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Guidelines for ethical relationships between health professionals and industry

Fourth edition

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Foreword

Note: These Guidelines have been developed primarily as a supportive educational resource and are intended to be voluntary rather than prescriptive. It is anticipated that these Guidelines will continue to evolve and, as per the RACP's policy archiving process, will be subject to a five-yearly review unless an earlier review date has been identified.

Readers wishing to provide feedback or suggest improvements to the document should email ethics@racp.edu.au.

This fourth edition of the Royal Australasian College of Physicians (RACP) Guidelines has been extensively revised. It reflects the substantial changes that have occurred in this area since the publication of the third edition.

Among the innovations introduced in this edition of the Guidelines is a wider definition of 'industry' to extend beyond the for-profit sector with recognition of the nature, importance and management of non-pecuniary conflicts of interest; more inclusive scope of the consideration to include health professionals of all kinds; more extensive guidance regarding management of conflicts of interest; and increased emphasis on the importance of sensitivity to issues of cultural relevance.

The Guidelines also provide an improved index, 'tools' and other points of guidance to assist in the use of the document and resolution of specific issues as they are encountered in the everyday life of the health professional. For the most part, it is intended that each chapter can be read as a stand-alone document, although, in places, full understanding depends on familiarity with concepts developed elsewhere in the Guidelines.

Among the many special features of this edition is new material relating to the following topics: devices; biotechnology companies; complementary medicines; global issues and issues relating to health professionals working overseas; receipt of gifts of any value and non-service related items; education and continuing medical education; off-label prescribing; sample and starter packs and product familiarisation schemes; transparency relating to practitioners and institutions; endorsements by practitioners and organisations; promotion and advertising; occupational and environmental physicians and their relationship with industry; internet issues; publication; research; and trainees and students.

These Guidelines are intended both to be comprehensive in scope and to adopt a rigorous approach to argumentation. It is recognised that many people will regard the outcome as somewhat long and complex and in some cases repetitive. This is, however, an effect of how it is intended that the document will be used, with each chapter being able to stand alone and to be read separately, with cross-references to related sections being maintained. It is also expected that the present work will form the basis for a range of other documents which can be accessed and applied in different settings, including compendia of recommendations and web-based summaries, bibliographies and discussions.

The text presented here is the result of wide and vigorous consultation with members of the RACP, other health professionals, consumer representatives and members of the general public. This is a constantly changing field and the RACP will welcome further comments and suggestions at any time.

Summary

These Guidelines for ethical relationships between health professionals and industry aim to support health professionals in identifying, assessing and managing conflicts of interest. Their overall goal is to preserve public trust by protecting the integrity of professional judgment in patient care and activities affecting the health of populations. Practitioners consulting this text are encouraged to consider the arguments and advice included within it, but are ultimately free to make their own decisions.

A number of key points inform the text. The most fundamental is that the primary concern of health professionals is for the safety and welfare of their patients and the community(s) in which they live. This central tenet of health care can, however, be compromised by pecuniary and non-pecuniary interests that lead to conflicts of interest, bias professional judgment, and adversely affect clinical decision making, patient care and population health activities.

Importantly, conflicts of interest arise not as a consequence of malign motivations but from the facts and settings in which they occur. Furthermore, neither dualities nor conflicts of interest, in themselves, inevitably cause harm; rather, it is ambiguity about goals and values and the possibility for harm that arouses concern.

There are many ways in which conflicting interests may arise, including, but not limited to, relationships with industry. Management of such conflicts of interest can be enormously challenging. While physicians generally accept that there are negative effects from certain interactions with industry, many physicians still believe they are personally immune to the influence of industry. Accordingly, the first step is to build awareness that health professionals often face dualities of interest, that some of these interests may bias or unduly influence professional decisions and that this influence can occur subconsciously, without the practitioner being aware of what has taken place.

Disclosure of interests is necessary in order to assess any relevant conflicts. Health care organisations and institutions have a role in recording disclosures of interests and advising on responses which may include removing conflicted individuals from particular decisions, maintaining public registers of relevant interests, and assessing the impact of perceived conflicts of interest. The Guidelines advocate leadership on the part of health institutions by actions which create a ‘firewall’ between industry and physicians such as providing sponsorship-free grand rounds and providing adequate resources for independent professional education.

While some relations with industry are inescapable or desirable, the Guidelines provide clear advice on avoiding interactions that do not further patient care or population health activities and which have the potential to bias professional judgment. In particular, the Guidelines advise against accepting gifts and hospitality and advise caution in considering industry support for conferences and other meetings. They also promote the provision of independent education for practitioners, trainees and students, and high standards of integrity in research.

Using the Guidelines

This work is organised into a number of chapters, each of which may be consulted independently. The key points from each chapter appear on p.13 to p.21 and are followed by tools for identifying and managing conflicts of interest. Chapters 1 and 2 describe the context of contemporary health care and provide a detailed account of values, interests and conflicts of interest. Chapter 3 provides guidance for individual health professionals across a range of activities, including promotional activities, meetings, employment and consultancies, research, publications and international activities. Chapter 4 engages with the ways in which trainees and students may be supported in developing critical awareness of, and strategies to avoid, conflicts of interest. Chapter 5 examines issues affecting institutions and professional organisations and provides detailed guidance on managing conflicts of interest arising in these settings. In Chapter 6, interests arising in the context of research are identified and discussed, including researcher responsibilities and dissemination of results. The bibliography contains a list of the materials consulted in the preparation of these Guidelines and suggested further reading.

Voluntary decision making

While there is broad recognition of the challenges that arise where health professionals interact with industry, there is no universal consensus about how to assess the influence of industry on health care and research or about optimal courses of action to respond to issues arising in specific settings.

Practitioners consulting this text are encouraged to consider the arguments and advice included within it, but are free to make their own decisions. We accept – and acknowledge the fact – that not everyone will agree with our advice and that on occasion individuals and organisations will choose other courses of action. Regardless of their conclusions, however, we strongly urge all those involved in the broad field of health care to reflect on the issues we raise and to develop their own strategies for responding to the dualities and possible conflicts that abound in our professional lives.

If, on reflection, you do not believe that the general advice contained in these Guidelines is appropriate to your circumstances, you may still find the tools below useful in developing your own strategy for responding to and managing particular situations.

Decision-making tools

The following four generic ‘tools’ are designed for health professionals working individually as clinicians; as members of clinical teams; as teachers and researchers; and as committee members, employees of, and advisers to, organisations such as professional colleges and societies, hospitals, universities, and community and for-profit organisations. Their purpose is to assist them to:

- recognise when there could be a real or perceived conflict involving interests of the profession and those of for-profit organisations
- distinguish between a duality and a conflict of interest
- manage possible and established conflicts of interest
- confirm that they are comfortable about establishing, continuing or changing the terms of a relationship with a for-profit organisation.

These tools may be adapted to suit the specific needs of individuals and groups of practitioners within particular organisations and institutions.

Definitions

- *Industry* refers to the full range of institutions and enterprises with a bearing on health care, distinguished from the actual work carried out by health professionals in their clinical and research practice.

- An *interest* is a commitment, goal, obligation or value associated with a social relationship or practice.

  Where two or more distinct interests coexist in a particular decision-making setting, a duality of interests is said to exist.

  When a relationship or practice gives rise to two conflicting interests, a conflict of interest exists. The precise condition that defines the presence of a conflict of interest is that in relation to a specific decision or action, two opposing and contradictory interests, as defined above, coexist.

- A *pecuniary interest* refers to the possibility of financial or other material gain arising in connection with professional decision making. A non-pecuniary interest is a goal or benefit not linked directly with material gain.

Tool 1: Identification of dualities

***Key question*:**

In a particular decision-making setting in which I am involved might I be facing a duality of interests?

Settings in which the question might arise

The question might arise for any health professional involved in making decisions in his or her work in the context, for example, of patient care, population health activities, research, teaching or membership of a committee of a professional association, health care institution or government committee, where the decision might be affected by a personal or financial interest.

Specific questions for individuals involved in discussions or decisions relating to their roles as health professionals

- What are the interests that are guiding or directing me as I consider this decision or participate in discussion about it?
- Are there any financial relationships outside this decision-making setting that could have a bearing on the position I might take?
- Are there any personal relationships that might affect my decision?
- Are there any personal motivations or beliefs that might limit or obstruct my open consideration of the issues I am expected to take into account here?
- In this setting, in relation to a particular issue or decision, are my various interests pulling me in two directions at once?
- Might some professional colleagues consider that some of my interests could conflict with my primary duty or responsibility here?
- Might some laypersons (e.g. family, friends, students, patients, community members) feel that one or more of these interests could inappropriately affect the way in which I am considering the matter?
- Might the relevant professional college or society consider that one of my interests might conflict with the interests that arise from my role within it?
- Might the relevant employer or funder consider that there could be conflicting interests that influence a position I take or a decision I make?

If the answer to any of the above is 'yes', has the matter been discussed with:

- those who might perceive the existence of a duality of interest, especially professional colleagues in institutions, colleges and societies?
- the college, professional society or a responsible body within the institution?

Tool 2: Identification of conflicts of interest

Key question:

Is this duality a conflict of interest?

Definition

A duality may become a conflict of interest when two or more contradictory interests are operating simultaneously within a particular relationship or practice - that is, where an individual finds that he or she has opposing duties, responsibilities or values.

Specific questions for organisations, committees or other bodies to which a duality has been declared

- Do any of the personal interests - pecuniary or non-pecuniary – that the individual concerned has declared conflict with or undermine the interests inherent in the role the individual is occupying in, for example, this clinical relationship, committee or position of authority?
- Could there be a perception among patients, research participants or community members that any of these personal interests – pecuniary or non-pecuniary - conflict with what they are likely to assume to be the individual's primary duty within this role?
- Are any of these interests (pecuniary or non-pecuniary) of the professional society or institution relevant to this decision or discussion in conflict with those of any of the other communities with which the individual is involved, including patient care, research, administration or business?
- Could there be a perception among patients, research participants or community members that any of the interests of the professional society or institution relevant to this decision or discussion conflict with those of any of the other communities to which the society or institution has a responsibility?

If the answer to any of the above is 'yes', has the matter been discussed with:

- those who might perceive the existence of a duality of interest, especially professional colleagues in institutions, colleges and societies?
- the college, professional society or a responsible body within the institution?

Tool 3: How should this conflict of interest be managed?

Key question:

Given that it has been judged that a conflict of interest exists involving a particular health professional, what steps should now be taken to manage it?

Specific questions for organisations, committees or other bodies managing a conflict that has been identified

- Is the conflict of a pecuniary or non-pecuniary nature?
- Does it reflect opposing duties linked to different social roles?
- Is it a consequence of interests associated with personal relationships, goals or career ambitions?
- What are the risks associated with this conflict?
- What are the worst outcomes that could result from it?
- Are there individuals whose wellbeing may be placed at risk if the conflict is not effectively resolved?
- How would this conflict be regarded by members of the community who place their trust in this health professional?
- Taking the answers to the above questions into account, what actions are necessary? They may include the following possibilities:
    - no action necessary
    - acknowledgment of the conflict but allow the conflicted individual to continue to participate in the decision or discussion process
    - require that the individual relinquish one of the roles generating the conflict at the point where the conflict occurs
    - require that the individual fully relinquish one of the roles generating the conflict
    - establish other mechanisms - such as assistance from an independent third party - to circumvent any risks associated with the conflict

Tool 4: Additional questions to be considered before initiation, continuation or change of a personal or organisational relationship

- Are the individuals involved familiar and comfortable with the organisation's corporate history and business practices?
- Are they confident that the relationship will not result in any actual or perceived loss of professional independence?
- Is the proposed association genuinely linked to clinical care, research, further education or ongoing professional development?
- How would patients, patients' families and carers, students, professional associations, colleagues, employers and the broader community regard any such association?
- Are the individuals involved prepared to be scrutinised by colleagues and by the public as to the propriety of this association?
- Would they be comfortable about this association being publicised on the front page of the newspaper, the internet, blogs, social media, court cases, in films or in radio or television programs?

Best practice key points for consideration

Chapter 1: Introduction: Background, context, process and principles		*Page*
1.1 General purpose of the document	1. Practitioners consulting this text are encouraged to consider the arguments and recommendations included within it, but to make their own decisions. 2. While it is generally accepted by physicians that there are negative effects from certain interactions with industry, many physicians still think they are personally immune to the influence of industry.	25
1.4 Interests - general definitions, scope, summaries of issues, problems	3. The safety and interests of patients are the primary concerns of medical and other health professionals. 4. In health care decisions, the safety and wellbeing of patients and population groups takes priority over commercial, financial, personal or other interests. 5. Where the possibility of a conflict of interest arises, regardless of the context, this should be declared openly to all relevant parties.	26
1.5 The issue	6. Many health professionals feel uncomfortable in their relationships with any component of industry – as unavoidable as these relationships may be. 7. It is important to clarify each of the interests involved, to identify dualities and conflicts among them, to develop ways of averting or managing actual conflicts, and to communicate openly with each of the constituencies.	27
1.6 Special questions relating to the pharmaceutical, devices and complementary medicines industries	8. Evidence shows that both health care decision making and the conduct of research are profoundly affected by all these influences, in ways not always beneficial to the wider community. 9. Health professionals may unwittingly become agents of industry.	28
Chapter 2: Interests, dualities of interest and conflicts of interest		*Page*
2.4 Practical strategies	10. It is important to identify both pecuniary and non-pecuniary interests and to consider their potential for influencing decision making. 11. It is important to identify dualities – which include conflicting interests – in relation to actual circumstances. 12. Disclosure alone does not resolve conflicts of interest, but is the first step in identifying and managing actual conflicts of interest. 13. Dualities should be disclosed to a relevant party - for example, a committee, or council or patient - which then considers whether further action needs to be taken.	34
2.5 The need for processes to guide responses to issues concerning values and interests	14. In every organisational or practice setting, a process should be established to ensure adequate responses to dualities and actual conflicts of interests.	35

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3.2.2 Gifts	15. The welfare and interests of patients are the primary concerns of medical and other health professionals. 16. It is important to identify both pecuniary and non-pecuniary interests and to consider their potential for influencing decision making. 17. Disclosure alone does not resolve conflicts of interest, but is the first step in identifying and managing actual conflicts of interest. 18. Acceptance of gifts, including service-oriented and non-service oriented gifts and items of small value, has the potential to exert influence and create conflicts of interest. Individuals should consider the context, potential implications and available alternatives before deciding on their personal courses of action. 19. The welfare of patients and population groups must take priority over commercial, financial, personal or other interests. 20. It is important to identify dualities and conflicting interests in relation to actual circumstances. 21. In every organisational or practice setting, a process should be established to ensure adequate responses to dualities and actual conflicts of interests.	41
3.2.3 Entertainment and hospitality	22. Acceptance of industry hospitality can create conflicts of interest. Individuals should consider the context, potential implications and available alternatives before deciding on their personal courses of action. 23. For the most part hospitatlity should be provided by emplyers or its costs should be covered by the health professionals themselves.	42
3.2.4 Drug samples, including starter packs	24. Use of drug samples, including starter packs, from industry pharmaceutical representatives is often not in the best interests of patients.	42
3.2.5 Patient support and ‘educational’ programs	25. Patients should be invited to participate in ‘support’ programs or provided with information about such programs only if they provide meaningful benefits and if the information provided is accurate and appropriate. 26. Health professionals should not facilitate direct contact between industry representatives and patients. 27. The conduct of ‘support’ programs should be carefully monitored by health care teams.	43
3.2.6 Off-label prescribing	28. Physicians should exercise caution in regards to ‘off-label’ prescribing, especially in unusual clinical situations and where alternative approved therapies are available.	44

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3.2.7 E-health and the use of medical software containing advertising	29. Practitioners using software for clinical functions should consider programs that do not include industry advertising or should disable the advertising functions of their programs.	44
3.2.8 Use of therapeutic devices	30. Practitioners should declare to their patients, organisations and to the public any relationships with producers and suppliers of devices. 31. Practitioners should not obtain benefits from the sale of medical devices to their own patients.	45
3.3.Meetings 3.3.1 Support for meetings and other educational activities	32. The nature of industry support and any obligations associated with them should be declared openly to those who might have an interest in knowing, including the public. 33. If possible, industry support for scientific meetings should be organised through independent bodies. 34. Meetings organised directly by industry should be recognised as promotional and critically scrutinised by organisers and attendees in relation to the possibility of bias or incomplete information.	47
3.3.2 Where support is offered in return for a formal contribution to an otherwise independent scientific meeting or conference program	35. Practitioners should not accept sponsorship to cover the cost of travel, attendance or family or friends. 36. Where personal support is offered in return for a formal contribution to a legitimate scientific meeting or conference program, it should be: • given indirectly, through an independent organising committee • not tied to the promotion of any commercial product or other industry concern • fully disclosed and agreed upon by the recipient's organisation.	49
3.3.3 Where support is offered to a practitioner not making a formal contribution to a scientific meeting or conference	37. Non-presenters who accept industry support to attend conferences should, where possible, seek agreement from appropriate institutional committees, make the necessary public declarations, and be aware of the potential for such acceptance to influence their practice. 38. Where support is provided to non-presenters, ideally this support should be made available through a fund that is independently managed by a third party such as a conference organising committee.	50
3.3.4 Support for medical 'grand rounds'	39. Grand rounds should be funded by the clinical organisation. 40. Where no alternative is available, industry supporters should have no part in determining the speakers, subject or content. 41. All industry support should be disclosed. 42. The presence of any industry representation, including promotional material, should be in an area separate from the one where the event is taking place.	50

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3.3.5 Support for local meetings of specialty groups and departmental scientific meetings	43. Wherever possible, department meetings should be funded by attendees or other organisational sources. 44. Where no alternative is available, the industry supporters should have no part in determining the speakers, subject or content. 45. Industry representatives should be excluded from clinical meetings where identifiable patient information may be discussed. 46. All industry support should be disclosed.	51
3.3.6 Product launches	47. Product launches should be recognised as promotional activities.	51
3.3.7 Meetings organised by industry	48. Health professionals should not take responsibility for the organisation and promotion of any meeting in which a company selects and provides speakers. 49. The conditions under which support for a meeting is provided should be disclosed.	51
3.3.8 Company support for continuing medical education or continuing professional development programs	50. Meetings supported by industry funds and branded as 'continuing education' should be held to the same standards as other kinds of meetings. 51. Clinical organisations making use of private CPD providers should audit the content of CPD sessions and be aware of, and demand disclosure of, any possible industry influence over the 'educational' material presented.	52
3.4 Employment, consultancies & remuneration for services 3.4.2 Employment	52. 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. 53. Membership of industry advisory boards should be disclosed in all relevant circumstances and recognised as a source of conflicts of interest.	53
3.4.4 Endorsements and 'advertorials'	54. Physicians should not endorse specific products. 55. Physicians should not participate in 'advertorials'.	55
3.4.5 Agreements with pharmaceutical companies about choice of drugs for inclusion in hospital formularies	56. When choosing a medication for a hospital formulary, priority should be given to clinical efficacy in relation to patients' best interests.	55
3.5 Research and development 3.5.1 Enrolment of patients in research studies	57. Where a clinician is involved in research that may recruit his or her patients, it may be appropriate for independent professionals to undertake formal recruitment of patients, discuss benefits and risks and obtain consent. 58. Physician–researchers should disclose their relationships with industry funders and any interests in the outcome of the research both to institutional Human Research Ethics Committees and to potential participants.	56

