatrists to participate in a variety of meetings. These include:

- local meetings of specialist groups that have an independent organiser or organising committee
- hospital grand rounds and departmental scientific meetings.

While these meetings usually have a clearly defined primary educational aim, the source and the extent of sponsorship should be openly disclosed. When psychiatrists organise or attend meetings that fall outside the scope of a national or international meeting organised by an independent organising committee, the following considerations should be made:

- Where possible, department and local meetings of specialty groups should be funded by attendees or other organisational sources. Similarly best practice is for medical 'grand rounds' to be funded by the clinical organisation. Where industry support is provided, it should have no part in determining the speakers, subject or content.
- If industry supports meetings in such ways as supplying catering or purchasing exhibition space this should, where practicable, be separated from the main event. Such meetings may be acceptable as long as the education meeting itself is organised in accordance with these guidelines and the hospitality is secondary to the purpose of the meeting and not disproportionate in nature. Discreet and proportionate acknowledgement of the contribution to the company sponsor can be made.
- Where the support of companies is sought for meetings, psychiatrists should maintain an even handed approach and be careful not to favour one company over others.
- The conditions under which support for a meeting is provided is disclosed and all industry support declared.

Entertainment and gifts provided to psychiatrists

Acceptance of gifts and entertainment has the potential to exert influence and create conflicts of interest. A gift is defined as 'a transfer of anything of value to a psychiatrist other than usual payment for professional services'. The acceptability of gifts however should not be determined by their monetary value, as any attempt to determine moral acceptability based on cost is an arbitrary measure of whether decision making is unaffected. Therefore the simplest, and most defensible, approach is for psychiatrists to err on the side of rejection of gifts, even those of trivial value.

Individuals should consider the context, potential implications and available alternatives before deciding on their personal courses of action. As a guide:

- Acceptance of entertainment and entertainment expenses as well as personal gifts (e.g. flowers for a birthday) not connected with education is undesirable and such offers should be declined.

Promotional material

The health care industry distributes material to psychiatrists to promote their products. For example drug samples, which are commonly medication starter packs for patients who need to commence treatment immediately. The provision of samples that may appear to be a service is a marketing exercise intended to accustom the clinician to prescribing a particular product, or to

establish a cohort of patients on a long-term treatment with a particular medication. Other products, such as medical software or an offer of a 'support program' may also be offered. As there may be mutual benefits for these initiatives, psychiatrists should judge for themselves what is and is not acceptable but should make efforts to minimise bias and maximise transparency. As a guide:

- Acceptance of company products, including service-orientated (e.g. teaching aids) and non service-orientated items (e.g. pens), and items of small value is not recommended.
- Acceptance and distribution of drug samples, including starter packs, from industry representatives is primarily a marketing exercise and should generally be avoided.
- Patients should be invited to participate in a 'support' program or provided with information about such a program only if it provides a meaningful benefit and if the information it contains is accurate and appropriate.
- Psychiatrists should exercise caution in regard to 'off-label' prescribing and consider its use only in line with the [RANZCP professional practice guideline 4: 'Off label' prescribing in psychiatry](#).
- Psychiatrists using software for clinical functions should choose programs that do not include industry advertising or should 'disable' the advertising functions of their programs.
- Psychiatrists should declare to their patients, organisations and to the public any relationships with producers and suppliers of medical devices and should not obtain benefit from the sale of a medical device to their own patients.
- Psychiatrists should only participate in post-marketing surveillance studies that have scientific or medical merit and objectivity and not designed for, or conducted as, a promotional exercise.
- Product launches should be recognised as promotional activities.

