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PHARMACEUTICAL INDUSTRY AND HOSPITAL STAFF LIAISON IN PUBLIC HOSPITALS

***A Position Statement of the
NSW Therapeutic Advisory Group Inc.***

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Key Messages

In Australia, the pharmaceutical industry provides information and training about new products, funding for conferences, support for professional and social activities, free samples, support for the conduct of research and information about its outcomes and opportunities to meet with peers. Guidelines and codes of practice from professional bodies, societies and hospitals exist in an attempt to ensure this interaction does not lead to a conflict of interest and an ethical issue. Some researchers have argued that pharmaceutical industry contact should be more limited and certain activities prohibited; however, there is a general expectation that the pharmaceutical industry will fund and support certain items. For example, in one study, a majority of Australian medical organisations were found to receive pharmaceutical industry support for conferences, continuing medical education (CME), research grants, travel and library purchases.

The question is how much of this interaction influences drug prescribing and to what extent it might damage professional relationships with patients and trust with the general public. Whilst there may not be anything inherently unethical in a duality of interest, the key is to recognise when one interest compromises the other and how to deal with this conflict. Strategies include disclosing the conflict, establishing a system of review and authorisation, and deciding whether action is necessary to separate or prohibit activities that lead to the conflict.

Training on how to interact with industry

All student health professionals who might be subsequently influenced by pharmaceutical industry interaction must receive training on the handling of this interaction. Doctors' interactions with the pharmaceutical industry begin in medical school and persist in practice with requests for adding their drugs to hospital formularies and changes in prescribing practice. It has been proposed that student doctors receive formal instruction about how to critically assess information from industry whilst at university. All healthcare related teaching establishments need to cover the role of industry, duality and conflict of interest and the evaluation and interpretation of industry material. Training should promote ethical values and high standards of behaviour. Students should be assisted in critically analysing their own professional behaviour, industry practices and the interaction between health professionals and the industry. It is also essential that they learn how to evaluate evidence, know the most reliable sources of information and they should not accept promotional materials or gifts.

How to interact with industry

Surveys have shown that the doctors who receive the most money and promotional items are the most likely to believe that drug representatives won't affect their prescribing. Most doctors tend to deny that their prescribing is being affected by their contact with the pharmaceutical industry, but this has been contradicted by objective research.

It is unrealistic and inappropriate to prohibit contact between health professionals and the pharmaceutical industry. Indeed, industry plays a valuable role in education and training and in healthcare provision to the community. Constructive engagement between industry and health professionals is strongly in the interest of patients. All healthcare personnel will interact with the industry during their professional career. It is important to recognise those activities that enhance clinical practice and those that potentially damage the relationship between the health professional and their patients. Suggested steps to minimise potential conflicts of interest include choosing to make full use of independent sources of evidence-based medicine and the development of policies by hospitals, colleges and professional associations to ensure their staff or members are independent of industry.

Strategies

The following general recommendations for pharmaceutical industry interaction may be made:

- **Identify any duality of interest**

Disclosure is appropriate in all circumstances.

The following steps suggested by the Royal Australasian College of Physicians should be considered and applied by all health professionals in their dealings with industry¹:

1. Those affected by the duality of interest (not the individual) decide whether there is actual or potential conflict.
2. If there is potential conflict the group decides whether action needs to be taken
3. If it is necessary to take action a strategy is devised to separate the two or more conflicting roles
4. Any action is communicated to those who could have been affected by the conflict of interest.

An example of these steps in practice: A health professional is a member of a pharmaceutical company advisory board and a product marketed by that company is being considered for inclusion in the hospital formulary by the Drug and Therapeutics Committee (DTC). The duality of interest is declared to the DTC, or a Conflict of Interests Committee, if this is in place. In a case such as this, a conflict of interest is likely to be confirmed. The DTC would exclude the health professional from those discussions around the drugs for inclusion in the clinical area of potential conflict. On publication of the final decisions of the DTC, the steps taken to prevent conflict can be made known. In this way the intentions of the group and the health professional involved are transparent, within the public domain and the interests of patients are protected.

- **Accept minimal or no gifts**

The activities involved in marketing include advertising, detailing, gifts, travel subsidy and entertainment. A 2001 estimate was that the Australian pharmaceutical industry spent about \$21000/year/doctor on drug promotion. There is general agreement that high-value gifts may compromise clinical decision making. Doctors tend to deny they are influenced but believe their colleagues may be swayed. Social science research has found that even small gifts, such as pens and coffee, are influential. One professional society asked its members if they would be happy for their patients, employers and the local press to witness their hospitality.