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3.6 Publications	59. Those involved in the publication process, whether as authors or reviewers, should declare all relevant dualities and conflicting interests, both pecuniary and non-pecuniary.	56
3.7 Health professionals and international health practice 3.7.4 Summary & conclusions	60. Practitioners working in overseas settings should scrutinise carefully their relationships with the various components of industry with which they engage and clarify the purposes and practices associated with their activities. 61. The practitioners themselves should assume responsibility for the details of these relationships, including short and long-term associated consequences. 62. The primary interest by which actions or decisions are assessed should be the wellbeing of the individual members of the communities the professional intends to serve, although this does not exclude the importance of public health considerations about the welfare of the wider society. 63. Ethics approval for research projects should be obtained both from the institutions from which the researchers come and from the relevant jurisdictions within which the participants are to be recruited. 64. Those involved in the planning and implementation of overseas aid programs should take whatever action is needed to provide protection from physical or psychological danger to aid workers.	58
Chapter 4: Issues affecting trainees and students		*Page*
4.1 Introduction	65. The issues arising in relation to individual practitioners and researchers apply equally to students, trainees and teachers. 66. Health care education curricula should include learning about the ethical issues arising in relation to the role of industry in the health professions.	59
4.2 Development of an ethical culture that fosters critical attitudes towards relationships with industry	67. Training programs should include discussions about the role of industry, dualities and conflicts of interest, and the evaluation and interpretation of industry material. 68. The role of institutional policies and the practices of individual clinicians, teachers and mentors in shaping the behaviour of trainees and students should be recognised in the development of curricula. 69. Undergraduate and postgraduate medical education should include education about the extent of interactions between industry and health professionals, the impact of these relationships, the ethical issues that arise as a consequence, and strategies for managing risks and realising benefits associated with them.	60

Chapter 4: Issues affecting trainees and students		*Page*
4.3 Interests and responsibilities of educational institutions and societies 4.3.2 Relations between educational institutions and industry	70. The relationships that educational institutions have with industry should be publicly declared and should be open for critique by practitioners, teachers, trainees and students. 71. Those involved in health professional education should declare the interests they have as a consequence of their relationships with industry. This information should be accessible to the professional education community, to trainees, students and to the public. 72. Teaching materials developed by industry should not be used in health professional education. 73. Hospitals, universities, academic medical institutions and medical centres should discontinue the practice of pharmaceutical company-funded lectures and meals.	61
4.4 Interactions with pharmaceutical representatives	74. Educational institutions, including universities, colleges and hospitals, should be encouraged to prohibit formal contact between trainees and students and pharmaceutical representatives. 75. Interactions with pharmaceutical sales representatives should be avoided at clinical teaching sites. 76. The general principles that apply to health practitioners should also apply to trainees and students.	61
4.4.1 Gifts, travel and attendance at meetings	77. Gifts from industry should not be offered to students and postgraduate trainees and they should not accept them. Exceptions include formal grants, awards or exchange programs administered through a third party, with no sponsor involvement in decisions concerning which trainees and students are awarded the grant.	62
4.6 Need for specific policies regarding trainees and students	78. Institutions involved in health professional education should develop policies covering sponsorship of meetings and grand rounds and the use of promotional materials. 79. Teachers and mentors should consider the examples they set to trainees and students in their personal attitudes and behaviours.	62
Chapter 5: Issues affecting institutions and professional societies		*Page*
5.3 Conflicts of interest involving officers of a society	80. Professional societies, including the Royal Australasian College of Physicians, should have in place processes for the declaration, management and public disclosure of relationships with industry, and of the competing interests of members and office holders. 81. These processes should apply to employees and office holders, as well as to the members of the professional societies.	64
5.4 Membership of disease-specific community health organisations	82. Health professionals and medical organisations should be aware of the ties between community-based organisations and industry. 83. Health professionals who interact with these organisations should take steps to avoid inadvertently privileging commercial imperatives over patient welfare, and to ensure that educational programs with which they are involved are free of bias stemming from sponsorship relationships.	65

	84. Appropriate firewalls should be maintained between professional societies and disease-specific community health organisations and industry sponsors to prevent conflicts of interest.	
5.5 Meetings 5.5.1 Where the professional association or organisation is organising and funding the meeting	85. Where the professional association or organisation is organising and funding the meeting: • The scientific, political or other commitments of organisations and office holders should not influence the content of educational or scientific presentations. • Organisational support for scientific/educational meetings should be disclosed to attendees. • Speakers at these meetings should disclose any relevant interests at the time of their presentations.	65
5.5.2 Where the professional association is seeking external commercial support for a meeting	86. Where the professional association is seeking external commercial support for a meeting: • Commercial supporters should not influence the planning, content, speaker selection or execution of a society's program or the subject matter of presentations. • Support for organisational activities offered by commercial organisations should be treated with caution.	66
5.5.3 Where the organisation is convening meetings to develop policy	87. Where the organisation is convening meetings to develop policy: • External funders of events in which policy or practice guidelines are developed should have no influence over the content, selection of speakers or participants or the content of reports, recommendations or guidelines produced as a result.	66
5.5.4 Support for association members who wish to attend external meetings	88. Professional associations and organisations should endeavour to fund health care professionals to attend meetings as part of their professional development and education. 89. Organisations should have processes in place to monitor situations in which members or employees are offered external funding to attend educational and scientific meetings.	67
5.6 Educational activities 5.6.1 Training programs	90. The institution accrediting an educational activity should be responsible for ensuring that the activity is free of biases related to industry sponsoring or presentation. 91. Clear guidelines, which include requirements for clear disclosure statements, should be provided to speakers. 92. The organising group should include a majority of individuals without conflicts of interest, and conflicts should be managed within the operation of the committee. 93. Measures should be adopted to ensure that the scientific, clinical and educational content is not affected by the presence or nature of commercial sponsorship. 94. Processes should be established to assess the outcome of the programs, including provision for feedback regarding possible biases from course participants.	68

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5.7 Endorsements 5.7.4 Endorsement of other publications or materials produced by outside organisations	95. Policies and processes should be in place to ensure that the preparation of statements of endorsement involves examination of the relevant evidence, appropriate management of dualities and conflicts of interest, and scrutiny of the statements, to exclude inappropriate industry influence.	70
5.8 Involvement of organisations in overseas activities	96. Institutions involved in overseas work should develop policies to ensure adequate attention is given to the protection of both the communities with which they are working and their own members who are offering services or conducting research.	71
5.9 Publications	97. Journals should establish clear policies that conform to international standards for author disclosures, review processes and advertising and other sources of support. 98. Income from the sale of reprints should be disclosed to readers.	72
Chapter 6: Issues affecting research		*Page*
6.2 Responsibilities of investigators 6.2.1 Overview of responsibilities of researchers	99. Competing interests should be disclosed to all relevant parties, including participants and the public. 100. The different roles and interests of the researchers should be kept distinct in order to protect the integrity of the research process and research participants.	75
6.2.2 Responsibilities where a researcher is offered financial compensation for being an investigator in a clinical trial	101. Financial compensation for participating as an investigator in a clinical trial should be commensurate with the work performed. 102. Remuneration for research participation should be paid into a specially designated fund, which is subject to auspice and audit according to institutional guidelines. 103. All payments to clinician–researchers or the departments in which research is conducted should be fully declared to trial participants.	76
6.2.3 Responsibilities where a researcher does not have an institutional affiliation	104. Any research project conducted by private practitioners should include an investigator with an institutional affiliation and be assessed by an ethics committee associated with that institution. 105. Financial compensation or payment to clinician–researchers should be approved by a responsible ethics committee and declared to research participants.	77
6.2.4 Responsibilities where companies provide grants for research	106. Research grants from industry should be made to the institution and not to individuals, and should be appropriately acknowledged in research and other publications. 107. Researchers should not be subject to confidentiality agreements that are not time-limited or specific. 108. Restrictions on publication of trial results are likely to be inappropriate. 109. Sponsors should not participate in the design of studies or analysis of results. 110. Researchers should not be subject to confidentiality agreements which may prevent public disclosure of trial results.	78

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6.5 Complexities of the management of interests in research	111. 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. 112. All clinical trials should be registered on an appropriate clinical trials registry. 113. Responsibility for decisions concerning publication of results should be taken by investigators without commercial conflicts of interest, and decisions should be made without undue influence from the sponsoring company. 114. Researchers should not agree to be authors on 'ghost-written' manuscripts.	80

Definitions

Code of conduct: a set of recommendations or injunctions regarding professional behaviours or issues that are authorised by an institution or society.

Conflict of interest: a situation in which two conflicting interests are acting in a social relationship or practice. The precise condition that defines the presence of a conflict of interest is that in relation to a specific decision or action where two opposing and contradictory interests coexist.

Continuing professional development (CPD) or continuing medical education (CME): activities, whether associated with formal, accredited programs or not, which extend or update the knowledge, skills and expertise of health practitioners.

Disclosure: a statement regarding interests or other personal characteristics to enable the identification and assessment of conflicts of interest.

Duality of interests: the coexistence of two distinct interests in a particular decision-making setting.

Education: teaching or training activities designed to enhance knowledge, skills and expertise and to develop faculties of critical analysis or awareness.

Endorsement: a statement of support or approbation from an individual or organisation for a product, recommendation or some other object or course of conduct by which the individual or organisation assumes a degree of responsibility for the ensuing outcomes.

Gift: a transfer of anything of value to a health professional other than usual payment for professional services, including gratuities, perquisites, honoraria, speaking fees, travel services, meals and entertainment.

Health care professionals: health practitioners in all specialities, those working in private practice and those in institutions such as hospitals, universities and research institutes; practitioners in other health professions such as pharmacists; representatives, employees and administrators of institutions such as universities and research institutes; fellows, members and employees of professional organisations; members and employees of community organisations with an interest in the management of a particular medical condition or aspect of research; and members of these various groups during the course of their undergraduate or postgraduate training.

Industry: the full range of institutions and enterprises with a bearing on health care, as opposed to the actual work carried out by health professionals in their clinical and research practice. Industry includes, but is not restricted to, the ‘for-profit’ sector, comprising the pharmaceutical and complementary medicines industries, the biotechnology industry, the medical device industry, the food industry and commercial providers of services related to clinical practice, research and education.

Interest: a commitment, goal, obligation or value associated with a social relationship or practice. In health care, safeguarding the safety and welfare of patients is the primary, although not sole, obligation or interest of health care professionals.

Interest, non-pecuniary: a goal or value not linked directly with material gain, such as enhancement of career or professional recognition, status or fame. Non-pecuniary interests include personal or family loyalties or other obligations arising out of personal belief systems or social commitments. In the medical setting, such interests are often powerful drivers of decision making, although they may be hard to identify and impossible to quantify.

Interest, pecuniary: a financial or other material gain such as shareholdings or board memberships; paid employment, including consultancies and commissioned fee-paid work, speaker fees and fees provided in return for an expert opinion; fellowships, research and educational grants; and travel grants, conference expenses, gifts and hospitality

Sponsor: an individual or organisation that provides support for an activity within a relationship that establishes a degree of obligation or responsibility.

Chapter 1: Introduction: Background, context, process and principles

Disclosure of previously discretionary information is fundamental to the public's trust in medicine. As a consequence of growing concerns about financial conflicts of interest in research, increasingly stringent disclosure rules have been introduced in many countries, including in Australia and New Zealand, especially since the early 1990s.

The first edition of the RACP *Guidelines*, published in 1992, took the form of a set of comparatively abstract principles to help guide physicians to make their own decisions regarding the drug industry. However, increasing awareness about the potential implications of the influence of the pharmaceutical industry on prescribers, medical societies and expert bodies, as well as on research outcomes, led to calls for further regulation in the late 1990s and early 2000s.

The third edition of the RACP *Guidelines*, published in 2006, laid out detailed, practical advice to physicians for managing dualities and multiplicities of interest, and avoiding any appearance of impropriety in such areas as authorship of pharmaceutical-sponsored research, society meetings and gifts.

The developing empirical understanding of pharmaceutical industry influence since 2006, as well as further intensification of public concerns, has set the stage for a new revision of the *Guidelines*. Goals of the present revision include expansion of their scope to other (non-pharmaceutical) industries; recognise the close involvement of nurses and allied health professionals in the operation of health care teams; integration of the approach to industry across the areas of clinical practice, social policy development, research and education; and explicit acknowledgment of the concomitant unequivocal constructive roles of industry.

International events have affected public awareness of the importance of these issues and have led to changed cultural expectations. The gradual but important strengthening of the Medicines Australia Code of Conduct has been another important step forward. Recognition of the need for a unified approach to the issues across different sectors, including generic and non-generic pharmaceuticals and complementary medicines, has increased. Overseas legislation mandating greater disclosure of relationships with industry and increasing public pressure are reflected in the present text.

The *Guidelines* include expanded discussion of electronic advertising, non-pecuniary interests, global issues, the role of 'educational' activities and various other topics. There has also been recognition of the fact that not all consumer groups express views independent of industry or government.

It is important to note that physicians working in occupational and environmental health have a unique relationship with industry, as indeed do other physicians who undertake medico-legal work. These physicians may need to manage conflicting responsibilities relating to individual patients under their care, workers in a particular workplace, employers, the general public and specific responsibilities under legislation. The Australasian Faculty of Occupational and Environmental Medicine has published its *Ethical Guidelines for Occupational and Environmental Physicians*, which should be referred to for more detailed guidance on the specific issues relating to these professions.

1.1 General purpose of the document

Like all guidelines, the current guidelines present views and recommendations that may not be universally shared. They have been developed by consensus through an extended process of discussion, debate and consultation, on occasions with vigorous contention.

The document is not only a philosophical statement. It seeks also to outline the ethical and philosophical issues that arise when health professionals interact with industry, to represent continuing debates within the College and the community in a fair and constructive manner and to provide a guide or map to inform and assist physicians in making practical decisions.

It is intended to provide guidance and advice, not to compel or limit decision making. Increased ethical competency requires free and voluntary decision making. A decision not made in an informed and voluntary manner is not ethically valid. Accordingly, practitioners consulting this text are encouraged to consider the arguments and recommendations included within it, but to make their own decisions. The Guidelines have attempted to link advice to the evidence regarding the influence of specific activities on patient care. While it is generally accepted by physicians that there are negative effects from certain interactions with industry, many physicians still think they are personally immune to the influence of industry. Although the broad perspective of the document represents official RACP policy, in the case of decisions by individual physicians regarding their clinical practice or personal affairs, the College respects their right to make decisions that vary from the recommendations presented here.

It is recognised and acknowledged that the issues facing individual health practitioners often differ sharply from those facing the various institutions comprising the health care industry. In particular, the responsibilities and interests of health practitioners may be distinguished from those of pharmaceutical companies and other commercial organisations. This is, in part, because health practitioners have an active responsibility to advocate for their patients and the community, which is not shared by industry. Accordingly, while we have sought to ensure as far as possible consistency between these Guidelines and those of other organisations – including Medicines Australia – the primary test we have applied where differences have emerged is the welfare of individual patients, their families and carers and the wider community.

As we have stressed, these Guidelines are primarily advisory in nature, and we support the rights of individuals and institutions to make decisions about their interactions with industry. Nonetheless, it is recognised that other bodies, such as the Australian Health Practitioner Regulation Agency, the Medical Council of New Zealand, the Australian Competition and Consumer Commission, the Consumer Protection branch within the New Zealand Ministry of Business, Innovation & Employment, Medicines Australia, Medicines New Zealand, Health Research Council of New Zealand and the National Health and Medical Research Council (Australia) might from time to time issue requirements of a mandatory nature relating to any of the matters discussed herein to which individual readers are subject.

Key points:

1. Practitioners consulting this text are encouraged to consider the arguments and recommendations included within it, but to make their own decisions.
2. While it is generally accepted by physicians that there are negative effects from certain interactions with industry, many physicians still think they are personally immune to the influence of industry.

1.2 How to use this document

Practitioners seeking guidance in respect of a particular issue may approach the document in three ways: by searching the index, which has been made more comprehensive in this edition; by browsing the list of key points on pp.13 to 21; or by reading the more detailed notes and explanations in the main text.

Additional resources offered by this text include a bibliography – which is not comprehensive – and decision-making tools. It is anticipated that short, accessible presentations on particular topics, as well as further information and materials and opportunities for responses and feedback from readers from all backgrounds, will be provided via the College website.

1.3 Target audience

The Guidelines are intended to offer guidance for individual Fellows, practitioners and other readers, rather than binding imperatives. The provisions relating to medical trainees and students and education are also offered to provide guidance to groups within the community who often lack protection from the codes of professional organisations; those active in this area as teachers, administrators and mentors are encouraged to seek ways to promote further discussion and understanding among their trainees and students.

1.4 Interests - general definitions, scope, summaries of issues, problems

The definitions of interests, and the management of dualities and conflicts of interest are presented in Chapter 2. Here, we consider briefly the broad problems the Guidelines seek to address.

Interests arise in clinical settings in many ways and affect all aspects of clinical decision making. They include both pecuniary and non-pecuniary interests, the latter on many occasions being much more powerful than the former.

Pecuniary interests giving rise to dualities and conflicts of interest may be associated with the relationships between health practitioners and industry, in the settings of clinical care and research, teaching, and other professional and employment responsibilities. These interests can include involvement of clinicians in and interactions with owners of private hospitals and pathology providers, educational opportunities funded by third parties, and honoraria for participation in education programs.

The principle that should guide decision making in all clinical settings is that the safety, wellbeing and other interests of patients and populations are primary and must not be compromised by pecuniary or non-pecuniary concerns.

Interests that may influence the decisions of all clinical practitioners should be clear and transparent. In the specific case of pecuniary interests, the relevant arrangements between clinical practitioners and the organisations concerned should be openly stated in a manner that is accessible to all individuals who could be affected. Where the possibility of a conflict of interest arises, regardless of the context, this should be declared openly to all relevant parties. A process should also be established to resolve any concerns. This may require disclosures - to institutions, Human Research Ethics Committees, patients, potential research participants and others - of financial arrangements or other commitments, and of values or obligations that might affect decision making.

Such disclosures of interests do not in themselves imply the existence of conflicts of interest. They do, however, facilitate the identification of conflicts where they do exist and help to avoid them where it is possible to do so. The ultimate test for the effective management of conflicts of interest in this setting is that practitioners' independence of judgment and decisions they might make concerning the safety and wellbeing of patients, their families and the wider community remain unimpaired by other interests, including benefits received from industry or non-pecuniary commitments.

Key points:

3. The safety and interests of patients are the primary concerns of medical and other health professionals.
4. In health care decisions, the safety and wellbeing of patients and population groups take priority over commercial, financial, personal or other interests.
5. Where the possibility of a conflict of interest arises, regardless of the context, this should be declared openly to all relevant parties.

1.5 The issue

The work undertaken to prevent, diagnose and treat disease, including the production and use of medicines and other therapies, and the conduct of research directed towards these ends, is the result of contributions from many people, including medical and other health professionals, researchers, employees of industry, consumers, governments, administrators of hospitals, and members of professional and community organisations. These people interact in different ways to facilitate the realisation of their various goals and purposes.

Although they undoubtedly share many common interests, all the parties have their own specific objectives that are not always consistent with each other. For example, in the for- profit sector – which includes the pharmaceutical industry, the biotechnology industry, manufacturers of devices and providers of various services – the generation of profit for owners and shareholders is a natural goal which may conflict with the primary ethical purpose of the health care system, which is to provide for the health care needs of the community. Similarly, professional associations are interested both in maintaining professional standards and in protecting the incomes and authority of their members; universities and research institutes have interests that are not limited to the realisation of the values of science, education and knowledge; and political and religious bodies have other interests. Universities, research institutes and community organisations enter into partnerships with the pharmaceutical industry and in some cases rely heavily on income derived in this way to conduct their day-to-day business.

In all these relationships, diverging interests can arise that affect the provision of enhanced health care to the community. Because of this potential for conflict and in spite of widespread recognition that contending perspectives can often lead to productive dialogues many health professionals feel uncomfortable in their relationships with any component of industry, a sentiment that has also been expressed both in the community and by government agencies.