Remuneration for services

Psychiatrists are entitled to remuneration for services provided to industry as consultants, researchers, educators/teachers, and/or employees. In all cases the relationship should be transparent and publicly acknowledged in any situation where there is a real or perceived conflict of interest. Psychiatrists should not request or accept a fee or equivalent consideration from industry in exchange for seeing their representatives in a promotional or similar capacity. As a guide:

- An individual psychiatrist may act as a consultant for the healthcare industry. This may be in general terms or in relationship to a particular product. The arrangement should be that of any business undertaking. If a psychiatrist acts as a consultant to the industry, this information should be transparent and reported in any situation where there is a real or perceived conflict of interests; for example when presenting at scientific meetings.
- Psychiatrists are not precluded from direct employment in the healthcare industry but this should be transparent.
- It is appropriate for a psychiatrist to become a member of or chair an Advisory Board established by the healthcare industry. Such a Board might be set up to give advice to the company about a particular medication or technique or a group of products, and opinion leaders will usually be sought. It is likely that membership of such a Board will encourage a feeling of commitment to a product as well as a feeling of reciprocity and friendship towards the pharmaceutical company and its representatives. Given this:

- Industry Advisory Boards should be formally constituted with terms of reference, meetings should be conducted according to accepted standards and there should be evidence that decisions have an impact on the organisations involved.
- Membership of an Advisory Board of a pharmaceutical company or other health care company should be declared as appropriate (for example to ethics committees considering clinical trials of products of that particular company or a competitor and at scientific and educational meetings) and psychiatrists should take care to minimise its impact on their clinical practice.
- Psychiatrists should not publicly endorse or promote specific products and should not participate in 'advertorials'.
- Promoting commercial interests in the guise of editorial comment is unacceptable. This proscription does not preclude legitimate support for products for which there is evidence of particular efficacy. In such cases evidence for the claimed efficacy should be outlined, and only generic medication names, and not trade names, should be used. The endorsement of products that contribute to public health is permitted, and in all cases direct payment or other arrangement should be openly declared in the advertisement.

Research and development

New discoveries by psychiatrists and the development of new medications, diagnostic tools, therapeutic devices or other agents should be encouraged, and those involved in these activities should be able to be remunerated for this work. Frequently such research and development is funded or part funded by industry. Psychiatrists should strive to minimise conflicts of interest in this area.

Responsibilities of psychiatrist investigators

In undertaking clinical trials and commissioned research projects, particularly those that are funded by industry, the investigator should consider whether the proposed study is to address important scientific questions, or whether it is a promotion to familiarise doctors with the medication, a device to encourage a particular brand usage, or a commercial undertaking merely to permit registration of a medication. Other key considerations include recognising and balancing the potential benefits and risks to participants, ensuring appropriate consent processes, assuring privacy and confidentiality, providing adequate information to participants, and taking into account resource issues including the costs of the study to the institution (investigations, bed usage, staff time) and expected demands imposed on researchers. To ensure appropriate processes and non-bias, the following applies:

- All trials should remain in accordance with various guidelines published by Australia's National Health and Medical Research Council (NHMRC), New Zealand's Health Research Council (HRC), the Therapeutic Goods Administration and other relevant bodies.
- All research projects involving human subjects are assessed by a Human Research Ethics Committee (HREC) that is constituted according to national guidelines such as those contained in the appropriate NHMRC and HRC codes. A list of relevant resources are provided in section 13 of this guideline.
- Researchers disclose their relationships with industry funders and any interests in the outcome of the research both to institutional ethics committees and to potential participants.
- The different roles and interests of the researchers are kept distinct in order to protect the integrity of the research process and research participants.
- All clinical trials are registered on an appropriate clinical trials registry.

- Where a clinician is involved in research that may recruit their patient, independent professionals should be available to undertake formal recruitment of patients into clinical studies, discuss benefits and obtain consent.