- **Avoid the use of free samples**

Samples allow doctors to initiate prescribing of new drugs but surveys have shown they may lead to long-term prescribing of non-preferred and more costly drugs.

- **Entertainment should not be lavish**

'Free lunch' has been described as one of the most effective sales techniques ever devised. It is still readily accepted by health professionals but has been linked to increased sales of promoted drugs.

- **Travel support is appropriate for meeting contributors only**

Paid attendance at symposia appears to influence the prescribing patterns of doctors. On occasions it may be acceptable to pay an individual's costs but recipients should be chosen by the meeting organising committee or, in the case of students or other trainees, the training institution. Payment and selection should not be directly from the industry.

- **The scientific content of meetings should be the responsibility of independent committees**

In Australia, there is increasing reliance on industry support for CME. It has been recommended that sponsorship should be provided through processes that are at arm's length from the development of the content itself.

- **Be aware that industry may influence the conduct and outcome of research**

Studies sponsored by the pharmaceutical industry are more likely to have outcomes favouring the sponsor than studies funded by other sources. Research-related industry gifts may be given conditionally and may lead to requests for addition of the trial drugs into formularies. Publication bias occurs because most clinical trials are funded by the pharmaceutical industry and multiple and selective publication of studies occurs. A Lancet editorial warned against the many temptations of the research-minded clinician, such as negotiating a lecture fee before agreeing to the subject matter, using material provided by the drug company, or becoming entangled in ghost-written publications and drug launches.

Introduction

The provision of specialised product information and promotion by the pharmaceutical industry of drugs approved by the Therapeutics Goods Administration (TGA) is an integral part of the healthcare environment. It is acknowledged that the pharmaceutical industry collaborates with hospital employees in areas such as clinical trials, research and development, staff education, meetings and travel sponsorship.

The relationship between the pharmaceutical industry and hospital staff must be maintained at the highest professional standard to ensure patient care takes precedence. Hospital employees should ensure that they understand the differences between their own roles and that of the pharmaceutical industry in the provision of pharmaceutical agents for patient care. Staff should be aware that interaction between pharmaceutical representatives and hospital employees is likely to have a promotional intent. Provision of patient care requires independence of judgement. If pharmacological intervention is necessary, selection, prescribing and acquisition of the most appropriate and effective product for treatment must be free from industry bias and in the best interests of the patient at all times.

It should be noted that the issues discussed in this position statement extend well beyond the pharmaceutical industry. They include providers of devices e.g. catheters, stents, surgical appliances, dressings etc., chemicals in pathology laboratories, machines and consumables in radiology departments etc. Health professionals are advised to be aware of this in their interaction with representatives in these fields. However, these areas are beyond the scope of this Position Statement which is confined to liaison with the pharmaceutical industry.

Objective

The objective of this Position Statement is to provide a framework and guidelines for ethical interactions between the pharmaceutical industry and New South Wales (NSW) public hospitals and their staff, including, but not limited to, medical, pharmacy and nursing staff. The intention is to ensure that the primary objective of professional interactions with pharmaceutical industries is the advancement of the health and well-being of the patient. In addition, the purpose of these guidelines is to protect the well-being of the individual patient, the fiduciary nature of the health professional-patient relationship and the legal interests of the hospital.

The first part of this document contains guidelines whilst the second part provides evidence and rationale for the guidelines.

Methodology

The Guidelines presented in this Position Statement are derived from similar guidelines that were provided as a draft by the South Australian Therapeutics Advisory Group (SATAG), last updated November 2007 and the Position Statement of NSW Therapeutics Advisory Group (NSW TAG) 'Pharmaceutical Representative and Hospital Staff Liaison in Public Hospitals', last updated in January 2004. The main changes occurred after consulting available evidence (see the Evidence section of this document) and as a result of review by NSW TAG and the reviewers (see Acknowledgements). The Position Statement is also aligned with recommendations provided by the Royal Australasian College of Physicians in 'Guidelines for ethical relationships between physicians and industry', 3rd Edition 2006.

This Position Statement replaces the existing NSW TAG Position Statement (January 2004).

For the Evidence section of this document, a search of Embase (January 1996-2007, week 48) using the following MESH terms was preformed: ("exp Drug marketing" or "exp Drug Industry")

and (“medical education” or “Physician Attitude” or “Physician”). All of the 1752 results were assessed, and the selected papers are presented in this document.