To respond to these concerns, it is important to clarify each of the interests involved, to identify dualities and conflicts among them, to develop ways of averting or managing actual conflicts, and to communicate openly with each of the constituencies. At times this will be a complex task because of the number and variety of both participants and interests, difficulties in identifying non-pecuniary interests, and the fact that many clinicians and researchers occupy multiple roles, as educators, advisers or paid consultants. The purpose of these Guidelines is to assist both individual health professionals and organisations to be able to recognise these problems and to develop effective strategies to address them. While the development of a productive and interactive relationship between industry, health professionals, consumers, government, and professional and community organisations has obvious community benefits, physicians involved in such relationships should be aware that the primary objective of industry is the promotion of their company and its products.

Key points:

6. Many health professionals feel uncomfortable in their relationships with any component of industry - as unavoidable as these relationships may be.
7. It is important to clarify each of the interests involved, to identify dualities and conflicts among them, to develop ways of averting or managing actual conflicts, and to communicate openly with each of the constituencies

1.6 Special questions relating to the pharmaceutical, devices and complementary medicines industries

One of the particular concerns of health care professionals and the wider community has been the promotional activities of the pharmaceutical, devices and complementary medicines industries. These activities take many forms, including overt advertising, the provision of gifts to individual practitioners or employing institutions, travel assistance, support for meetings and educational programs, and dissemination of information to the community via the popular and electronic media. The concern is heightened by the fact that the targets of these activities - usually health practitioners - are not the actual consumers of the products, but rather act as the agents of both patients and the wider community, whose welfare they are entrusted to protect and promote.

Health care professionals of all kinds often assume they are immune from skilled advertising techniques. However, evidence shows that both health care decision making and the conduct of research are profoundly affected by such influences, in ways not always beneficial to the wider community (see the bibliography for representative references). This raises the possibility that health professionals may unwittingly become agents of industry and draws attention to the need for them to consider establishing systematic ways of recognising potential sources of influence and ensuring that they are not inappropriately affected by them.

Similar issues are raised by relationships involving educational and research activities, and the management of hospitals and professional organisations, including those with religious and political affiliations. These Guidelines are intended to contribute to the process of clarifying all these issues and developing potential ways of responding that protect and preserve the interests of patients and the wider community.

Health professionals have a range of responsibilities in relation to the development and use of medicinal agents and other therapeutic devices. Clinical practitioners have specific responsibilities to their patients, researchers have responsibilities to the community of scientists, and administrators have responsibilities to those who set the policies they are appointed to execute. Depending on the professional roles involved, these responsibilities may include:

- using existing medicinal agents and devices in the most effective and appropriate way as part of treatment and care
- monitoring their use and reporting adverse reactions
- participating in clinical trials of new drugs and other therapeutic agents and in company-sponsored trials of marketed drugs
- participating in post-marketing surveillance of new drugs and therapeutic devices
- keeping up to date with scientific developments in their fields and with available information about new drugs and changed information about established ones
- considering the implications of new technologies and pharmaceutical agents for the community as a whole and contributing to discussion about the most appropriate use of resources
- contributing to community knowledge about therapeutics in order to enhance the abilities of patients and consumers to make informed choices
- engaging directly in research or contributing to or supporting such research.

These responsibilities substantially overlap with the objectives of many aspects of industry, with which health professionals often develop and maintain fruitful relationships. It is important to acknowledge these constructive engagements, which are often beneficial both to the participants and to the community as a whole. Health professionals can provide knowledge and experience which can enhance the outcomes of the work undertaken by industry. Conversely, industry can supply resources that facilitate development of new diagnostic and therapeutic possibilities.

Key points:

8. Evidence shows that both health care decision making and the conduct of research are profoundly affected by all these influences, in ways not always beneficial to the wider community.
9. Health professionals may unwittingly become agents of industry.

1.7 Why relationships between health professionals and industry are important

In summary, while the interests of health professionals and the various components of industry overlap, they are not identical and at times may diverge or come into conflict with each other.

If the relations between health care professionals and industry are inadequately managed, this may lead to:

- a loss of commitment to or change in underlying goals or purposes
- undermining of the processes of professional judgment
- inappropriate outcomes or outcomes at variance with the underlying values of the health care professions or of the community
- a negative impact on the quality of care, and ultimately patient health
- loss of trust by patients, government and the wider community.

In other words, inappropriate or poorly managed relationships between health professions and industry can lead to an erosion of the integrity of the professions and an undermining of the trust between practitioners and the community on which the health care system depends. To address these risks, we offer guidance to individual practitioners in their interactions with industry, to researchers in the planning and execution of their work, and to institutions and professional organisations charged with the responsibility of delivering health care and overseeing educational activities and research practice.

We stress that the Guidelines are only advisory. There is no universal consensus about how to assess the influence of industry on health care and research or about optimal courses of action to respond to issues arising in specific settings. It is recognised that there are often differing views about the most appropriate course of action: indeed, such diversity of views is encouraged and welcomed. In addition, it is emphasised that judgments must be made in relation to the specific details of individual cases, which may be infinitely variable. Together, these factors impose limitations on the extent to which effective guidance can be provided in the form of general principles and summary formulations.

We consider that matters as complex and varied as those discussed here should be regulated on a voluntary basis, according to local conditions and needs, by individuals who are themselves engaged in practice and administration. We accept - and welcome the fact - that not everyone will agree with our recommendations, and that on occasion individuals and organisations will choose other courses of action. Regardless of their conclusions, however, we strongly urge all those involved in the broad field of health care to reflect on the issues we are raising and to develop their own strategies for responding to the dualities and possible conflicts that abound in our professional lives.

1.8 The question of evidence

These Guidelines have evolved from guidance developed by the RACP over more than two decades. They are based on identifying and interpreting the best practice currently available. Although we have undertaken extensive reviews of the literature, we have not attempted to reference every factual claim we have made. This reflects the necessity that guidelines represent the results of extensive and often

complex processes of interpretation and debate concerning not only data but also cultural attitudes and possibilities.

To provide guidance regarding the now very extensive literature in the field, we have included an extensive, annotated bibliography.

1.9 Feedback invited

The production of this document has involved extensive consultation with a wide range of contributors, from the medical and other health professions, industry and consumer groups. We note particularly our appreciation of the contributions of consumers, which have provided great assistance in the development and refinement of the Guidelines. Because the field of interactions between health professionals and industry continues to evolve rapidly, so also do these Guidelines need to develop and change. To this end, suggestions and critical comments from all members of the community are specifically invited and are welcome at any time. These can be directed to Ethics@racp.edu.au.

Chapter 2: Interests, dualities of interest and conflicts of interest

2.1 Theoretical framework

All medical (and other) decisions that refer to values or ethical contexts invoke interests of one kind or another. In the fields in which health professionals work - clinical practice, research, education, and policy development and implementation - there are always multiple interests at play. From an ethical point of view, decisions are rarely unambiguous, and usually require careful analysis of values and negotiation and compromise among conflicting positions. The process is made more complex as a result of the variety of roles individual practitioners play and of the moral obligations they thereby incur. In other words, as will be explained below, the process of decision making in health care invariably involves a careful balancing of interests, values, ethical perspectives and personal and other preferences.

For the most part, in the normal course of decision making the proliferation of interests is managed in a routine and non-antagonistic manner. It is part of the skill of the professional to navigate his or her way through the complex manifold of values, purposes, commitments and obligations which are presented. On occasions, however, the complexity can be so great that the optimum course of action is uncertain. The various interests may suggest contending or confusing possibilities leading to conflicting demands.

These cases - known as conflicts of interests (COIs) - need to be identified and managed appropriately. It is important to define the concept of a COI carefully and to clarify strategies available to address and resolve such conflicts. It is emphasised, however, that the absence of COIs does not imply that residual decisions relating to the play of interests are not complex and difficult. Accordingly, although COIs are important it is essential not to exaggerate their role or to use them to obscure the importance of the interest-laden decisions that are made routinely.

To clarify these ideas, it is first necessary to define the concepts:

- An *interest* is a commitment, goal, obligation or value associated with a social relationship or practice.

- Where two or more distinct interests coexist in a particular decision-making setting, a *duality* of interests is said to exist.

- When a particular relationship or practice gives rise to two or more conflicting interests, a *conflict of interest* exists.

These definitions emphasise certain important points:

- All choices and decisions raise issues related to values. We occupy multiple roles, incur various ethical obligations and enter into multiple commitments. This reflects the diversity of societies and the plurality of our individual roles. Inevitably, different roles lead to varying obligations, so conflicts may arise.

- The negotiation of value pathways through dense manifolds of interests is usually required, since decision making involves judgments about such interests.

- In decision making settings, opposing and contradictory interests often coexist. Whereas in common usage, the expression ‘conflict of interest’ is often taken to imply the existence of ignominious or unethical behaviour, in reality, conflicts usually arise in the absence of personal errors or faults. COIs arise from the facts and settings and not from malign motivations. Furthermore, neither dualities nor COIs in themselves inevitably cause harm; it is the ambiguity about goals and values and the possibility for harm that arouses concern.

- It is sometimes difficult for individual participants in a given decision-making setting to recognise that a conflict exists. That is why systematic processes are needed to identify the play of interests that are at stake and to assess their significance.

As explained below, the decision about whether a duality constitutes a conflict should not rest with the individual concerned but with the affected community. If a conflict is judged to exist, actions need to be taken to separate the conflicting elements. There are different levels at which change can occur, including at the individual and institutional levels.

2.2 Pecuniary and non-pecuniary interests

Interests can be ‘pecuniary’ or ‘non-pecuniary’ and both can lead to conflicts and dualities. A pecuniary interest refers to the possibility of financial or other material gain arising in connection with professional decision making. Examples of pecuniary interests include:

- shareholdings or board memberships
- paid employment, including consultancies, commissioned fee-paid work, speaker fees, fees provided in return for an expert opinion and performance bonuses tied to particular outcomes
- fellowships, research and education grants
- travel grants, conference expenses, gifts and hospitality.

Non-pecuniary interests refer to goals, benefits, commitments or obligations not directly linked with material gain. These encompass personal goals and relationships, including family or other commitments, enhancement of career and the possibility of acquiring professional recognition, status or fame. They also include individual belief systems that may influence decision making, membership of religious and political groups, and adherence to ideologies that guide the operations of institutions.

Neither pecuniary nor non-pecuniary interests are in themselves good or bad, ethical or unethical. They are part of the dynamic of any decision-making process. The key issue is how these interests interact with each other and their implications for the various practices – of clinical care, research, education and health policy – within which they are embedded. Although most attention is given to pecuniary interests in health care settings, on many occasions non-pecuniary interests are the most potent and troublesome drivers of action.

2.3 Examples of interests, dualities and conflicts

Dualities of interests exist whenever health professionals find themselves having to decide between two contending interests in a given decision-making context. Dualities may or may not constitute conflicts, depending on the circumstances.

Examples of settings in which dualities of interest exist, some of which could also be characterised as conflicts of interest, are as follows:

- Health practitioners or their family members hold shares in a pharmaceutical company, the products of which the practitioner may prescribe.
- A department head faces demands to cut budgets in spite of expanding clinical or other needs.
- A health care practitioner undertakes paid employment, with commissioned or
- non-commissioned fees for working as a speaker, author or expert adviser on behalf of a pharmaceutical company.
- An officer of a professional society is also a member of a political or social organisation which requires loyalty to a policy platform.
- A clinician, researcher or a professional organisation employee holds a fellowship or position supported by a pharmaceutical company, directly or indirectly.
- A professional society accepts payments from commercial sources to support its activities such as continuing education.
- A physician, who is also a researcher, is approached by a current patient considering participating in a clinical trial with which the physician is involved.
- A researcher receives support from a pharmaceutical company for carrying out research.
- A clinician is involved in the research and development of a new device which, if successful, could greatly enhance his or her reputation and professional stature.
- A clinician accepts gifts or hospitality, even of minimal value, from a company whose products he or she prescribes.
- A clinician or researcher receives support from industry for travel and conference expenses.
- A physician is paid to report on a diagnostic test undertaken by a for-profit company with a view to that company selling the devices to the patient.
- A trainee organising an educational event for his or her peers accepts financial support from an industry source.

2.4 Practical strategies

The effective management of dualities and COIs lies in identifying them, making clear declarations, maintaining openness and transparency, and developing appropriate processes to deal with specific issues. While it is essential that dualities and conflicts are dealt with in an open and transparent manner, it is important to recognise that, in many cases, mere disclosure is not in itself sufficient. Specific action will often need to be taken to separate the activities or roles that are in conflict. The whole process will commonly include the following sequence of steps:

1. Individuals reflect on the pecuniary and non-pecuniary interests associated with their various social roles and relationships.
2. Individuals declare all pecuniary and non-pecuniary interests that might generate or suggest interests.
3. All pecuniary and non-pecuniary interests are considered by a deliberative body that is appropriate to the circumstances – for example an ethics or departmental committee, an independent advisory group or a council of community members directly affected.
4. An assessment is made concerning whether the dualities constitute actual conflicts.
5. If a conflict of interest is considered to be likely, practical strategies are devised to separate the pursuit of the conflicting interests. In some cases, this will entail withdrawal from or curtailing a particular activity, while in others it will be sufficient to delegate functions or roles to another individual or group of individuals or committee.
6. The circumstances, decisions and practical outcomes are communicated openly to affected individuals and organisations.

The details of the process will obviously vary according to circumstances and contexts. For example, in the case of presentations at meetings, organising committee should develop policies that ensure open and complete disclosure in a manner that permits audience members to interpret the content of presentations appropriately. Where there is overlap between the roles of researcher and clinician, the elements deemed conflicting should be separated by delegating one of them to a colleague or assistant. Individuals with political or religious commitments that limit free debate or decision making may need to recuse themselves when decisions are being made.

Key points:

10. It is important to identify both pecuniary and non-pecuniary interests and to consider their potential for influencing decision making.
11. It is important to identify dualities - which include conflicting interests - in relation to actual circumstances.
12. Disclosure alone does not resolve conflicts of interest, but is the first step in identifying and managing actual conflicts of interest.
13. Dualities should be disclosed to a relevant party for example, a committee, or council or patient - which then considers whether further action needs to be taken.

2.5 The need for processes to guide responses to issues concerning values and interests

As discussed in Chapter 1, the manifold of interests can be very complex and the issues raised can refer to a wide variety of clinical, research and institutional contexts. In addition, the settings themselves can be diverse and may change and evolve over time. As a result, guidance must be formulated at a high level of generality that permits application in changing settings. Detailed analysis of the circumstances of individual cases and interpretation of the needs of the relevant affected communities are usually required. This necessitates reflection and debate within such communities.

For individual health professionals, recommendations in this document are proposed as advisory only and are not linked to a prescribed, formal method of enforcement. This is appropriate for ethical decision making in general because it requires constant scrutiny of issues and principles that cannot be replaced by legislative imperatives. Indeed, clinical practice requires that ethical decisions are taken in a setting of dynamic negotiation and compromise among participants with differing values.

This means that when dilemmas or problems arise, there is a need to access processes that can indeed respond to the details of individual circumstances and contexts. It is therefore recommended that in each relevant organisational setting, a process is established to ensure adequate responses to issues relating to dualities and conflicts of interests. Considerations that may be taken into account during this process include:

- identification of the main issues regarding relations with industry relating to that setting
- establishment of procedures for assessing and managing dualities and conflicts of interest within the given context
- development of measures to ensure adequate transparency and communication with the relevant communities
- maintenance of records of declared dualities and identified conflicts and how they are managed
- development of methods for reviewing the impact and appropriateness of procedures and recommendations.

In many cases, organisations will delegate these tasks to bodies with appropriate skills and experience such as an ethics committee, or they may establish committees specifically for such purposes, which will often include community representatives. Details of how an organisation deals with dualities and conflicts of interests should be publicly available. In many cases, responsibility for the various functions is likely already to be spread among a number of existing bodies.

Key point:

14. In every organisational or practice setting, a process should be established to ensure adequate responses to dualities and actual conflicts of interest.

Chapter 3: Issues affecting health practitioners

3.1 Introduction: Negotiating the manifold of interests

In their daily decision-making practices, individual clinical practitioners constantly negotiate a great range of interests, including personal values and aspirations, professional and institutional obligations, and interests created by relationships with for-profit providers. The latter include the pharmaceutical industry and manufacturers of devices.

Clinicians often command control of substantial resources because of their ability to call on social wealth allocated by governments. This imposes a serious responsibility on them to assess carefully the interests involved and to make the most judicious decisions possible.

Because of the influential position of clinicians, the for-profit industry, especially the pharmaceutical industry, applies significant resources to the task of influencing their behaviour. This increases the importance for practitioners of taking care to ensure that their decisions are not unduly influenced or not biased in relation to any particular drug, device or service provider.

Most of the evidence regarding the influence of the pharmaceutical industry on clinical practice relates to health practitioners, who prescribe rather than use the products themselves. Accordingly, the focus of much of the discussion that follows will be on medical practitioners, although similar considerations undoubtedly apply to nurses, allied health professionals and pharmacists.

Because of its importance and the public concern the promotion of pharmaceutical products has evoked, this chapter focuses especially on issues arising in relation to the effects of the latter on clinical practice. These include assessment and management of dualities and conflicts of interests, interactions with pharmaceutical representatives, gifts, entertainment, the use of drug samples, familiarisation programs and other promotion strategies, therapeutic devices, support for meetings and other educational activities, sponsorship of travel and meetings of various kinds, and employment and consultancies. It offers guidance in relation to each of these matters. In general, the view taken is that all interactions between clinical practitioners and industry should actively serve the interests of patient care and population health and that in cases where a clear benefit to clinical practice is less certain, great caution should be exercised.

3.1.1 Pecuniary and non-pecuniary interests

The key issue in clinical decision making is the welfare and wellbeing of patients. Negotiation is required about how best to proceed in relation to, for example, an individual patient's value system, the preferences of family and carers, and the prevailing social and cultural milieu. Our concern here is with the *additional* influences and interests to which clinicians are exposed that may affect their decisions. Not all of these are negative or harmful, but all practitioners need to develop sufficient awareness to control or limit influences that have the capacity to compromise their clinical obligations.

Interests arising from sources other than the pharmaceutical industry can also affect clinical decision making. These include pecuniary interests associated with the complementary medicines, device and fine chemicals industries, as well as personal financial interests of clinicians and pressures imposed on them by their employing institutions.

Non-pecuniary interests are also relevant. Health practitioners work not merely for financial gain but also for personal satisfaction, status, reputation and other career objectives. Their decisions also need to consider working relationships with other health professionals.

3.1.2 Evidence

The interactions between evidence and values raise some important issues. ‘Evidence’ itself inherently reflects value choices: about how to represent reality, about what constitutes legitimate or valid data or phenomena, and about how to regard contending or alternative systems of knowledge. This is important in relation to the ways in which practitioners with Western scientific training regard non-Western approaches to medicine and healing, the evidence for which may be based on widely varying epistemological principles.

Evidence provided by the conventional mechanisms of science, such as clinical trials, also reflects value choices about what is considered relevant, both in terms of the data themselves and of the relevance of the clinical context. Clinical trials, with good reason, frequently focus on a narrow and clearly defined population. Diverse comorbidities are often excluded, including those associated with the extremes of age. Consequently, clinical trial data may be of only limited assistance to a clinician who faces a more complex clinical problem. Caution is required if a clinical trial medication is used in this off-label situation.

It has repeatedly been shown that health practitioners are influenced by their contact with industry. Advertising and other forms of drug promotion, including provision of gifts and entertainment, travel assistance to meetings, sponsorship of scientific meetings and appointment to advisory boards, all increase demand for specific products. Promotional materials distributed by pharmaceutical companies are often biased, incomplete or unsupported by evidence and may encourage unapproved uses. Contact with drug retailers and advertising materials erodes physicians’ ability to identify wrong claims, increases non-rational prescribing and results in acceptance of commercial rather than scientific views. Physicians typically deny or are unaware that promotional activities influence their behaviour.