Payments to investigators, departments or institutions

- Grants of money or equipment by the health care industry to hospitals, health care centres and universities specifically for the purposes of research are generally acceptable but should be made to the institution, and be appropriately acknowledged in research and other publications and to the public. If the donation is linked to a clinical trial or specific research project, a formal contractual arrangement should be in place.
- Financial compensation to clinical researchers in a clinical trial should be commensurate with the work performed and should be administered under a formal contractual arrangement approved by a responsible ethics committee.
- If an investigator derives any personal or financial benefit from the conduct of an industry sponsored clinical trial, including proposed payments and provisions of other resources required to carry out the study, this should be transparent and with the full knowledge of the ethics committee.
- Proposed payments to participants should be approved by the appropriate ethics committee.
- Remuneration for research participation should be paid into a specially designated fund, which is subject to auspice and audit according to institutional guidelines.
- All payments to clinician-researchers or the departments in which research is conducted should be appropriately declared to trial participants. The nature of the compensation to be paid to the investigators should be declared in the plain language statement provided to potential participants.
- Any research project conducted by private practitioners should include an investigator with an institutional affiliation and be assessed by the human research ethics committee associated with that institution. Funds associated with the project should be distributed in accordance with the requirements of the ethics committee and conform to the normal requirements of the institution.
- Research grants from industry should be made to the institution and not to individuals. Such grants should be appropriately acknowledged in research and other publications, and to the public.

Publication of results

- Responsibility for decisions concerning publication of results should be taken by investigators without commercial conflict of interest, and decisions should be made without undue influence from the sponsoring company
- With multi-centre trials, a committee of the investigators, together with the sponsoring company, should be responsible for the analysis of the results and preparation of the results for publication.
- It should be a condition of both agreement to participate by researcher and approval by ethics committees that there is a commitment to make all results (both positive and negative) publicly available.
- All relevant competing interests (both financial and non-financial) should be appropriately declared.

- Researchers should comply with all aspects of the Australian Code for the Responsible Conduct of Research and the New Zealand Ethical Guidelines for Observational Studies, including those relating to authorship.

Responsibilities of psychiatrists as members of ethics committees

- Psychiatrists may be called upon to become members of ethics committees, or research or medication committees.
- Psychiatrists should absent themselves from discussions concerning research projects in which they are personally involved. Where an ethics committee is to discuss a project involving a company with which a psychiatrist has a present or previous relationship that could raise the possibility of a conflict of interest, this should be declared.
- Ethics committees have a responsibility to ensure that trials are conducted in accordance with national standards, as set out in various statements, including the NHMRC Code on Human Experimentation. The main principle to be followed is that the likely benefits of the proposed experimentation are reasonable in terms of any risks or potential discomfort to participants, and that valid consent for participation is freely given. The issues that should be addressed by ethics committees naturally overlap with those mentioned above for psychiatrists as investigator.

Peer review

- When invited to review a manuscript, clinicians should consider whether they have competing or conflicting interests and, if so, whether these are such that they should decline the invitation.
- All relevant competing or conflicting interests (both financial and non-financial), as well as more subtle biases, should be declared to editors.

Education and training

The RANZCP promotes that continuing medical education programs and training programs should include discussions concerning the role of industry in the health care field and potential conflicts of interest, and the unbiased evaluation and interpretation of industry-sponsored material. The role of institutional policies and the practices of individual clinicians, teachers and mentors in shaping the attitudes and behaviour of students and psychiatrists-in-training should be recognised in the development of curricula.

- Individual psychiatrists should, as appropriate and required, assist in promoting discussion amongst the profession and the community about these issues.
- When involved in the development of educational events or resources, psychiatrists should adhere to these guidelines.

Industry expectation

Psychiatrists should be aware that the healthcare industry itself has a self-regulatory approach to engagement with healthcare professions, including psychiatrists. It is the expectation that in its dealings with psychiatrists, industry complies with its various obligations such as that outlined by organisations such as Medicines Australia and Medicines New Zealand. Further information about these policies can be found in the reference list.

Disclaimer

This information is intended to provide general guidance to practitioners, and should not be relied on as a substitute for proper assessment with respect to the merits of each case and the needs of the patient. The RANZCP endeavours to ensure that information is accurate and current at the time of preparation, but takes no responsibility for matters arising from changed circumstances, information or material that may have become subsequently available.

REVISION RECORD

Contact: Executive Manager, Practice Policy and Partnerships			
Date	Version	Approver	Description
07/2026	1.0	PPPC	New Document

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