Duality of Interest: Declaration

In ‘Guidelines for ethical relationships between physicians and industry’ (3rd Edition 2006), the Royal Australasian College of Physicians recommend the establishment of Conflict of Interest Committees to form a process within an institution to identify and deal with duality and conflict of interest.¹ It is recognised that hospitals in NSW may not yet have such committees in place but the same principles of decision making can be applied by any nominated group to ensure adequate policies are in place within the hospital to deal with duality and conflict of interest. Essentially, the group directly affected by a duality of interest decide if such a duality is a conflict and any necessary subsequent action. In this way the integrity of the individual, the hospital and the interests of the patient are maintained. In practise, the group dealing with each potential conflict of interest may be an ethics committee, the Drug and Therapeutics Committee (DTC), departmental committee or any other ad hoc group according to local conditions. Importantly, the hospital has an open and democratic approach to conflict of interest.

The NSW Health Code of Conduct Oct 2005 refers to ‘conflict of interest’, which, within the context of the Policy Directive includes ‘duality of interest’. The Code requires openness and transparency in the management of conflict of interest. It stipulates that any actual, potential or perceived conflict of interest be reported to immediate supervisors, Health Service Chief Executive or his/her delegate at the first available opportunity. A Conflict of Interest Register will be maintained by the Manager of the Health Service Internal Audit or other delegated officer. Refer www.health.nsw.gov.au/policies/pd/2005/PD2005_626.html. Accessed 26 May 2008.

Guidelines

Pharmaceutical industry representatives

Pharmaceutical industry representatives attending NSW public hospitals should comply with the following guidelines:

1. Observe the Code of Conduct of Medicines Australia in all interactions with hospital employees.
2. Wear appropriate identification (i.e. name and company) at all times while at the hospital.
3. New pharmaceutical representatives should arrange a meeting with the Director of Pharmacy before making initial contact with any hospital staff member.
4. Attend the hospital by appointment only at a time and place that is not likely to interfere with the staff member's usual work or patient care.
5. Not to meet with hospital staff in patient care areas, including clinics and emergency departments.
6. Meet with hospital staff in non-patient care areas on wards or staff facilities provided prior arrangements have been made with the relevant hospital staff.
7. Appointments with individual members of staff:
 - a. Medical staff: In general, appointments for individual meetings may not be made with medical staff in their first three postgraduate years, except with the permission of the Head of Unit for each appointment. There may be specific guidelines for medical staff liaison within individual Functional Units. Pharmaceutical representatives and medical staff should ensure that they are familiar with any individual Unit guidelines.
 - b. Pharmacy staff: Appointments for individual meetings may only be made after authorisation has first been obtained from the Director of Pharmacy.
 - c. Nursing staff: Appointments for individual meetings with nursing staff may only be made after arrangement with the Clinical Nurse manager of the relevant area.
8. Indications for a product that have not been registered by the Therapeutics Goods Administration (i.e. off label use) should not be promoted in accordance with the Code of Conduct of Medicines Australia.

Hospital staff

Hospital staff are employees of the New South Wales Government and are required to observe the Code of Conduct for New South Wales Public Sector Employees (pdf available at www.health.nsw.gov.au/policies/pd/2005/PD2005_626.html . Accessed 4 December 2007). In addition, they are expected to abide by any existing legislation, the Code of Professional Conduct of their registration authority and by the policy of their employer.

1. Medical Staff: New South Wales Medical Board, Code of Professional Conduct, July 2005 (available at www.nswmb.org.au/index.pl?page=44 . Accessed 4 December 2007).
2. Pharmacy Staff: Pharmaceutical Society of Australia, Code of Professional Conduct, March 1998 (available at www.psa.org.au/site.php?id=628 . Accessed 4 December 2007).
3. Nursing Staff: Australian Nursing and Midwifery Council, Code of Professional Conduct for Nurses in Australia, January 2003 (available at www.anmc.org.au/docs/Publications/ANMC%20Professional%20Conduct.pdf . Accessed 4 December 2007).
4. All hospital staff are bound by privacy principles and the principle of patient confidentiality and must not divulge patient details to individuals not involved in the care of that patient.

Staff members acting as consultants

1. Staff members who act as pharmaceutical industry consultants should openly declare their involvement in applications for research studies or drug formulary applications.

Where conflicts of interests may exist these should be managed appropriately, as outlined above.

2. Staff members who act as consultants are encouraged to pay any honoraria into a 'special purpose' fund managed by the hospital or affiliated university and not receive these as personal payments.