While physicians may appropriately continue to interact with pharmaceutical representatives, they should develop procedures to minimise the risks. Such behaviours should entail critical evaluation and feedback on all unsubstantiated material, including journal reprints.

Choices of speakers and topics at meetings can have significant implications for the ensuing discussion and the clinical choices that will follow from it. Biases can be introduced into any kind of event, including continuing professional development activities and departmental and other meetings. Sponsorship that is, the provision of funds in return for a benefit, which may be minimal or inapparent often enhances support in favour of a company's products; for example, it is known that prescriptions for sponsors' of pharmaceuticals increase in the six months after any kind of promotional event, even when no overt advertising of the products occurs.

Financial relationships between the for-profit industry, scientific investigators and academic institutions are widespread. Sponsorship affects research outcomes. There is a significant association between sources of funding and trial outcomes. Industry sponsorship is associated with pro-industry conclusions and restrictions on publication and data sharing. Research funded by drug companies is less likely to be published than research funded by other sources and is more likely to produce outcomes favouring the sponsor. Evidence regarding the activities of nurses and allied health professionals is more limited but is likely to raise similar issues. Physicians may be unaware that promotional activities affect their behaviour, and may believe themselves to be less influenced than their peers. While this is understandable, it underlines the importance of standards other than one's own judgment about whether one is influenced.

3.1.3 The popular media

The presentation of the achievements of, and the challenges facing, medicine and science in the popular media, play an important role in shaping not just the attitudes of patients but also the choices made by clinical practitioners. Typically, news reports tend to focus on medical 'breakthroughs', high technology solutions to clinical problems, and novel drugs, devices or procedures, at the expense of the traditional values of caring and prudent decision making. In this sense, the popular discourses can be seen as advocating for particular interests in place of others, which may be more appropriate or relevant in the given clinical circumstances.

The popular media - including social media networks - also provide powerful mechanisms by which advocates for particular products or approaches to treatment can promote their perspectives. The growth of the internet has greatly enhanced the access of community members to a range of viewpoints and sources of data, while also making it more difficult to distinguish information sources and to determine whether the information is commercial in nature.

3.1.4 The requirement of transparency

In recent years, much debate has focused on the extent to which pecuniary relationships into which health professionals enter should be publicly disclosed. There are very few defensible reasons to limit transparency and health professionals should commit to full disclosure of their relationships with all aspects of the for-profit industry. Such circumstances may include relationships that require commercial confidentiality or personal financial dealings that have no direct or indirect bearing on clinical or research outcomes.

The need for transparency also extends to non-pecuniary interests. As discussed in Chapters 1 and 2, these are both very varied and are capable of exerting profound influences on clinical decision making. It is the responsibility of all clinicians to undertake a rigorous process of reflection to identify the non-pecuniary influences to which they are exposed, including institutional constraints and demands, religious and political commitments, and personal goals and ambitions. Where appropriate, these should also be declared to patients in a clear and factual manner.

It should be noted that transparent disclosure of relationships is just one aspect of the available processes for managing dualities of interests involving health professionals and industry. As indicated in these *Guidelines*, many other strategies may also be used according to the context.

3.1.5 Pharmaceutical and complementary medicines, therapeutic devices and other health products

While much of the evidence and public discussion about the interests directing clinical decisions have focused on the role of the pharmaceutical industry, it is important to remain aware that the same arguments apply to all other health products. The field of complementary medicines – which includes herbal medicines, vitamins and food supplements – is less -regulated than that of pharmaceuticals, potentially posing the risk of greater abuses in some cases. The food industry, like the pharmaceutical industry, has a long history of interaction with health care institutions, public health bodies and individual practitioners (most notably that between paediatricians and breast milk substitute/infant formula manufacturers and retailers) and continues to exert considerable influence over public health policies and clinical guidelines. The device industry is a powerful, although less conspicuous, participant in the for-profit health industry.

Providers of other services, such as radiology and pathology services, are equally exposed to pecuniary and non-pecuniary forces, which may influence their decisions. The arguments relating to the pharmaceutical industry apply equally to these other aspects of the health industry.

3.2. Promotional activities

3.2.1 Industry promotion

Of particular concern to both the public and clinical practitioners are relationships that may affect health care delivery – for example, those involving the pharmaceutical, complementary medicines, medical devices and biotechnology industries. Clinicians and industry share common goals in that they are engaged in the prevention, control and management of disease and the conduct of research directed towards improvements in health care and patient outcomes. However, the interests of clinicians and industry diverge, because the primary obligation of for-profit organisations is to their shareholders, while that of clinical practitioners is to their patients. The main obligations of researchers are to their research participants and to the generation of knowledge.
In recent years, the promotional activities of industry have been the focus of intense public and professional debate. There are various reasons why this is the case, including the following:

- Promotional activities, by their very nature, are intended to create influence – to change prescribing behaviour, the choice of tests or interventions, and the focus and outcomes of research.
- Industry may use persuasive techniques other than arguments based upon evidence such as emotive techniques.
- Industry may present or interpret evidence in ways that reflect or promote its own interests.
- It is impossible, both practically and linguistically, to distinguish clearly between different forms of influence, including education, persuasion and coercion. Thus, while educational activities may function to increase knowledge, they can also promote particular views, ideas or interests.
- Promotion has consistently been shown to influence practice in ways that may create harm to patients, health care providers and the community.

- While promotional activities are increasingly aimed at consumers, including patients, they mainly still target clinicians – who are trusted agents of both their patients and the community.
- It is increasingly recognised that industry promotion adds significantly to the costs of therapeutic and diagnostic products, especially prescription pharmaceuticals. The additional costs are ultimately borne by patients themselves and by the community.

3.2.2 Gifts

There is compelling evidence that the giving of gifts to health practitioners is an effective marketing activity which erodes the independence of their judgment. Acceptance of gifts, including discrete gift items, payment for dinners, entertainment or expenses associated with daily living, is associated with an increased likelihood that health practitioners will prescribe products produced by those pharmaceutical companies, even in the absence of supporting scientific data. Often health practitioners are unaware that they are subject to such influence: indeed, they often consider that they are not affected.

There are, in fact, only rare occasions in which acceptance of gifts could be considered to be in the interests of patient care and population health. These generally involve provision of service-oriented items - for example, clinical examination equipment or teaching aids – which are not otherwise readily available. Even in these cases caution should be exercised, because often such items are in fact readily available, or are unnecessary to the provision of optimal care, and may come at considerable cost, such as the undermining of the assumption of independence of health professionals from industry and therefore the trust on which clinical relationships depend. In this regard it is important to note that even items of small value that superficially appear to be innocuous are intended to sway health practitioners' judgments and, at the least, may suggest to patients that the independence of the practitioner has been compromised.

Various kinds of advice have been offered to health practitioners about accepting gifts. These range from blanket rejection, to a gradient of moral acceptability based on cost, to application of the principle that decision making is unaffected, to the test of whether the recipient would be willing to have the arrangements publicly known. Each approach that attempts to define a gradient of acceptability is, however, problematic because it ultimately depends on arbitrary or subjective distinctions and criteria. For these reasons the simplest, and most defensible, approach is for health professionals to err on the side of rejection of gifts, even those of trivial value.

While individual practitioners always need to be alert to the potential that gifts influence attitudes and practice, it should not be left to individual practitioners to determine whether or not particular gifts are accepted. Institutional policies and guidelines regarding the acceptance of gifts may be more efficient and effective and remove the burden for making decisions from individual practitioners.

Key points:

15. The welfare and interests of patients are the primary concerns of medical and other health professionals.
16. It is important to identify both pecuniary and non-pecuniary interests and to consider their potential for influencing decision making.
17. Disclosure alone does not resolve conflicts of interest, but is the first step in identifying and managing actual conflicts of interest.
18. Acceptance of gifts, including service-oriented and non-service oriented gifts and items of small value, has the potential to exert influence and create conflicts of interest. Individuals should consider the context, potential implications and available alternatives before deciding on their personal courses of action.
19. The welfare of patients and population groups must take priority over commercial, financial, personal or other interests.
20. It is important to consider dualities and conflicting interests in relation to actual circumstances.
21. In every organisational or practice setting, a process should be established to ensure adequate responses to dualities and actual conflicts of interests.

3.2.3 Entertainment and hospitality

'Hospitality' is the provision of food and beverages by industry in association with a meeting or event covering topics of relevance to professionals. 'Entertainment' is the provision by industry of access to cultural, sporting or artistic events, that is, with no purported associated professional content.

Current practice is for health practitioners to reject industry entertainment invitations, and this response is appropriate and expected. The case of hospitality, however, is somewhat more complicated and remains the subject of discussion. For example, information sessions may be held in the evening after a day's work and it may be appropriate for them to be combined with the modest provision of food and drink. While this may be acceptable, the fact or even appearance of impropriety should be considered before accepting such benefits, even where they are accompanied by scientific presentations.

Food and drink may also be offered by industry to make grand rounds or similar meetings within hospital settings more attractive. While this may seem innocuous, it facilitates relationships between clinicians and industry providers that may adversely influence both doctors and medical trainees, and students, and influence prescribing practices. The practice may also arouse concerns within the community. For all of these reasons, hospitality at professional and institutional meetings should generally be provided by attendees themselves or by their employers.

The advent of transparency 'sunshine' requirements in different jurisdictions will ensure that in many cases acceptance of hospitality or entertainment expenses by individual practitioners will become public knowledge. This is appropriate, as the information is of genuine public interest and there is no reason to conceal it. However, it is recognised that on occasions judgment on these matters will still sometimes be difficult, and in these cases it might be helpful to seek advice from colleagues, institutional representatives, the employing authority or an ethics committee.

Key points:

22. Acceptance of industry hospitality can create conflicts of interest. Individuals should consider the context, potential implications and available alternatives before deciding on their personal courses of action.
23. For the most part, hospitality should be provided by employers or its cost should be covered by the health professionals themselves.

3.2.4 Drug samples, including starter packs

Drug samples are pharmaceutical products distributed by manufacturers or their agents to health practitioners. Starter packs are samples that can be provided to patients who are about to commence treatment. In some cases, samples may be sought by a clinician in order to obtain a drug unavailable on the Pharmaceutical Benefits Scheme (PBS), while in others, they may be used to provide immediate access to drugs in emergency circumstances, to allow safe escalation of starting doses, or to assess patient acceptability of medications.

There are different views in the community about the appropriateness of health practitioners accepting drug samples and starter packs from industry. On occasion, it is certainly argued that there can be benefits for patient care. Nonetheless, there can be no doubt that the provision of samples is primarily a marketing exercise that is intended to create relationships of reciprocity between clinicians and industry representatives, to accustom clinicians to prescribing particular products, and to establish cohorts of patients on long-term treatment with newer and often more expensive drugs. Further, employment of product samples often compromises the quality use of medicines and works against principles of rational prescribing.

It is sometimes claimed that the use of samples is justified by the inflexibility of prescribing regulations, which make no provision for short-term trials of the acceptability of new medications. However, while this argument has obvious plausibility, it is undermined by the fact that the persistence of the sample system actively limits attempts to establish regulatory regimes that are more readily adapted and applied to patient needs.

Key point:

24. The use of drug samples, including starter packs, from industry pharmaceutical representatives is often not in the best interests of patients.

3.2.5 Patient support and 'educational' programs

Some manufacturers have introduced 'support' programs that offer patients a range of services, including telephone helplines, 'educational' literature, access to websites and even additional medical treatments. Although such programs may facilitate optimal use of a drug as well as a measure of support to patients, clinicians should bear in mind that they also often function as promotional devices. As such, they have the ability to influence the attitudes of patients and health practitioners to

use particular medications and frequently contain information that favours the products or services of particular companies.
Support programs also create relationships between companies, practitioners and patients that can be used to support particular clinical and research objectives, including applications for public subsidisation of products. This may increase patient dependency, with potentially adverse consequences when a program is discontinued. Of particular concern is the possibility of direct contact between industry representatives and patients, which would undermine the independence of clinicians and the integrity of their clinical relationships. Accordingly, the conduct of 'support' programs should be carefully monitored by members of health care teams.

Practitioners who have the opportunity to enrol patients in industry 'support' programs or are asked to provide patients with information about these services, should consider the reliability of the information to be provided and whether patient care will indeed be meaningfully enhanced.

Key points:

25. Patients should be invited to participate in 'support' programs or provided with information about such programs only if they provide meaningful benefits and if the information provided is accurate and appropriate.
26. Health professionals should not facilitate direct contact between industry representatives and patients.
27. The conduct of 'support' programs should be carefully monitored by health care teams.

3.2.6 Off-label prescribing

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).
Off-label prescribing is particularly common in the treatment of rare or orphan diseases and in immunology, oncology, palliative care, psychiatry and paediatrics. In paediatrics in particular, many commonly used drugs have not been specifically tested on children so their use is categorised as 'off label' for this reason alone, even when it is fully accepted as routine.

In recent years, off-label prescribing has attracted substantial debate. On the one hand, it is argued that it is needed in order to speed access to drugs for new indications, ensure flexibility for clinicians and provide options for patients for whom alternatives are limited. It is also noted that off-label prescribing may be based on high-quality evidence that has simply not been presented to regulatory agencies for commercial or other logistical reasons.

On the other hand, a number of concerns have been raised about off-label prescribing, including that it is not always evidence based (or is based on 'low level' evidence such as clinical experience or anecdote) and can therefore put patients at risk; that it undermines pharmaceutical innovation, clinical

research and regulatory systems; and that it can add to health care costs. Another concern is that off-label prescribing is often the outcome of the promotional activities of pharmaceutical companies anxious to extend the market for their products. While industry promotion of off-label prescribing of their products is prohibited in Australia and elsewhere, such practices are common and are known to have significant effects on prescribing behaviour.

Given these potential dangers and untoward commercial influences, prescribers should always exercise caution about prescribing medicines for non-registered indications.

Key point:

28. Physicians should exercise caution in regards to 'off-label' prescribing, especially in unusual clinical situations and where alternative approved therapies are available.

3.2.7 E-health and the use of medical software containing advertising

Some software programs used by health practitioners to assist with clinical functions include the advertising of pharmaceutical and other products. When computers running such programs are positioned in such a way that they can be seen by patients during consultations, they may raise in the minds of the latter the possibility that their practitioners are subject to influence from industry or bias as a result of their associations with it. More generally, by allowing commercial values to intrude into relationships between doctors and patients, such advertising may undermine the key ethical assumption of the clinical encounter of the primacy and paramount importance of the interests of patients.

For these reasons it is recommended that, where possible, practitioners should choose software that does not include industry advertising or, when using such software, they should disable the advertising functions.

Key point:

29. Practitioners using software for clinical functions should consider programs that do not include industry advertising or should disable the advertising functions of their programs.

3.2.8 Use of therapeutic devices

Therapeutic devices are physical objects other than medicines that are employed by clinical practitioners for therapeutic purposes. A wide range of devices are available, covering many aspects of medical practice. They include, for example, devices to deliver asthma drugs, continuous positive air pressure devices for the treatment of sleep apnoea, cardiac pacemakers and stents, breast implants, artificial joint prostheses, and blood pressure and glucose monitoring devices.
Because they are produced in a commercial setting, the potential exists for dualities and conflicts of interest to arise, as is the case for medications. There are also issues relating to the advertising, promotion and sponsorship of therapeutic devices. Much that has been said about medications therefore also applies to devices.

Because the regulatory systems relating to drugs and devices vary, and because devices may also be promoted and used by health practitioners, there are additional issues that need to be considered. Clinical practitioners may have financial or non-financial interests in the development, manufacture or sale of devices. For example, they may hold shares in or receive payment of royalties from a company that produces a device. If they had been personally involved in the product's design, testing, refinement or commercialisation, they may also stand to gain benefits in the form of enhanced personal prestige or reputation.

A clinical practitioner may enter into a special arrangement with the manufacturer or distributor of a particular device or type of device. For example, special benefits, either in cash or in kind, may be provided in return for prescribing or using a device. Alternatively, an arrangement may be entered into with a manufacturer to provide a device at a favourable cost to patients, to the apparent advantage of both doctor and patients.

A practitioner who stands to gain financially or non-financially from the success of a new device may be inclined to recommend its use to patients. The obvious competing interests in this case may raise issues about the independence of the clinical judgment that is being exercised. In such cases, care needs to be taken to ensure adequate disclosure and, where appropriate, referral of specific patients to other clinicians.

A manufacturer or distributor of a device may also advertise directly to the public or offer special benefits, such as free medical assessments, as an inducement to use their product. This has the potential to place pressure on clinicians to use products, and may create or exacerbate any conflicts of interest of the clinician.

These examples illustrate distinctive ways in which commercial and other interests associated with devices can intrude into clinical practice. The non-pecuniary influences may be just as potent, although they may be less conspicuous to all parties. The examples given emphasise the importance of careful attention to the identification and disclosure of dualities of interests, associated with formal and transparent processes for review and management of any actual conflicts.

Relationships between clinical practitioners and producers and manufacturers of devices should be subject to the same transparency requirements as those with pharmaceutical companies. Individual interactions involving transfers of value between practitioners and commercial entities should be declared in a manner that is freely accessible to the public.

Key points:

30. Practitioners should declare to their patients, organisations and to the public any relationships with producers and suppliers of devices.
31. Practitioners should not obtain benefits from the sale of medical devices to their own patients.

3.3 Meetings

3.3.1 Support for meetings and other educational activities

Both the pharmaceutical industry and, increasingly, the biotechnology industry provide financial and in-kind support for the organisation of meetings and for practitioners to attend them. Other industries, including the complementary medicines industry, pathology companies and other commercial service providers, and professional and political associations, might also wish to provide support for meetings.

Support provided by industry organisations for meetings can include paying for speakers, venues, satchels, refreshments and exhibitions of pharmaceutical or scientific products. This support is usually provided with the stated aim of contributing to educational or scientific activities. However, there is evidence that the association of pharmaceutical industry support for such events can affect decisions clinicians make in their practices, with the result that these decisions are not always based on objective scientific data and therefore may not contribute optimally to patient care or population health.

Pharmaceutical industry support of meetings therefore carries a risk of influencing the capacities of clinical practitioners to make disinterested decisions on behalf of their patients. In view of this, great care should be exercised before accepting support from industries, even for validly constituted meetings or other educational events. The nature of industry support, and any obligations associated with it, should be declared openly to those who might have an interest in knowing. Where a meeting is organised directly by an industry sponsor, the presentations should as a matter of course be subjected to formal critical scrutiny in relation to the possibility of bias or incomplete information.

The best way for industry to support scientific meetings is through independent organising bodies which use the funds provided by industry to defray the costs of bringing in invited speakers, and for other purposes. To qualify as independent, an organising committee should be free of industry sponsor representation (which can be difficult to define for industries that are not clearly for profit - for example, where members of the association work in the military services, government departments or charitable organisations). The committee should also ensure that the relevant professional details of each committee member are placed in the public domain and dualities of interests both pecuniary and non-pecuniary are publicly declared.

The costs of travelling to, and attending, such meetings should in general be met by those who attend them because of their educational value. If they accept financial support outside these arrangements, individuals should determine that the meetings will have educational value, that they will not lead to loss of professional independence and that public scrutiny of them would not raise concerns.

In addition to clinical and scientific meetings organised by independent organising committees, industry organisations sometimes provide sponsorship to clinicians to participate in a variety of other events such as local meetings of specialist groups, hospital grand rounds, departmental scientific meetings, product launches and continuing professional development programs. While these meetings usually have a clearly defined primary educational aim, industry support may provoke suspicion that attendance will result in clinical decisions being influenced by associations with industry. Practitioners involved in organising or attending such meetings should have a high level of

awareness of this risk. They should take deliberate steps to ensure that the source and extent of sponsorship are fully disclosed (acknowledging that disclosure alone may not be effective in countering industry influence) and that the primary educational purposes of the meetings are achieved.

Before any form of industry support is accepted, the following questions should be considered:

- Will acceptance of support be likely to result in any actual or perceived loss of professional independence, either during or after the period of support?
- Is the proffered support genuinely and clearly linked to further education or ongoing professional development which is likely to benefit the community?
- Do the potential supporter's organisational history and practices, either locally or internationally, raise concerns?
- Have the criteria used to select invited speakers and delegates to an industry-supported meeting been publicly disclosed?
- Have the scientific and promotional components of the meeting been sufficiently separated by the organisers?
- Are there any dualities of interest that need to be declared?
- Would patients and their families be concerned by such sponsorship?
- Will the propriety of the sponsorship stand up to scrutiny by colleagues and the public?
- After consideration of the above, do the potential benefits outweigh the risks?

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.

Key points:

32. The nature of industry support and any obligations associated with them should be declared openly to those who might have an interest in knowing, including the public.
33. If possible, industry support for scientific meetings should be organised through independent bodies.
34. Meetings organised directly by industry should be recognised as promotional and critically scrutinised by organisers and attendees in relation to the possibility of bias or incomplete information

3.3.2 Where support is offered in return for a formal contribution to an otherwise independent scientific meeting or conference program

Industry support may be offered to individual health professionals to travel to meetings in which they will be involved as speakers, chairpersons or in other significant capacities such as contributors to the organisation of subsequent meetings. This form of sponsorship recognises the standing of the individuals and may be necessary if there is no other means by which these contributions can be recognised. However, it is important that the sponsorship is indirect, untied and fully disclosed. Support should be indirect. Where payments are to be made to individuals in return for participation at a meeting, such payments ought to be made by the independent meeting committee and not by the

industry sponsor. Payments should be commensurate with the services provided and not excessive as judged by the independent organisers of the meeting or others.

In general, it is inappropriate for health professionals to accept sponsorship directly from industry and independently of the meeting organisers. Sponsorship (either direct or indirect) to cover the cost of travel, attendance or meals for family or friends is never acceptable.

Support should be untied. Support that is tied to the promotion of commercial products or other industry concerns should not be accepted, even if payments are received via an independent organising committee.

It is the responsibility of individual practitioners receiving support from industry to ensure that any information or research presented at meetings is unbiased and in accordance with the accepted norms of scientific inquiry. It is important that such information or research does not lend itself to be interpreted (rightly or wrongly) as an endorsement of commercial products or other industry concerns. For example, practitioners ought to be careful to use product non-specific terms when presenting (e.g. drug class rather than drug brand names). Where reference to a specific product is unavoidable, the generic name should be used and both commercial trade names and mention of individual pharmaceutical and health technology companies should be avoided.

Before payment or an honorarium is accepted in return for participation in a meeting, it should be confirmed that the scientific and commercial (or other industry-oriented) elements of the meeting have been sufficiently separated. Speakers should declare dualities of interest at the beginning of their presentations, including direct or indirect support they have received to attend the meeting.
Support should be fully disclosed. Industry support received and used by a meeting organising committee to pay clinicians for their contributions ought to be fully disclosed and placed in the public domain prior to the meeting. Such disclosures should include:

- names and brief descriptions of the relevant activities of industry supporters
- statements of the nature and size of both monetary and in-kind contributions
- declarations by industry supporters attesting to the untied nature of their contributions
- statements by the committee regarding promotional rights granted in return for support (e.g. advertising space)
- list of criteria for selecting invited speakers or other participants who qualify for financial payments or honoraria.

Health professionals need to be careful about accepting payments from organising committees that fail to meet high standards of public disclosure about industry support. Particular care should also be taken for meetings that are not regular meetings of recognised professional societies, especially if there is no independent organising committee and the meeting is organised by industry. In these cases, it should be recognised that invitations almost certainly arise from the fact that for profit companies and, to some degree, not-for profit organisations, consider that clinicians' contributions will be to their benefit. In addition, the lack of an independent organising committee may call into question the independence of a speaker. If accepted, support for contributions to such events should be declared in accordance with the criteria above to hospital, university or other bodies with which the practitioner is affiliated.

Key points:

35. Practitioners should not accept sponsorship to cover the cost of travel, attendance or meals of family or friends.
36. Where personal support is offered in return for a formal contribution to a legitimate scientific meeting or conference program, it should be:
    - given indirectly, through an independent organising committee
    - not tied to the promotion of any commercial product or other industry concern
    - fully disclosed and agreed upon by the recipient organisation.

3.3.3 Where support is offered to a practitioner not making a formal contribution to a scientific meeting or conference

The distinction, familiar in educational settings, between those presenting educational materials and those in the audience receiving them, does not always apply exactly to scientific or clinical meetings, where audience members may often be actively engaged and contribute vigorously. However, the roles of presenters and of other attendees at a meeting are nonetheless different, and in relation to questions of industry sponsorship they are associated with different levels and kinds of risk.

While concerns about supporting speakers relate primarily to the likelihood of biased messages being promulgated, support for attendees is risky mainly because of the conscious or subconscious sense of personal obligation that may be induced. This is exacerbated by the fact that in cases where a formal contribution is not being made, sponsorship is almost always provided directly by a company to an individual. Under these circumstances, even if the potential educational value of the meeting is unquestionable, acceptance of support to cover travel and attendance costs is very likely to lead to perceived or actual conflicts of interest in subsequent decisions regarding the sponsor's products. As a result, both the risk of compromising the personal and professional standing of practitioners and the level of community concern about their conduct are high.

Accordingly, in such cases practitioners should exercise extreme care. If, after having considered the questions listed above, a health professional believes that accepting support in a particular case is reasonable, steps ought to be taken to reduce the risk of being unduly influenced. Agreement should be sought specifically from appropriate institutional committees (e.g. of a hospital, university or professional society) prior to acceptance of the sponsorship. The necessary public declarations should be made and be available for scrutiny.

Sponsorship of non-presenters to attend conferences or meetings may be less problematic where there is a clear separation between sponsorship, the decision to sponsor particular individuals, and the individuals themselves. This could be achieved, for example, by the industry sponsor creating a general fund that is managed independently by a third party (e.g. a conference organising committee).

As discussed above, it is always inappropriate for practitioners to accept sponsorship (either directly or indirectly) to cover the cost of travel, attendance or meals for family or friends. The principles for accepting group sponsorship for attendance at meetings and conferences are the same as for individuals. Group sponsorship in no way mitigates individual responsibility or ethical obligations.

Key points:

37. Non-presenters who accept industry support to attend conferences, should, where possible, seek agreement from appropriate institutional committees, make the necessary public declarations and be aware of the potential for such acceptance to influence their practice.
38. Where support is provided to non-presenters, ideally this support should be made available through a fund that is independently managed by a third party such as a conference organising committee.

3.3.4 Support for medical 'grand rounds'

Medical grand rounds are a time-honoured and valued institution within medical training and ongoing professional development. Grand rounds may also be expensive to run. Not only may funds be required to provide remuneration for an invited specialist or expert speaker, but organisers often wish to provide attendees with food and other incidentals in order to promote attendance.
Financial support for grand rounds should be sought from the clinical institution or from alternative sources, including attendees. This is especially important in teaching institutions because of the additional responsibilities to trainees and students.

If industry support is accepted, organisers should minimise any real or perceived conflict of interest by:

- insisting that all industry support is untied and fully disclosed
- ensuring that the industry supporter has no part in determining the speaker, subject or content matter for the grand round
- ensuring that all speaker dualities of interest are declared prior to the event
- ensuring that all content is presented in accordance with the accepted norms of scientific practice, including that all information be presented in an unbiased and balanced manner, especially where any product of the industry support is mentioned
- ensuring that any free food and incidentals provided are standard fare and do not detract from the primary educational focus of the grand round
- ensuring that displays of industry materials and interactions with industry personnel are kept to a minimum.

Key points:

39. Grand rounds should be funded by the clinical organisation.
40. Where no alternative is available, industry supporters should have no part in determining the speakers, subject or content.
41. All industry support should be disclosed.
42. The presence of any industry representation, including promotional material, should be in an area separate from the one where the event is taking place.

3.3.5 Support for local meetings of specialty groups and departmental scientific meetings

Given the relatively small size of such meetings, combined with the risk of the appearance of impropriety, health professionals and meeting organisers should question whether industry support is necessary, including for meals. Many of the costs for such meetings can be defrayed by nominal attendance fees and other organisational sources.

Where industry support is required for such meetings, individual practitioners and meeting organisers should take steps to ensure there are no real or perceived conflicts of interest. As stated above, all effort should be made to ensure that external support is indirect, untied and fully disclosed.

Key points:

43. Wherever possible, department meetings should be funded by attendees or other organisational sources.
44. Where no alternative is available, the industry supporters should have no part in determining the speakers, subject or content.
45. Industry representatives should be excluded from clinical meetings where identifiable patient information may be discussed.
46. All industry support should be disclosed.

3.3.6 Product launches

The primary purpose of product launches is promotional rather than educational. This premise should always guide decisions concerning access to such events. In teaching institutions, decisions about access should also take into account the additional educational responsibilities to trainees and students.

Key point:

47. Product launches should be recognised as promotional activities.

3.3.7 Meetings organised by industry

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. If the topic is likely to be of interest to a significant number of people, then professional bodies or other sources separate from the company may decide to advise their members.

An industry body might provide a speaker for a meeting primarily organised by health professionals. Use can be made of visiting speakers, but care should always be exercised in acceptance of such offers to ensure that an unbiased presentation will be made. Companies may be disinclined to provide speakers unless it is known that the speakers are likely to support the objectives of the company. If areas are known to be contentious, care should be taken to ensure there is an appropriate balance of speakers canvassing alternative views.

Key points:

48. Health professionals should not take responsibility for the organisation and promotion of any meeting in which a company selects and provides speakers.
49. The conditions under which support for a meeting is provided should be disclosed.

3.3.8 Company support for continuing medical education or continuing professional development programs

At times, industry might offer support for meetings that are presented as 'continuing professional development' (CPD) or 'continuing medical education' (CME). The principles described above should apply to such meetings, and efforts should be made to ensure that they are legitimate in the sense of maintaining a primary commitment to scientific and educational objectives. The main goals of such meetings should be educational rather than commercial. As previously stated, formal processes should be established to critically evaluate the content of such events and to ensure that they are free from bias.

Privately funded educational institutions are an increasing part of the CPD landscape. Clinicians and clinical organisations making use of the services of these institutions should be aware that they may be funded by industry. To minimise the risk of marketing masquerading as education, they should ensure that:

- all industry support for the CPD organisation, and any speakers they provide, is fully disclosed
- all content is presented in accordance with the accepted norms of scientific practice, including that all information is presented in an unbiased and balanced manner, especially where any product of the industry support is mentioned
- presentation slides prepared by industry or its agents are avoided
- food and incidentals provided are standard fare and do not detract from the primary educational focus of the meetings
- there are mechanisms in place to evaluate the content of the meetings, especially in relation to the integrity of the presentations and discussion, and that the results of these evaluations are made publicly available.

Key points:

50. Meetings supported by industry funds and branded as 'continuing education' should be held to the same standards as other kinds of meetings.
51. Clinical organisations making use of private CPD providers should audit the content of CPD sessions and be aware of, and demand disclosure of, any possible industry influence over the 'educational' material presented.

3.4 Employment, consultancies and remuneration for services

Practitioners are entitled to remuneration for their services except where their right to provide such services is limited by their conditions of employment. Remuneration for services provided to industry should be disclosed to patients and employers.

Health practitioners should not accept fees or equivalent considerations from companies in exchange for seeing them in a promotional or similar capacity.

In many employment settings, conditions are imposed on clinicians about what is considered acceptable or appropriate practice, including drugs available for prescription and the use of specific therapeutic devices. Such conditions may reflect limitations in resources or consensus views of

panels of experts. They may raise issues for clinicians who are concerned to find that in some cases the most effective treatments for their patients are not available for use.

3.4.1 Consultancies

Individual practitioners who provide services to pharmaceutical or other companies, including those in the investment industry, are entitled to fair remuneration for these services. Such relationships with industry often create dualities, however, which may raise the question of conflicts between duties to industry and to patients. For example, when a practitioner becomes publicly associated with the products of a particular company, the independence of his or her recommendations to patients in relation to all the products that are available may be questioned.
If a clinician acts as a consultant to industry, this fact should be public knowledge and reported to relevant committees, heads of department, employing institutions and patients. The relevant institutions in accordance with the procedures laid down in these Guidelines should decide whether dualities constitute a conflict of interest and what actions need to be taken to avoid compromise of the doctor's primary responsibility to patients.

3.4.2 Employment

Practitioners may be directly employed in industry or subject to contracts with other employers. They may as a result be subject to a variety of interests, including obligations imposed as conditions of employment. For example, industry may restrict communication of commercially sensitive information; managed care organisations may impose limits on the extent and kinds of treatments that are available or even actively intervene in clinical relationships to direct health practitioners' decisions; or hospitals may impose limits or restrictions on available treatments.
The implications of such employment arrangements have been discussed elsewhere. Where conflicts arise, health practitioners should inform their patients about the details that affect them and their implications. In some cases, practitioners may need to make decisions about whether it is ethical to continue to work in this setting.

Key points:

52. 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.
53. Membership of industry advisory boards should be disclosed in all relevant circumstances and recognised as a source of conflicts of interest.

3.4.3 Membership of advisory boards

Pharmaceutical companies and other institutional bodies often establish advisory boards to give advice about products or practices, including particular drugs or techniques. In the case of the pharmaceutical industry, such advice may involve all aspects of product development, from pre-clinical studies to marketing. Individual practitioners may appropriately contribute to such boards; indeed, this is one way in which they can use their clinical knowledge to increase the likelihood that therapeutic and other practices satisfy community needs.

To ensure that advisory board procedures are satisfactory, prior to their appointments practitioners should ensure there are formal, defined terms of reference, agendas for each meeting and that minutes are recorded and approved in accordance with usual practices. Members should be also satisfied that their involvement is meaningful, rather than purely symbolic.
It is possible that membership of an advisory board will encourage feelings of commitment to products, and sometimes to the organisation and its representatives. While such sentiments are common following any such collaboration, practitioners should ensure that clinical recommendations are based on sound principles. A health practitioner should not be subject to any obligation to prescribe a particular product or to take a particular course of action to make particular recommendations to other clinicians.

In view of the fact that membership of an advisory board poses questions of dualities of interest, members of such boards should openly declare their involvement. 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.

It is possible that in some circumstances an association with industry will be judged to lead to a conflict of interest and, therefore, to require that other activities of the practitioner involved are affected, for example involvement in a committee of a professional or government body or engagement in research. Outcomes might range from withdrawing from a particular discussion to withdrawal from the activity itself.

3.4.4 Endorsements and 'advertorials'

Clinical practitioners, particularly those who are regarded by members of industry as having special influence within their professional community, may be asked to make public comments supporting particular products, policies or courses of action.

There is an assumption in the community and among the patient population that health professionals are trained to analyse scientific evidence and to provide advice about health practices and community health needs. It is important to avoid using one's status and the good faith associated with it to promote commercial interests or the interests of other organisations when they do not support the welfare of the community or of individual patients.

It is necessary to distinguish between scientific comment and support for particular products. The context in which the comments appear may be very important. A paid advertisement from a company may legitimately quote comments made in a scientific publication. However, comments should not be provided for the express purpose of supporting the advertisement of a product. If a comment is intended as an educational contribution, the appropriate procedures should be followed.

The practice of providing endorsement of a product in the form of a public statement, sometimes called an 'advertorial', clouds the boundary between professional responsibility and commercial interest and is unacceptable (see also Section 4.6 below).

Companies promoting newer pharmaceutical products sometimes arrange presentations by practitioners willing to suggest that the use of older - and usually cheaper - agents may be undesirable due to their more severe side effects. Clinicians taking part in industry-sponsored presentations should not promote such suggestions unless they are supported by robust evidence.

Key points:
54. Physicians should not endorse specific products
55. Physicians should not participate in 'advertorials'

3.4.5 Agreements with pharmaceutical companies about choice of drugs for inclusion in hospital formularies

Hospital pharmacies (public and private) have a long tradition of receiving rebates (often financial) from industry when they dispense a particular medication. More recently, this practice has occurred with highly specialised drugs used under the PBS Section 100 program and can involve significant amounts of money (as an example, this behaviour commonly occurs with erythropoiesis-stimulating agents). When more than one drug is used for a specific indication and some of them have an associated rebate program, a hospital practitioner may be asked to consider:

- deleting one or more competing products from the hospital formulary due to storage problems, or
- limiting the prescribing of drugs without a rebate to maximise the institutions resources.

Despite the potential value of the rebate to the institution or to the clinical department, decisions should be based primarily on clinical efficacy and on what is in the best interests of patients. The cost to the PBS is an additional factor that should be considered.

Key point:
56. When choosing a medication for a hospital formulary, priority should be given to clinical efficacy in relation to patients' best interests.

3.5 Research and development

3.5.1 Enrolment of patients in research studies

It is desirable and appropriate for clinicians to be involved in research. When clinicians are also researchers, however, particularly in the clinical setting in which they practice, significant conflicts of interest may arise. These issues are discussed in detail in Chapter 5.

A particular issue for health practitioners is the recruitment of patients under their care for research in which they are personally involved. This raises the possibility of a conflict between the interest in conducting the research most effectively and that of making clinical judgments in the best interests of patients.

The Australian National Statement on Ethical Conduct in Human Research (NHMRC, ARC, UA, 2007 - updated May 2015), which provides guidance both for researchers and Human Research Ethics Committees, sets out the principles to be followed regarding consent and other issues in clinical research. These principles should be observed. While exceptions may apply for low-risk studies, it is

generally undesirable for health practitioners engaged in research involving their own patients to be primarily responsible for the process of seeking consent for participation from them. Information should be provided, and discussion about the pros and cons of involvement undertaken, either through or with the help of third parties who do not have direct clinical relationships with the patient involved. In the event that a patient of a researcher is recruited for a study, the researcher should explain clearly the nature of his or her involvement in the study; links with third parties including industry and the risks involved; non-pecuniary interests; and personal views on the pros and cons of this patient's participation.

It is important that patients considering participating in research projects are provided with opportunities to seek independent advice and that consent processes are undertaken by persons other than the clinicians primarily responsible for their care. In addition, where conflicts could arise in the conduct of such projects between the requirements of research and those of clinical decision making, it is essential that clear disclosures are made to patients, together with discussion of all available options. In many cases it is best for clinicians to withdraw from clinical management during the conduct of such projects, or at least from those aspects of them in which conflicts may arise.

Key points:

57. Where a clinician is involved in research that may recruit his or her patients, it may be appropriate for independent professionals to undertake formal recruitment of patients, discuss benefits and risks and obtain consent.
58. Physician-researchers should disclose their relationships with industry funders and any interests in the outcome of the research both to institutional Human Research Ethics Committees and to potential participants.

3.6 Publications

Health professionals involved in the publication process should be aware of the ethical issues that may arise there. Further discussion on this subject can be found in Chapter 5 and in other texts. Here, attention is merely drawn to the need for both authors and reviewers to declare relevant dualities and conflicts of interest. These includes sources of financial and other support, past and present, associations with sponsoring companies, and non-pecuniary interests associated with a research topic.

Key point:

59. Those involved in the publication process, whether as authors or reviewers, should declare all relevant dualities and conflicting interests, both pecuniary and non-pecuniary.

3.7 Health professionals and international health practice

Health professionals may become involved in overseas work in a variety of capacities: as clinicians working for aid groups, as advisers for government or non-government organisations involved in health-related activities, as clinical researchers in projects that include overseas sites, as academic researchers involved directly or indirectly in projects that involve overseas issues, or as editors of journals which publish material relating to developing countries. Each of these roles raises specific

ethical issues and health professionals should be aware of them. The most sensitive issues relate to developing countries.

In the international health practice setting, industrial players include overseas aid organisations, government and non-government organisations/bodies, which often support agendas that reflect their own local interests. Also, research institutes, members of the pharmaceutical, biotechnology and device industries, and universities may be engaged in overseas practice in support of the interests they represent.

At times, the various interests are difficult to define because of the number of parties involved, varying and sometimes conflicting intentions, and in the absence of formal relationships between patients and doctors. In addition, language and cultural differences may complicate relationships and communication about goals, purposes and values. Furthermore, constraints associated with limitations of resources may be severe.

Here as elsewhere, the primary interest by which actions or decisions are assessed should be the wellbeing of the individual members of the communities the professional intends to serve. In the public health setting, however, this often has to be delicately balanced with the welfare of the wider society.

The importance of effective communication and dialogue needs to be especially emphasised. Practitioners may find it very difficult to communicate with individual patients or community members. Cultural attitudes and religious practices may vary widely from those with which health professionals are familiar, based on their own backgrounds, residence and experiences. There may be discrepancies between the motivations and values of individual practitioners and funding agencies.

Health professionals working in this field are advised to seek detailed assistance as required. The following additional brief comments are intended merely to illustrate the scope of the issues that arise.

3.7.1 The pharmaceutical industry and international health practice

Concerns have been raised about exploitation of people from poorer countries by pharmaceutical companies. This may include non-observance of industry or practitioner guidelines, non-availability of key medications and, for workers, low wages and unsafe conditions. In places where pharmaceutical distribution is poorly regulated, the use of medications in the community may be inappropriate and excessive.

3.7.2 Research in the international setting

In research projects conducted by industry, issues may arise about community benefit, recruitment of participants, consent processes, coercion, use of placebos and availability of test medications after the conclusion of studies. Ethics approval for such projects should be obtained both from the institutions from which the researchers come and from the relevant jurisdictions within which the participants are to be recruited. If there is a chance that the standards of the various institutions involved in the research may conflict, in general, it is the more stringent of the various competing rules that should prevail.

3.7.3 Foreign aid

Practitioners may contribute to global health activities as advisers or mentors either based in their home country or when deployed in developing countries. Such work is important for addressing issues of health and poverty. However, it is also subject to the interests of funding agencies, including governments and private philanthropic foundations.

The agendas of foreign agencies themselves may be problematic because they are often driven by political, religious and social interests and because standards of oversight and probity may differ. Foreign aid can often result in unexpected and unwanted consequences owing to cultural, economic and political circumstances; accordingly, the sensitivities of local communities and practitioners need to be considered.

On occasions, overseas deployments can be associated with danger, either physical or psychological, to the practitioners themselves. Those involved in the planning and implementation of overseas aid programs should remain aware of this and take whatever action is needed to provide protection to aid workers.

3.7.4 Summary and conclusions

Practitioners working in overseas settings should carefully scrutinise their relationships with the various components of industry with which they engage and clarify the purposes and practices associated with their activities. The practitioners themselves should assume responsibility for the details of these relationships, including both the short and long-term associated consequences.

Key points:

60. Practitioners working in overseas settings should scrutinise carefully their relationships with the various components of industry with which they engage and clarify the purposes and practices associated with their activities.
61. The practitioners themselves should assume responsibility for the details of these relationships, including short and long-term associated consequences.
62. The primary interest by which actions or decisions are assessed should be the wellbeing of the individual members of the communities the professional intends to serve, although this does not exclude the importance of public health considerations about the welfare of the wider society.
63. Ethics approval for research projects should be obtained both from the institutions from which the researchers come and from the relevant jurisdictions within which the participants are to be recruited.
64. Those involved in the planning and implementation of overseas aid programs should take whatever action is needed to provide protection from physical or psychological danger to aid workers.

Chapter 4: Issues affecting trainees and students

4.1 Introduction

An important part of any educational program is the establishment of a lifelong commitment to learning, to the cultivation of habits of critical reflection and to ongoing relationships with respected colleagues and mentors. Institutions should pay attention to the achievement of such goals, especially in relation to the inherent values of learning and practice. This will involve particular attention to the core question of pecuniary and non-pecuniary interests.

Exposure of health care trainees and students to industry marketing and promotion influences the development of their attitudes and practices. Many of the issues raised in relation to qualified practitioners - for example, those concerning industry-sponsored travel to conferences or meetings, drug samples, meals, and receipt of gifts – apply equally to trainees and students and other members of the health professions. There are, however, some additional issues that arise specifically in the educational setting.

There is evidence that pharmaceutical promotion to medical students and postgraduate trainees is widespread, is accepted by trainees, and changes behaviour. Students may be particularly vulnerable to approaches by industry representatives because they are unfamiliar with the issues involved, lack the critical faculties necessary for evaluating them and, having limited financial resources, find small gifts and other perquisites attractive.

It should be one of the objectives in the education of health professionals (at the undergraduate, postgraduate and professional levels) to promote awareness of the issues regarding relationships with industry, including the importance of constructive engagements and the risks associated with pecuniary and non-pecuniary dualities of interest.

Key points:

65. The issues arising in relation to individual practitioners and researchers apply equally to students, trainees and teachers.
66. Health care education curricula should include learning about the ethical issues arising in relation to the role of industry in the health professions.

4.2 Development of an ethical culture that fosters critical attitudes towards relationships with industry

The environment in which education and training takes place has an important impact upon teaching and learning. Educational institutions, professional organisations, hospitals and individual practitioners should, therefore, seek to set good examples through their own practices. This may require avoidance of pharmaceutical sponsorship of grand rounds, clinical meetings and other events.

Hospitals sometimes encourage the use of certain pharmaceutical products or devices or restrict the use of others after negotiating with manufacturers or distributors in relation to cost. These actions may be interpreted, especially by trainees and students, to mean that the products supported have greater efficacy or safety than alternatives available in the community. Practitioners, medical educators and institutions involved in training should ensure that such arrangements are not misinterpreted by trainees and students. Students should be encouraged to reflect critically on the role of industry marketing on clinical policy and practice, especially the distribution of promotional material and industry-controlled presentations as well as their own possible unconscious bias.

Key points:

67. Training programs should include discussions about the role of industry, dualities and conflicts of interest, and the evaluation and interpretation of industry material.
68. The role of institutional policies and the practices of individual clinicians, teachers and mentors in shaping the behaviour of trainees and students should be recognised in the development of curricula.
69. Undergraduate and postgraduate medical education should include education about the extent of interactions between industry and health professionals, the impact of these relationships, the ethical issues that arise as a consequence, and strategies for managing risks and realising benefits associated with them.

4.3 Interests and responsibilities of educational institutions and societies

Institutions involved in education in the health care setting - including universities, professional societies and hospitals - have responsibilities both to their trainees and students and to the wider community to address the issues concerning relationships between practitioners and industry. These issues include both the content of teaching programs and the relationships the institutions themselves establish with various industrial organisations.

4.3.1 Content of teaching programs

A key objective of teaching programs should be to develop the abilities of trainees and students to think critically about both scientific and ethical issues, including those concerned with the nature of evidence and its relationship to clinical and research practice, the social roles and responsibilities of the professions, and the potential influences of industry on both practice and policy development. Teaching programs should also contain explicit discussion about the concepts of interests, dualities and conflicts of interests; the implications of relationships between the health professions and industry; and strategies to ensure that the purposes and processes of the professions are protected from inappropriate influences. It is important that the nature and potential significance of both pecuniary and non-pecuniary interests are covered and the conditions needed to ensure open, unobstructed dialogue in the clinical and research settings.

4.3.2 Relations between educational institutions and industry

As emphasised previously, health care education should be undertaken exclusively by organisations and institutions that are free from commercial obligations and agendas and should be distinguished from training or promotional activities associated with industry.

Educational institutions should establish clear and transparent policies regarding their relationships with industry. They should ensure that any activities in which they are involved, with educational content, are free from influence from commercial interests. This will generally require policies that separate the development of educational or scientific programs from the possibility of influence from pharmaceutical companies or other industry representatives in the manner specified elsewhere in these Guidelines. It may also require public disclosure of transfers of value between the institutions and industry.

Key points:

70. The relationships that educational institutions have with industry should be publicly declared and should be open for critique by practitioners, teachers, trainees and students.
71. Those involved in health professional education should declare the interests they have as a consequence of their relationships with industry. This information should be accessible to the professional education community, trainees, students and to the public.
72. Teaching materials developed by industry should not be used in health professional education.
73. Hospitals, universities, academic medical institutions and medical centres should discontinue the practice of pharmaceutical company-funded lectures and meals.

4.4 Interactions with pharmaceutical representatives

Marketing strategies of pharmaceutical companies often target undergraduate students and postgraduate trainees, who as a result may be less sceptical of the claims made by industry. In spite of this, trainees and students often do not believe that their own prescribing habits will be influenced by pharmaceutical industry interactions.

Trainees and students should be encouraged to be cautious regarding their interactions with industry and should consider carefully how they wish to conduct such interactions throughout their working lives.

Key points:

74. Educational institutions, including universities, colleges and hospitals, should be encouraged to prohibit formal contact between trainees and students and pharmaceutical representatives.
75. Interactions with pharmaceutical sales representatives should be avoided at clinical teaching sites.
76. The general principles that apply to health practitioners should also apply to trainees and students.

4.4.1 Gifts, travel and attendance at meetings

Trainees and students should in general not receive gifts of any kind from industry. This includes medical equipment, food and entertainment, drug samples, travel support and support for student organisations and publications.

Hospitals, universities, academic medical institutions and medical centres should not accept pharmaceutical company-funded lectures and meals.

Exceptions include formal grant, award or exchange programs administered through a third party, as these are provided according to clearly stated guidelines and subject to auspice by professional or educational bodies. In cases of uncertainty, an ethics committee may be consulted.

Key point:

77. Gifts from industry should not be offered to students and postgraduate trainees and they should not accept them. Exceptions may include formal grants, awards or exchange programs administered through a third party, with no sponsor involvement in decisions concerning which trainees and students are awarded the grant.

4.5 Supervision, mentoring and continuing professional development programs

As discussed in Chapters 3 and 4, continuing educational programs are potentially subject to influence from industry providers in a manner that may distort their content and compromise their educational value. It is desirable that such programs remain under the supervision of independent, disinterested educators committed primarily to discharging their pedagogical responsibilities. The conditions discussed previously in relation to such programs should be rigorously observed.

4.6 Need for specific policies regarding trainees and students

It is recommended that policies be devised by institutions involved in health professional education about ethical issues relevant to trainees and students, postgraduate trainees and their teachers. Hospitals, universities, academic medical institutions and medical centres may need to give consideration to sponsorship of meetings and grand rounds, and individual practitioners involved in training may need to review their personal approaches to the use of promotional materials. It is important that teachers and mentors provide good examples to trainees and students in their own personal attitudes and behaviours.

Key points:

78. Institutions involved in health professional education should develop policies covering sponsorship of meetings and grand rounds and the use of promotional materials.
79. Teachers and mentors should consider the examples they set to trainees and students in their personal attitudes and behaviours.

Chapter 5: Issues affecting institutions and professional societies

5.1. Responsibilities of institutions and societies

Professional societies and health-related industries may establish mutually beneficial relationships. Societies may receive financial or other support from industry for publications, meetings, conferences and educational programs. Industry may, in turn, have the opportunity to showcase their products to a sophisticated and responsive audience. In addition to receiving money directly from industry, societies that allow companies to market products such as credit cards, insurance and stationery might receive royalties from any products sold. Societies might also be paid for the sale of their membership lists and may participate in the marketing of products related to medicine or health care. Council and committee members may have shareholdings in companies. All of these arrangements have the potential to create conflicts of interest.

The relationship between the professions and industry raises sensitive professional and public concerns because associations between societies and industry can compromise the societies' objectives and damage their public standing. Indeed, the mere fact of a society's association with industry may undermine its standing as an independent, disinterested contributor to debates about health and health policy.

Societies should, therefore, take care to ensure that their objectivity or public standing is not compromised by corporate or other sources of income. Dualities of interests should be disclosed in a transparent, timely and comprehensive manner, as described below.

5.2 The requirement of transparency

Detailed disclosure of interactions between individual practitioners and industry are becoming standard in Australia, New Zealand and in many other countries. Typically, responsibility is imposed on industry to provide publicly accessible data regarding direct and indirect payments, or other transfers of value to health care professionals. Industry also has a responsibility to provide data about direct and indirect payments to third parties made at the request of, or on behalf of, health care professionals. Payments to be reported include consulting fees; payments for other services, including those of an educational or teaching nature; honoraria, irrespective of whether these are received directly by the individual or are directed to a nominated trust fund, research fund or charity; provision of food and beverages; travel and accommodation; educational expenses; charitable contributions; royalties or licence fees; and research and other grants.

Professional associations should consider themselves subject to the same requirements of transparency as individual practitioners. That is, receipt of benefits or other transfers of value from industry - including government and non-government sources - by either a society or its individual members, should be fully disclosed and open to adequate public scrutiny.

To meet the requirement of transparency, organisations should establish mechanisms for the detection, management and public disclosure of relevant interests. In the case of individual practitioners, these mechanisms should include sufficient safeguards to ensure the accuracy of the data and the protection of the privacy of individual society members.

5.3 Conflicts of interest involving officers of a society

Officers of a society, including members of its council and committees and employees and volunteers, may have either pecuniary or non-pecuniary interests relevant to their roles within the society. These interests may take the form of shareholdings or paid consultancies, other commitments in the form of advisory positions, scientific collaborations, or any of the full range of pecuniary or non-pecuniary interests discussed above (see, for example, Sections 2.2 and 3.1.1).

In these cases, the general rules for dualities and conflicts of interest should be applied; that is, that the dual interests should be declared, that an appropriate body should assess whether a conflict exists and, if the latter turns out to be the case, that appropriate action is taken.

If action is required, the nature of this will depend on the circumstances. Action may vary from the mere acknowledgment of the interest to withdrawal from participation in the body in question. Although those who participate in the activities of a society are entitled to privacy, this should be balanced against the need for the society members to be confident that their interests are being appropriately served.

As in other cases of disclosure, appropriate standards of transparency should be applied to ensure both the possibility of adequate scrutiny and protection of the privacy of the individuals involved.

Key points:

80. Professional societies, including The Royal Australasian College of Physicians, should have in place processes for the declaration, management and public disclosure of relationships with industry, and of the competing interests of members and office holders.
81. These processes should apply to employees and office holders, as well as to the members of the professional societies.

5.4 Membership of disease-specific community health organisations

Many health professionals are involved with community-based organisations that deal with specific diseases such as cancer, asthma, diabetes or heart disease, or deal with specific sub-populations, such as Indigenous health organisations. Since many of these organisations are established by industry, work collaboratively with industry, support industry applications for registration and funding, and/or attract significant industry funds, their views and activities might be oriented towards, or influenced by, commercial imperatives. Clinicians working with community health organisations should therefore be aware of the specific links that these organisations have with industry; clarify the organisation's policies with respect to industry; encourage the organisation to develop guidelines and policies for involvement with industry and declare its involvement with industry; and ensure that they maintain their own independence when associating with community organisations. Clinicians should also ensure that any community-based educational programs with which they are involved are free of bias.

Membership by clinicians of community organisations may present interests that need to be disclosed in particular settings. The individuals concerned should be aware of this and, where relevant, disclose involvement and implied or incurred obligations.

Key points:

82. Health professionals and medical organisations should be aware of the ties between community-based organisations and industry.
83. Health professionals who interact with these organisations should take steps to avoid inadvertently privileging commercial imperatives over patient welfare, and to ensure that educational programs with which they are involved are free of bias stemming from sponsorship relationships.
84. Appropriate firewalls should be maintained between professional societies and disease-specific community health organisations and industry sponsors to prevent conflicts of interest.

5.5 Meetings

5.5.1 Where the professional association or organisation is organising and funding the meeting

At times, professional associations and clinical organisations ('organisations') might want to arrange research conferences or educational sessions, and are in a position to fund these meetings themselves without external financial support. In these situations, organisers should ensure that the scientific, political or other commitments of the organisation and its office holders do not inappropriately influence the content of the meetings. An organisation's support of a meeting should be appropriately disclosed to meeting attendees.

Key point:

85. Where the professional association or organisation is organising and funding the meeting:
    - The scientific, political or other commitments of organisations and office holders should not influence the content of educational or scientific presentations.
    - Organisational support for scientific/educational meetings should be disclosed to attendees.
    - Speakers at these meetings should disclose any relevant interests at the time of their presentations.

5.5.2 Where the professional association is seeking external commercial support for a meeting

Sources of commercial funding should not influence the scientific, educational or public policy decisions of societies. In situations where professional associations and health care organisations wish to seek external commercial funding to support their meetings, the association should convene an independent organising committee and adhere to the principles outlined in Section 3.3.

In particular, commercial supporters should not be able to influence the planning, content, speaker selection or execution of any program of a society, and commercial sponsorships should not influence the subject matter of any meetings arranged under its auspices. It should be made clear that the display of commercial products or services at society meetings, and advertisements in a society's journals or social event sponsorship, does not imply warranty, endorsement or approval of the products or services. It should also be made clear that such promotion is in no way an endorsement of effectiveness, quality or safety of the products or services.

Key point:

86. Where the professional association is seeking external commercial support for a meeting:
    - Commercial supporters should not influence the planning, content, speaker selection or execution of a society's program or the subject matter of presentations.
    - Support for organisational activities by commercial organisations should be treated with caution.

5.5.3 Where the organisation is convening meetings to develop policy

There are various special settings in which particularly complex issues of sponsorship may arise. These include conferences convened to discuss specific clinical or scientific issues and meetings of experts to develop clinical and public policy guidelines. These may be sponsored by professional societies or organisations or by external commercial industries.

Because policy and practice guidelines may, by definition, have greater impact on the design and delivery of health care than educational or scientific meetings, a greater degree of caution should be exercised regarding any possibility for commercial or political interests to influence these processes.

Nevertheless, the general rules described above apply. Outside funders of an event should have no influence over its content, over selection of speakers or participants, or over the content of reports or other documents, recommendations, guidelines or policies produced as a result. In general, individual societies should review, and accept responsibility for, any such documents.

Clear and rigorous rules for disclosure should be established for all such meetings, and should be publicised in relevant documentation. It is desirable for participants to include a majority with no pecuniary or non-pecuniary conflict of interest in the matter under study. Individuals with conflicts of interest may participate in such events as long as the appropriate public disclosures are made. The disclosures should also be appropriately managed by a planning committee that is independent of influence by commercial sponsors.

Key points:

87. Where the organisation is convening meetings to develop policy:
    - External funders of events in which policy or practice guidelines are developed should have no influence over the content, selection of speakers or participants or the content of reports, recommendations or guidelines produced as a result.

5.5.4 Support for association members who wish to attend external meetings

It is appropriate that professional associations and health care organisations (rather than industry) provide funds for members, students, trainees and staff members to attend or present at educational or scientific conferences, provided that the selection of the recipients is equitable and transparent.

In cases where members of the organisation are offered commercial funding to attend meetings, they should disclose this to, and obtain permission from, the organisation, which should have relevant policies and procedures in place. The principles outlined in Chapter 3.3 should be applied.

Key points:

88. Professional associations and organisations should endeavour to fund health care professionals to attend meetings as part of their professional development and education.
89. Organisations should have processes in place to monitor situations in which members or employees are offered external funding to attend educational and scientific meetings.

5.6 Educational activities

5.6.1 Training programs

As with other activities sponsored by industry, in the case of educational programs – including continuing professional development (CPD) programs (sometimes also referred to in the medical context as 'continuing medical education' (CME) programs) – there is convincing evidence that sponsorship alone often influences both the content of these programs and the effects they have on the behaviour of those who undertake them. Furthermore, because the conduct of educational activities is often a core responsibility of scientific and clinical societies, the independence of these programs is of profound importance both for the members of the societies and for the broader community.

Internationally, there has been a tendency for CPD to be delivered by for-profit companies that have strong links with the pharmaceutical industry. In Australia, it is increasingly common for meetings of purported educational intent to be organised by commercial entities for the achievement of profit, or for events of an obviously promotional kind to be referred to as an 'educational' activity. Industry-funded CME that is designed for promotional purposes should not be disguised as education or science.

By its very nature, education cannot be subject to commercial or other sectional interests. Accordingly, in general, the use of the term 'education' should be restricted to contexts that are free of such interests. The activities of industry in providing information about their products – for example, distributing materials that argue a specific case for a particular product with which they are associated, and conducting training programs in relation to the use of equipment supplied by them - should be distinguished from education and recognised as serving other purposes. It is important that adequate measures are taken to ensure that educational programs undertaken under the auspices of professional associations are free from the possibility of bias of any kind towards commercial sponsors and that the community can have full confidence that this is the case.
This means that for any such program:

- The group responsible for organising it should include a majority of individuals who do not have relevant conflicts of interest.
- Clear rules of management of dualities and conflicts of interest should be observed within the organising committee.

- High standards of transparency should be maintained, with public disclosure of relevant interests of the organising committee.
- The scientific, clinical and educational content should in no way be affected by the presence or nature of commercial sponsorship.
- Speakers should be meticulous about declaring dualities and conflicts, and steps should be taken to ensure that their presentations are balanced.
- Processes should be established to assess the outcomes of the programs, including provision for feedback regarding possible biases from course participants.

Various mechanisms are available for ensuring that the above conditions are met. It is desirable that educational programs sponsored by a society do not involve industry support at all. However, if this is not possible, such support should be paid into a fund that is available to the society to conduct these and other activities. The process of negotiating with industry sponsors should be separated from that of designing the program. It is inappropriate for receipt of sponsorship support to be made contingent on conditions of any kind regarding choice of speakers or topics or inclusion of particular content.

The organising committee should adopt procedures to ensure that individuals with conflicts of interest may provide input into discussion, but should not participate in the actual decision-making process relevant to that issue. The committee should be able to provide a formal undertaking that the scientific, clinical and educational content are in no way affected by the presence or nature of commercial sponsorship. Alternatively, if this is not possible, the committee should provide a written statement of the way in which such sponsorship did affect the program content.

Clear guidelines and disclosure statements should be provided to prospective speakers and other teachers. When speakers have conflict of interests, their presentations may be subjected to review before delivery by a reviewer without such conflicts to ensure that it is balanced.

The policies and practices that have been adopted for a particular program should be open to public scrutiny. Independent observers, who can provide a disinterested assessment of the outcomes, should be identified.
It is the responsibility of the institution accrediting an educational activity to ensure that accreditation of a particular activity implies that the activity was free of inappropriate biases related to industry sponsorship or representation.

Key points:

90. The institution accrediting an educational activity should be responsible for ensuring that the activity is free of biases related to industry sponsoring or presentation.
91. Clear guidelines, which include requirements for clear disclosure statements, should be provided to speakers.
92. The organising group should include a majority of individuals without conflicts of interest, and conflicts should be managed within the operation of the committee.
93. Measures should be adopted to ensure that the scientific, clinical and educational content is not affected by the presence or nature of commercial sponsorship.
94. Processes should be established to assess the outcome of the programs, including provision for feedback regarding possible biases from course participants.

5.7 Endorsements

5.7.1 The concept of endorsement

The term ‘endorsement’ is used to refer to a statement of support or approbation from an individual or organisation for a product, recommendation or some other object or course of conduct by which the individual or organisation assumes a degree of responsibility for the ensuing outcomes. This responsibility includes decisions by a society to approve or participate in a particular activity or to provide public support for a particular event, activity or product that has been planned or developed by an outside entity. These may include participation in consensus conferences to develop clinical guidelines and position statements; to endorse publications or educational activities not developed by the organisation; or to provide links in websites to such publications or educational activities.

The practice of endorsement raises a range of ethical issues, mainly relating to the processes according to which the original activities or products were generated, and how the various interests involved were managed at the time. Endorsement may involve material and other support, such as marketing assistance, and it may result in some benefit or advantage to the society in return for the assistance provided.

5.7.2 Endorsement of statements or communiqués generated by conferences

Such conferences (previously referred to as ‘consensus events’) include ‘state of the science’ conferences, ‘expert opinion’ conferences and ‘best practices’ conferences.
When endorsing the outcomes of such conferences, societies should consider whether they are satisfied that the processes according to which the conferences were organised and managed conform with the principles outlined in these Guidelines, in particular, whether outside funders have had any influence over the content or conduct of the event, the selection of speakers and participants, or the content of reports or other documents they produced. In addition, societies should consider whether such events have followed the appropriate procedures for disclosure and management of interests relating to each of the issues and topics discussed. These procedures should be fully documented in the body of relevant reports.

5.7.3 Endorsement of clinical guidelines

A role of professional organisations is to inform and educate the public and government about specific issues concerning medicine, science and clinical practice. From time to time, this may require taking positions in relation to the nature and consequences of particular health problems and treatments. This could include support for specific therapeutic agents or endorsement of clinical guidelines that support particular therapies.

The development of statements of endorsement of guidelines or treatments should be undertaken with great care to avoid compromising the objectivity and credibility of the organisation in the eyes of the broader community. Rigorous policies are needed concerning the processes according to which such statements are generated and reviewed. These policies and processes should ensure that in each case statements are based on relevant evidence; the conditions under which they were prepared included appropriate management of dualities; and any contributions from industry in support of their preparation are provided through arrangements that ensure the processes remain free

of influence and are fully disclosed. Conditions should be satisfied where endorsement of statements or policies developed by other societies is considered similar.

Endorsement of clinical guidelines may be appropriate if the following conditions are satisfied:

- The evidence on which the various statements in the guidelines are based was gathered and assessed using methods such as those of the Cochrane Collaboration or an equivalent body.
- The guidelines will be reviewed and updated according to a defined schedule.
- Appropriate processes for disclosure and management of interests will be employed in the production of the guidelines.
- In particular, there has been no influence from pharmaceutical or other for-profit industry representatives.

5.7.4 Endorsement of other publications or materials produced by outside organisations

The principles described above also apply to materials derived from other sources, including other professional societies, government bodies and community groups.

In all these cases, care needs to be taken to ensure that both pecuniary and non-pecuniary interests have been appropriately managed. Materials generated by religious or political bodies, or community groups advocating for particular issues or points of view, are especially susceptible to biases. Care should be exercised when considering whether to offer support to such organisations.

In general, it is desirable that such materials are produced by committees or groups in which the majority of participants do not have a relevant interest at a level that is likely to compromise their judgments or decisions. Procedures should also be adopted to ensure adequate disclosure and management of interests, and that outcomes are appropriately documented and annotated to advise how this was achieved.

Key point:

95. Policies and processes should be in place to ensure that the preparation of statements of endorsement involves examination of the relevant evidence, appropriate management of dualities and conflicts of interest, and scrutiny of the statements, to exclude inappropriate industry influence.

5.8 Involvement of organisations in overseas activities

As discussed in Section 3.7, individuals and organisations may be involved in overseas activities in relation to clinical practice, education, research and business or other activities. Educational institutions may have their own interests in relation to international activities, which may provide important sources of revenue. They have a responsibility both to trainees and students and to employees to ensure that their own commercial interests do not adversely or inappropriately impact on educational values.

Organisations working overseas need to be mindful of specific legal, cultural, religious and political issues that might arise. These may be of particular importance where the work involves engagement

with vulnerable communities. Care must be taken to ensure that activities are undertaken with proper respect for local standards and traditions and that the professionals who engage in them have adequate cultural training. In some cases it may be appropriate to establish special processes for consulting with local communities and for reviewing decisions and practices that might raise cultural or legal issues.

Issues involving cross-border research are discussed above, and in national codes and regulatory documents. The principles that guide research in Australia and New Zealand apply equally for Australian and New Zealand researchers conducting their work in other settings, subject to the need to abide by local cultural and other requirements.

Key point:

96. Institutions involved in overseas work should develop policies to ensure adequate attention is given to the protection of both the communities with which they are working and their own members who are offering services or conducting research.

5.9 Publications

Professional societies often contribute to the development of the understanding of medicine and other aspects of health care by financing the publication of scientific journals or other newsletters. In these settings, like the others discussed above, it is possible that both pecuniary and non-pecuniary conflicts of interest may arise. These include circumstances where editors, reviewers or others involved in the publication process have a personal interest in the content of an article submitted for publication: for example, when a reviewer working in a similar area could benefit from delaying the publication of the article in question, or when editors could benefit from promoting their own work. Because journals often obtain significant earnings from advertising and from reprints bought by companies for distribution to health practitioners, the possibility also arises of such payments influencing editorial decision making.

Journal editors should adhere to the principles of the International Committee of Medical Journal Editors or to other standards on which their editorial boards have agreed. Authors' disclosures should be required in all cases and published together with the corresponding articles. Reviewers, editors and committee members associated with publications should be asked to declare dualities of interest. Persons with significant conflicts of interest should be excluded from consideration of the manuscripts involved. Journal editors should also recuse themselves from reviewing work in which a conflict of interest exists and transfer this responsibility to other appropriate parties.

In general, the sale of display advertising space is a legitimate source of revenue for professional journals. Advertising should not in any way influence decisions on editorial content. Decisions on the positioning of advertisements should be made independently of decisions made in the editorial departments on the content of a specific issue. Readers should be able to distinguish between advertising and editorial content. Submitted advertisements should be subject to approval by a medical panel, the members of which are cognisant of relevant standards. Advertisers are responsible for ensuring that advertisements comply with relevant laws.

Key points:

97. Journals should establish clear policies that conform to international standards for author disclosures, review processes and advertising and other sources of support.
98. Income from the sale of reprints should be disclosed to readers.

5.10 Conclusions regarding issues arising in relation to societies and institutions

The independence of professional and scientific societies may be affected in a number of ways by relations with industry. These relations may involve individual members, employees or the society itself. In all cases, care should be taken to ensure that appropriate mechanisms are available to deal with the particular issues.

Dualities and conflicts of interest in the conduct of the business of such societies should be approached in a systematic manner, which should, at the very least, include the following steps:

- Establishment of a defined process for identifying dualities and assessing their potential to constitute conflicts and, if necessary, developing strategies in response.
- Disclosure of financial and other interests in an appropriate manner.
- Assessment of which interests are potentially relevant and examination of potential for conflict.
- In the case of conflict, development of strategies to avoid compromising either the individual involved or the work of the society/institution/college.
- Public communication of the outcomes of the process in appropriate ways.

Societies and institutions should establish mechanisms to ensure transparency in their relationships with industry, which will normally include provision of information in a publicly accessible form. Additionally, societies and institutions may wish to consider the principles highlighted in these *Guidelines* to develop their own policies and procedures.

Chapter 6: Issues affecting research

6.1 Introduction

All stages of biomedical research are influenced by their sources of funding. An extensive literature addresses the ways in which the design, conduct, outcomes and publication of research may be affected by industry support and, importantly, by researchers' relations with industry, especially the pharmaceutical industry. This might take the form of researchers receiving financial or in-kind support to conduct a study or recruit participants, or being employed directly by a company. Matters are complicated further by the increasing involvement of individual researchers in the commercialisation of their own work, and increasing acceptance that they may retain intellectual property, hold patents and maintain shareholdings in pharmaceutical or biotechnology companies related to their research. These circumstances raise particular questions about the independence of research and the reliability of data that are made available to the public.

Non-pecuniary interests also have the potential to impact negatively upon the independence and reliability of research and its dissemination. Researchers may, for example, be tempted to distort the design, conduct or publication of research because they are intellectually committed to a particular hypothesis, wish to protect their academic or clinical reputations, or need more publications for academic advancement. In many cases, these may be more significant than financial considerations.

While competing interests may not themselves result in harm to others involved in research, they may raise concern because of their potential to do so. In addition, they may complicate the process of interpreting the presentation of research results and impair public confidence in medical research.

These issues apply both to clinical and basic research. The vast majority of clinical trials are funded by the pharmaceutical industry. Clinical researchers may benefit directly from their research financially through payment for work performed in enrolling and managing patients in industry-sponsored studies or indirectly through investment in, or ownership of, companies sponsoring clinical trials, as a result of which they may have beneficial interests in the outcomes of these trials. They may also benefit from their research through non-financial means, as discussed above. Opportunities to profit from clinical research financially or academically may affect or appear to affect researchers' commitments to their primary obligations to pursue new knowledge or understanding through research, and to protect patients' and research participants' interests. Competing or conflicting interests may influence study design (including selection of study drug doses and comparison with placebo or active comparator), patient selection, data collection and analysis, adverse event reporting, or the presentation and publication of research findings. Financial conflicts may also arise when an investigator becomes involved in a commercial venture that may impinge on other aspects of his or her research.

The arguments about whether investigators with direct financial interests in the outcomes of research should be permitted to participate in such research are complex, as indeed are the organisation and structure of individual research projects. It is important that this complexity is appreciated and that a flexible approach is maintained. In individual instances, it is often possible to identify specific moments in the research process at which dualities may become conflicts and to devise specific strategies to protect the integrity of the research process.

This document does not purport to provide a comprehensive guide for the conduct of research or of the business of Human Research Ethics Committees: for this, readers should refer to the relevant extant publications. However, it is recognised that in such publications, the relationships between individual researchers and other practitioners involved in the conduct of research and industry are often either not well covered or do not contain sufficient detail to provide guidance to researchers working in particular settings. Accordingly, the following notes and recommendations are intended to enhance existing practices and provide a practical guide to practitioners.

6.2. Responsibilities of investigators

6.2.1 Overview of responsibilities of researchers

The responsibilities of investigators paid to conduct or recruit patients for clinical trials are treated in detail elsewhere, but are summarised here. Many of these principles would apply even to investigator-driven research, where non-pecuniary interests can cause similar distortions. To guard against dualities becoming conflicts, investigators and Human Research Ethics Committees should consider:

- Whether the questions to be addressed by the proposed study are sufficiently important to justify the involvement of participants. For example, is it merely a promotion to familiarise health practitioners with a drug or device to encourage a particular brand usage, or a commercial undertaking to permit drug registration in the absence of any substantive scientific content? If so, researchers should reconsider their involvement.
- Whether the discomfort and inconvenience or risks, to which participants are to be exposed, are justified by the benefits of the study, taking into account the nature of the project, the participant population to be studied and the likely benefits.
- Whether the design of the study is appropriate and will meet the study's objectives, including whether the use of placebos as comparators is justified when there is available treatment that has been clearly shown to be effective; this is of particular importance when the test drug is related to a currently available medication.
- Whether patients will be able to consent freely to participation and whether other consent issues are satisfactorily addressed.
- Whether relevant social or cultural issues are adequately taken into account.
- Whether the information to be provided to patients includes an adequate description of the nature of the project and any risks or potential discomfort associated with it.
- Whether potential participants are likely to be subject to any form of coercion.
- Whether payments to research participants are large enough to constitute an inducement to participate in the project.
- Whether the institution has the resources (investigations, bed usage and staff time) to conduct the research to a high standard.
- Whether there is adequate separation between funders and researchers, and researchers have control over the conduct and publication of the research.
- Whether the results are going to be published, regardless of the outcomes of the trial and all data will be made available to other researchers.

All research projects involving human participants should be in accordance with relevant guidelines published by the National Health and Medical Research Council (NHMRC), the Therapeutic Goods Administration, the Health Research Council of New Zealand, the World Medical Association and other relevant bodies, and should be assessed by a Human Research Ethics Committee, which is

constituted and functions in accordance with the *National Statement on Ethical Conduct in Human Research (NHMRC, ARC, UA, 2007 - updated May 2015)*. Since payments to investigators, departments and institutions have ethical implications, the Human Research Ethics Committees should be made aware of financial arrangements for research projects and specially sponsored clinical trials, including proposed payments to researchers and research participants. If physicians are to receive payments for assisting with the recruitment of a research study, the details of such payments should be disclosed to potential participants. In addition, the provision of other resources required to carry out the study should be explicitly declared according to institutional ethical and governance guidelines.

Where there is a competing interest, because researchers or their departments are being compensated, paid to conduct research or recruit participants, or have interests in the outcome, the following steps should be followed:

- Competing interests should be fully disclosed by the researchers and considered by the relevant community or communities, in this case usually a research ethics committee or the researchers' organisations.
- An assessment should be made concerning whether competing interests constitute a conflict of interest and, if so, how likely the conflict is to distort the research process.
- The decisions and practical outcomes of these deliberations and actions should be communicated to the constituency affected, including fellow researchers and research participants.
- Competing interests, whether financial or non-financial, should be disclosed to research participants; to regulators as required by statute or regulation; to research funders or sponsors; to the editors of any publications to which manuscripts concerning the research are submitted; and in any substantive public communications of the research results, whether oral or written.
- Where conflicts arise, special arrangements may need to be created to separate the different roles and interests of the researchers; these will often include the appointment of independent researchers to approach and interact with participants; 'arm's-length' processes to collect, store and analyse data and to monitor safety; and the development of clear policies regarding publication and dissemination of results. The specifics of these arrangements will depend on the nature of the conflict and the structure of the research project itself.

Key points:

99. Competing interests should be disclosed to all relevant parties, including participants and the public.
100. The different roles and interests of the researches should be kept distinct in order to protect the integrity of the research process and research participants.

6.2.2 Responsibilities where a researcher is offered financial compensation for being an investigator in a clinical trial

Researchers involved in industry-funded studies may receive financial compensation for their roles as investigators. This can take the form of direct payment for services, compensation for personal and departmental expenses, gifts or untied funds, and financial incentives for recruitment of participants. At all times, the benefits a clinician or department gains from the conduct of an industry-sponsored clinical trial should be subject to review and approval by an appropriately constituted ethics committee.

It is appropriate that adequate compensation is provided for personal expenses arising from the trial, including reimbursement of practice expenses where applicable. The amount of compensation should reasonably relate to income or time lost, bearing in mind that the meaning of what is 'fair payment for services rendered' may be ambiguous. Any assistance received for a project should be paid into a specially designated fund established for the conduct of research, which is subject to auspice and audit according to established institutional guidelines. Other uses of these funds should adhere to the institution's arrangements.

Financial incentives for the recruitment of patients, whether in the form of payments on a per-capita basis or of other arrangements, directly raise the possibility of a conflict between the research and clinical responsibilities of a physician and his or her financial gain. For this reason, such arrangements should be specifically approved by a responsible ethics committee and care should be taken that participants are included in the trial only according to the approved protocol and inclusion is not influenced by the payment system. All payments to clinician–researchers or the departments in which research is conducted should be fully declared to trial participants.

Research consent forms should also disclose the existence of any other significant financial interests or any other relevant relationships between the researcher and the company. In no event should referral ('spotter') fees be paid to investigators or other clinicians.

Key points:

101. Financial compensation for participating as an investigator in a clinical trial should be commensurate with the work performed.
102. Remuneration for research participation should be paid into a specially designated fund, which is subject to auspice and audit according to institutional guidelines.
103. All payments to clinician–researchers or the departments in which research is conducted.

6.2.3 Responsibilities where a researcher does not have an institutional affiliation

Research projects conducted by private investigators without institutional affiliations may pose additional challenges. This is because on the one hand, surveillance and monitoring of the conduct of such projects is more difficult and, on the other, the investigators do not have access to the protection of such institutions. Where possible, research projects conducted by private practitioners should include investigators with institutional affiliations and be assessed by an ethics committee associated with that institution, which is also responsible for monitoring and oversight of the research. In addition, funds associated with the project should be distributed in accordance with the contractual arrangements approved by the ethics committee and conform to the normal requirements of the

institution. Where a formal institutional attachment is not possible, an alternative arrangement should be made that also involves ethics committee review and oversight and clearly defined and transparent processes for the management of funds. The nature of the compensation to be paid to the investigators should be declared in the explanatory statement provided to potential participants.

Key points:

104. Any research project conducted by private practitioners should include an investigator with an institutional affiliation and be assessed by an ethics committee associated with that institution.
105. Financial compensation or payment to clinician-researchers should be approved by a responsible ethics committee and declared to research participants.

6.2.4 Responsibilities where companies provide grants for research

Grants of money or equipment by pharmaceutical companies to hospitals, health care centres and universities specifically for the purposes of research are generally acceptable but should always be made to the institution and not to individuals, and should be appropriately acknowledged in research and other publications. If the donation is linked to, or contingent upon, a clinical trial or specific research project, a formal contractual arrangement which is open to scrutiny should be in place.

Before any form of industry support for research is accepted, the following general questions should be considered:

- Is industry support necessary for the conduct of the research?
- Are there alternatives to industry support for research that raise fewer ethical issues, for example support from professional organisations that do not have an interest in the content or outcomes of the research?
- Is the support genuinely and clearly linked to research that is likely to benefit the community?
- Do the potential supporter's organisational history and practices, either locally or internationally, raise concerns?
- Will the industry support be appropriately disclosed to the relevant Human Research Ethics Committees, research participants and the general public?
- Will acceptance of industry support be likely to result in any actual or perceived loss of institutional independence as to research either during or after the period of support?
- Would the proposed sponsorship raise concerns among patients, their families or the wider community?
- Will the propriety of the sponsorship stand up to scrutiny by colleagues and the public?

Key points:

106. Research grants from industry should be made to the institution and not to individuals, and should be appropriately acknowledged in research and other publications.
107. Researchers should not be subject to confidentiality agreements that are not time-limited or specific.
108. Restrictions on publication of trial results are likely to be inappropriate.
109. Sponsors should not participate in the design of studies or analysis of results.
110. Researchers should not be subject to confidentiality agreements which may prevent public disclosure of trial results.

6.3 Disclosure forms and processes

Submissions for publication should contain the following information:

- all sources of revenue obtained by the authors in relation both to the study and to other studies over the previous three years
- 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.

Presentations at public forums that refer to research projects in which the presenter has been personally involved, including in scientific and educational meetings, should specify the sources of funding of the research itself, other industry associations and other interests that may have affected the design, conduct or interpretation of the work.

Researchers contributing to committees or panels preparing clinical guidelines or joint expert statements should ensure that similar disclosures are made in relation to each item under consideration. In such cases, it is often appropriate for the resulting publication to provide detailed annotations regarding the roles of each participant and the processes adopted to manage dualities and conflicts of interest.

6.4 Dissemination of results

All industry-sponsored clinical trials should be included on a relevant clinical trials register, and a commitment made to report all results.

Before an industry-supported study commences, the company and principal investigators should agree upon the conditions of access to the raw data from the study and how these are to be used, including in publication.

Publication of results - whether positive or negative - is expected. Ideally, this should be in a refereed journal. This should be clearly stated in the protocol and other relevant documents and in submissions to Human Research Ethics Committees. If a study is likely to have clinical relevance, a commitment to publish results should be a condition of both agreement to participate by researchers and approval by Human Research Ethics Committees.

It is desirable that the responsibility for decisions concerning publication and other forms of dissemination or results, including preparation of manuscripts and presentations at scientific meetings should lie with investigators who do not have financial or non-financial conflicts of interest. Decisions should be made without influence from the sponsoring company. With multi-centre trials, it is desirable that analysis of the results and preparation of results for publication are undertaken by a committee of investigators who are independent of the sponsoring company.

Financial and other support for any aspect of the project should be declared. This includes disclosures at scientific meetings, in educational sessions and in publications. Associations with sponsoring companies (e.g. shareholdings) and other competing interests of relevance to the content of the article should also be declared. These declarations should include both pecuniary and non-pecuniary interests.

6.4.1 Public accessibility of clinical trial data

In addition to registration of descriptions of the design and methods of clinical studies, 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 for scrutiny by other scientists and regulators. These data should, of course, be appropriately de-identified to protect the privacy and confidentiality of trial participants.

The data should be sufficient to allow the published outcomes of the study to be adequately verified and any adverse or unexpected outcomes to be identified. Access should be provided in a timely manner, with sufficient information about design and methods to permit meaningful analysis by independent researchers.

6.4.2 'Guest' and 'ghost' authorships

A 'guest' author is a researcher - usually with perceived prominence - who is included as an author to enhance the stature of a publication in spite of a lack of contribution to the project in question. A 'ghost' author is someone - usually an industry employee - who has contributed to an article but who is not acknowledged in the publication.

The practices of including either category of author should be avoided. The integrity of scientific literature depends to some extent on the ability of readers to have confidence in the identity of the authors and adequate knowledge about their contributions, affiliations and any interests that may influence their work.

6.5 Complexities of the management of interests in research

While these conditions are desirable, they are often difficult to achieve in practice. In addition to facing pressure from companies to report only favourable results, investigators may themselves have competing interests as a result of being employees of the sponsoring company or having direct or indirect pecuniary or non-pecuniary interests linked to the trial outcomes. In multi-centre trials, it is often only the sponsoring company that has access to all data. Although undesirable, members of data management boards may also face competing interests as a result of their relationships with sponsoring companies. Even if companies agree to submit negative results for publication, it is often difficult for authors to have papers reporting negative results accepted by journals. Further disclosure

of conflicts of interest in publication is not in itself enough to ensure a disinterested presentation of data. Where publication in peer-reviewed journals proves to be impossible, researchers should attempt to make data available for public scrutiny through web publication or related resources. In particular, this may be an effective way of publishing negative results.

Key points:

111. 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.
112. All clinical trials should be registered on an appropriate clinical trials registry.
113. Responsibility for decisions concerning publication of results should be taken by investigators without commercial conflicts of interest, and decisions should be made without undue influence from the sponsoring company.
114. Researchers should not agree to be authors on 'ghost-written' manuscripts.

6.6 Responsibilities of health professionals as members of Human Research Ethics Committees

Individuals may be called upon to become members of research ethics or scientific review committees. Committees are often asked to consider applications that have been developed jointly by investigators and industrial sponsors as local projects or parts of multi-centre trials. Following the accepted processes of such committees, individuals who are personally involved in these projects should disclose their interests and, where appropriate, recuse themselves from discussions. Where a committee is to discuss a project involving an industry partner with which an individual has a present or previous relationship that could raise the possibility of a conflict of interest, this should be openly declared. In these cases, it is the responsibility of either the ethics committee itself or another body identified to decide whether any additional steps need to be taken.

Human Research Ethics Committees have a responsibility to ensure that clinical trials are conducted in accordance with national standards, as set out in various statements. The responsibilities of these committees for reviewing clinical trials are treated in full detail elsewhere (e.g. the *National Statement on Ethical Conduct in Human Research*). To protect against the effects of undue influences both pecuniary and non-pecuniary on researchers, the considerations of Human Research Ethics Committees include the following:

- Are the likely benefits of the proposed research sufficient to justify experimentation reasonable in terms of any risks or potential discomfort to participants?
- What is the regulatory status of the drugs to be used in the study?
- Is the design of the study appropriate to its aims and objectives? Is the study likely to provide an answer to the questions being asked? Are doses and durations of medications consistent with those used previously?
- Does the protocol include a clear statement of the number of participants to be enrolled in the study, the proposed method of recruitment and of the selection of participants?
- Do pre-clinical and clinical data indicate that the risks associated with the proposed use of the drug or devices are justified and acceptable? What procedures are proposed for monitoring

safety? What are the criteria according to which the trial is to be stopped in the event of new data regarding safety or efficacy becoming available?

- How is consent to be obtained? Have special provisions been made for the protection of vulnerable groups or individuals? Will participants be adequately informed about the implications for existing treatments that they might be receiving? Will participants be adequately informed about all payments made to researchers or other interests that researchers have in the research or its outcomes?
- Are there resource issues that might affect the conduct of the trial or its outcomes? Do researchers face conflicts of interest? Are relevant dualities of interest to be disclosed to potential participants and institutions?

Appendix 1: Disclosures of members of the working party, Ethics Expert Advisory Group and Ethics Committee*

Professor Paul Komesaroff is an adult endocrinologist and Professor of Medicine at Monash University and the Alfred Hospital in Melbourne, Executive Director of Global Reconciliation, Director of the Centre for the Study of Ethics in Medicine and Society, a Director of Praxis Australia (a not-for-profit company established to support research and ethics in Australia and internationally). He is the RACP Adult Medicine Division (AMD) President, a board member of the RACP and a former chair of the RACP Ethics Committee. He has conducted collaborative research involving a number of pharmaceutical companies.

In addition to clinical work, Paul is involved in undergraduate and postgraduate teaching and laboratory, clinical and social science research. He is Ethics Editor of the Internal Medicine Journal, Chair of the Editorial Board of the Journal of Bioethical Inquiry and author of more than 400 articles and 14 books.

Professor Ian Kerridge a Staff Haematologist/BMT Physician at Royal North Shore Hospital, Sydney and Professor of Bioethics and Medicine at the University of Sydney. He is Chair of the South-Eastern Sydney LHD Clinical Ethics Committee and a member of the NSW Health Department's Clinical Ethics Advisory Panel and was previously a member of the Australian Health Ethics Committee (AHEC) from 2012-5.

Ian is the current RACP Ethics Committee, Chair

Ian is also Director of Praxis Australia - a Not-for-Profit initiative aimed at promoting and providing education and ethics in research. He has a long interest in research ethics and in research in medicine, haematology, BMT and philosophy/ethics and is the author of over 300 papers in peer-reviewed journals and five textbooks of ethics, most recently Ethics and Law for the Health Professions (Federation Press, 2013). He is or has been an investigator on numerous investigator-initiated and industry-sponsored clinical trials in haematology and BMT and actively recruits patients to clinical trials but otherwise receives no support from industry, does not work as an advisor or consultant to industry, receives no travel or conference support from industry and owns no shares in the pharmaceutical, biotechnology or pathology industries

Dr Greg Stewart is Director Primary Integrated and Community Health at South Eastern Sydney Local Health District and a former member and chair of the RACP Ethics Committee. He is a former President of the Australasian Faculty of Public Health Medicine, and a former member of the RACP Board, Finance Committee and Congress Organising Committee. He is a member of the Public Health Association of Australia, NSW Medico-Legal Society and a Fellow of The Royal Australian College of Medical Administrators. He receives no payments or reimbursements from industry for any services, travel, attendance or presentations at meetings and does not have any other financial relationship that could be perceived as a conflict of interest

Dr Wendy Lipworth is an Associate Professor of bioethics at Sydney Health Ethics, University of Sydney. She leads a program of research on the ethics of emerging technologies with a particular focus on how medicines and other therapeutic technologies (e.g. medical devices, companion

diagnostics, biological therapies) are developed, commercialised, regulated, funded, marketed and taken up into practice. She has no industry associations or other relevant interests to declare.

Dr Jon Jureidini is a child psychiatrist who heads Adelaide University's Critical and Ethical Mental Health research group (CEMH), which promotes safer, more effective and more ethical research and practice in mental health; and the Paediatric Mental Health Training Unit (PMHTU), which provides training in non-pathologising approaches to primary care mental health.

Dr Rob Loblay is a clinical immunologist who is a Senior Lecturer in Immunology at the University of Sydney and Director of the Allergy Unit at the Royal Prince Alfred Hospital where he is also Chair of the Ethics Review Committee. He has no industry associations or other relevant interests to declare.

Professor Russell Gruen is a general and trauma surgeon at major public hospital in Singapore and is the former Director of the National Trauma Research Institute, which is funded through competitive and other government grants, and occasionally receives industry funding which is independent of research methods and reporting. He receives no payments or reimbursements from industry for any services, travel, attendance or presentations at meetings nor does he have any other financial relationships that could create conflicts of interest.

Dr Ken Harvey is an Associate Professor of Public Health at Monash University and a consumer advocate. He was a member of the expert group that drafted the World Health Organization's 'Ethical Criteria for Medicinal Drug Promotion'. More recently he represented CHOICE (the Australian Consumers' Association) on the Therapeutic Goods Administration (TGA) Transparency Review Panel, the Government's Natural Therapy Review Advisory Committee, the TGA Working Group on Regulatory Reform of Complementary Medicines and the Therapeutic Goods Advertising Code Council.

Dr Phillipa Malpas is Associate Professor of Clinical Medical Ethics working at the University of Auckland (in the Faculty of Medical and Health Sciences). She is interested in the medical education of students, especially the ethical dimension of their training.

Professor Cameron Stewart is a member of Sydney Health Law at Sydney Law School, the University of Sydney. He is the Legal member of the NSW Medical Council and a member of the NSW Ministry of Health's Clinical Ethics Advisory Panel.

Associate Professor Henry Kilham a paediatrician involved in clinical ethics at the Sydney Children's Hospitals Network, and is an associate of Sydney Health Ethics, University of Sydney (previously the Centre for Values, Ethics and the Law in Medicine). He has no association with the pharmaceutical industry, nor any relevant dualities or conflicts of interest to declare.

Dr Christopher Clarke is a retired consultant thoracic physician. He has no associations with the pharmaceutical industry or other relevant dualities or conflicts of interest to declare.

Dr Shane Carney is Associate Professor of Medicine at the University of Newcastle & Honorary Medical Officer, Department of Nephrology John Hunter Hospital.

Professor Wendy Rogers is a member of Clinical Ethics at Macquarie University, Co-Chair of NSW Health Clinical Ethics Advisory Panel and a former member of the Australian Health Ethics Committee. She has a longstanding interest in conflicts of interest and research ethics, and has published widely on these and other topics.

Dr Alina Iser is a paediatrician at Alice Springs Hospital with outreach to remote communities. She is a member of RACP Ethics Committee. She has no industry associations or conflict of interests.

Dr Danielle Ko is a Palliative Care Consultant and Clinical Ethics Lead at Austin Health, and is a member of the RACP Clinical Ethics Committee. Prior to practicing medicine, she worked as a lawyer. She has no associations with the pharmaceutical industry or other relevant dualities or conflicts of interest to declare.

Dr Alastair Macdonald is a retired renal physician, and now a clinical ethics advisor with the Capital & Coast District Health Board (CCDHB). He is a member of the CCDHB Clinical Ethics Advisory Group and Choosing Wisely Committee. He is also involved in the formation of a clinical ethics network in New Zealand. His appointment to the RACP ethics committee is an important part of his work in ethics.

Associate Professor Jill Sewell is the Clinical Director of the Children's Bioethics Centre, and a senior paediatrician in the Centre for Community Child Health at the Royal Children's Hospital. She is Chair of the Victorian Clinical Council, and President of the Australian Medical Council. She has no industry associations or other relevant interests to declare

Dr Linda Sheahan is a Palliative Care Physician, and the Clinical Ethics Consultant for South East Sydney Local Health District. She is an Honorary Associate with Sydney Health Ethics at the University of Sydney, and a Clinical Conjoint with University of NSW School of Medicine. Linda has a Fellowship in Clinical and Organisational Ethics from the Joint Centre for Bioethics in Toronto, Canada, and remains an affiliated Ethicist with the Joint Centre. She is a Member of the RACP Clinical Ethics Committee, the SESLHD Clinical Ethics Committee, Australian Association of Bioethics and Health Law, Australian and New Zealand Society of Palliative Medicine, and Palliative Care Australia.

Professor Ron Paterson is a Legal Professional and former Board Director based in Auckland. Ron has no industry associations or other relevant interests to declare.

Professor Ngiare Brown, a Yuin Nation woman from the south coast of New South Wales (NSW), is a Senior Aboriginal Medical Practitioner and holds an academic appointment at the University of Wollongong as Professor of Indigenous Health and Education.

Professor Brown was the first identified Aboriginal medical graduate from NSW and is one of the first Aboriginal doctors in Australia. She has qualifications in medicine, public health and primary care, and has studied bioethics, medical law and human rights. Ngiare has also undertaken doctoral research in law, addressing Aboriginal child protection systems and practice.

Ngiare is part of a new international network, International Indigenous Genomics Alliance, addressing cultural governance protocols, and the ethical and legal impacts of genomic research and Aboriginal and Torres Strait Islander people. Ngiare has been a chief investigator, associate investigator and

named investigator on a range of National Health and Medical Research Council (NHMRC) funded grants, valued at more than $10 million. She has also been a member and chair of numerous committees, including contributions to the NHMRC, some of which include:

- Founding member and previous Foundation Chief Executive Officer of the Australian Indigenous Doctors' Association (AIDA)
- Founding member of the Pacific Region Indigenous Doctors' Congress (PRIDoC) and Chair of the Health, Rights and Sovereignty committee
- Board Member for the Bangarra Aboriginal Dance Theatre
- Board Member for the Australian Research Alliance for Children and Youth
- Inaugural and current member of the Prime Minister's Indigenous Advisory Council
- Commissioner, National Mental Health Commission
- Advisory Board Member of the National Centre for Indigenous Genomics ANU

Dr Hirini Kaa is of Ngati Porou, Ngati Kahungunu and Rongowhakaata descent. Hirini has worked in a range of areas including in the social services sector, for the Anglican Church and for his iwi. He currently lectures in History and Theology at the University of Auckland and is a trustee of the Te Taurahere o Ngati Porou ki Tamaki Trust.

Ms Eliza McEwin holds a Master of Bioethics and is a member of the RACP Ethics Committee and Ethics E-learning Resource Working Party. Eliza currently works at The Australian Commission on Safety and Quality in Health Care (ACSQHC).

Mr Peter Martin's first career was in education where he was a secondary teacher of Economics and Geography, eventually becoming a long-serving Principal of secondary schools in the government system. He was also heavily involved in professional leadership at Regional, state and national levels as well as becoming involved in representative roles in professional development, working parties and negotiating teams at high levels.

Other interests and involvement included ambulance services (both management and front line), service clubs (Lions) for over 35 years, health, (membership of a public hospital board for 18 years), health regulation (state and national dental boards), ethics (Dental Health Services Victoria), firearms regulation, transport facilities in rural areas, services for older persons, 10 years as a Bail Justice, currently a Justice of the Peace, and, numerous and varied consumer representative positions in health and related areas such as infection control; also rural health services' finances, safety, quality and governance. Currently a Community Sessional Member of the Post Sentence Authority in Victoria.

Peter is very concerned that consumers and the general community are genuinely involved in all decisions which are relevant to them. He is particularly passionate that rural people are involved to the maximum extent possible in these decisions despite the practical difficulties involved. His experience tells him that far too often they are ignored or at least just tolerated in debates about the provision of services which urban people regard as 'normal' and to which they feel entitled.

Peter is a Member of the Order of Australia in recognition of his contributions to education and the community.

Mr Tim Benson has been a Western Australian based Health Consumer Representative, Advocate, and Consultant for over 20 years.

He is a member of the Consumers Health Forum of Australia and the Health Consumers Council of WA, and has served on both their Boards of Management, additionally he is a Patient for Patient Safety Champion for the World Health Organisation, a member of the WA Consumer & Community Health Research Network, a contributor to the International Consortium for Health Outcomes Measurement Diabetes Standard Project Group, and a member of the Ethics Committee of Audiology Australia.

Among his many previous roles has been a ministerial appointment as the inaugural community member of the National Lead Clinicians Group (a role he then held for the life of the group), a member of the Western Australian Clinical Senate Executive, and the Chairman of the North Metropolitan Health Service Community Advisory Council (WA) .

His passion for the involvement of the patient and carers in the safety and quality of the Patient Journey makes him a valuable contributor to RACP's Ethics Committee. Tim has been a member of the RACP Ethics Committee since 2016.

** declarations were operative at the time that the member made their contribution to the update of the Guidelines; note that the names of bodies or organisations in the declaration may no longer be current*

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