Sponsored meetings and events

Hospitals should not provide public opportunities for pharmaceutical companies to promote their products unless there is a specific educational or patient care purpose and they are invited by a staff member who retains control of the event. With regard to any sponsored meeting or event:

1. They should be arranged in consultation with an appropriate senior member of the professional staff.
2. Sponsorship should be explicitly declared and acknowledged.
3. With the exception of in-service training on a specific product, functions should address general topics and not be orientated towards one product.
4. Discussion should be based on sound evidence.
5. There should be an opportunity for staff to express independent views relating to the meeting topic.
6. Ideally, funding should be provided for education that is untied to any particular topic.
7. Materials provided at functions should be educational in nature and useful to hospital staff for the care and treatment of patients. Individuals attending the meeting must be aware of the source of this material and adopt a critical approach. Even educational material must be viewed as promotional if it has been supplied by the industry. Ideally, any materials would be sent to the meeting organiser for advice and approval prior to the meeting.
8. Direct product promotion at hospital meetings and events is not permitted. Meetings must be educational. However, CME meetings can, and do, have a high impact on clinical practise. Guidelines for meetings must be planned as carefully as possible to ensure impartiality. Presenters must declare their interest, be given guidelines on the content of their presentation which should be seen by the meeting organiser prior to the meeting. An opportunity for delegates to give opinion at the meeting in writing, via feedback forms, is valuable in maintaining integrity. It is often difficult to judge whether content is educational or promotional but it is important for the meeting organiser or organising committee to develop processes to ensure the educational content predominates.
9. The meeting or event should not be used as a forum to provide samples.
10. In-service training supported by industry should not be undertaken without prior approval from an appropriate senior staff member, such as Head of the Nursing Unit or Director of Pharmacy.

Staff members presenting at meetings

A legitimate scientific meeting to enhance understanding and exchange ideas for educational purposes is often an appropriate way for the industry to use sponsorship. In this circumstance the sponsorship must be indirect, untied and fully disclosed.

- Industry sponsorship for presentation at a meeting should be indirect, through a third party i.e. the organising committee of the meeting. If it is not possible to involve a third party, the staff member should ensure appropriate hospital committees are informed and the appropriate declarations of interest made.
- Sponsorship should be untied. Staff members should ensure that all material presented by them at the meeting is not tied to the promotion of any commercial product e.g. slides declaring product or company logo.

- Sponsorship must be disclosed. It is the responsibility of the staff member to maintain high standards of public disclosure when accepting payments either directly or preferably from meeting organising committees. As in the case of consultancy, any honoraria (including travel reimbursement) should be paid into a 'special purpose' fund.

Travel sponsorship

1. Hospital employees are encouraged not to accept travel sponsored by pharmaceutical industries unless it is to attend a meeting at which the staff member is making a formal contribution.
2. Staff members have a responsibility to ensure the transparency of the travel arrangements and declare the nature of the sponsorship to their Divisional Chief/Director, or the Conflict of Interest Committee, if in place, to determine if any conflict of interest exists.
3. Acceptance of travel sponsorship must be clearly linked to a significant contribution at the meeting attended and there must be no loss of professional independence.
4. Staff members' cost of travel should be paid from a 'special purpose' account, the income of which may be partly or wholly derived from payments by the pharmaceutical industry.
5. Accepting travel sponsorship or entertainment expenses from a pharmaceutical company for a spouse or partner is not acceptable.

Gifts

As a general rule, health professionals should not accept gifts, or at most only token items. All hospital staff must be aware that even nominal gifts are provided with an expectation that behaviour can be influenced by this action. The NSW Health Code of Conduct Oct 2005 stipulates cash must not be accepted and where minimal gifts (e.g. pens, notepads) are accepted, these must take the form of a token of appreciation, not to secure favour. NSW Health stipulates a Gifts and Benefits Register will be maintained by the Manager of the Health Service Internal Audit Unit or delegate for the purposes of recording receipt of non-token gifts (pdf available at www.health.nsw.gov.au/policies/pd/2005/PD2005_626.html. Accessed 18 June 2008).

Drug acquisition

Management of pharmaceutical products at NSW public hospitals is by use of a drug formulary. The hospital DTC, or other delegated person or body, approves drugs for inclusion in the formulary following consideration of applications from senior medical staff at the hospital. Approval is on the basis of proven clinical and scientific merit and cost benefit in relation to alternatives.

1. The Director of Pharmacy has the sole delegated responsibility for price negotiation, contracting, procurement and distribution of pharmaceuticals, including clinical trial, Special Access Scheme (SAS), compassionate use drugs, and Product Familiarisation Programs (PFPs).
2. Appropriate consultation with clinical units or users should take place.
3. Individual staff members, departments, or the hospital as a whole should not be under any obligation to a pharmaceutical company, which could result in the inclusion of the particular company's products into the hospital drug formulary. In this regard, those involved in approving drugs for inclusion in the formulary must declare all consultancy positions, paid or unpaid, acceptance of gifts (of any size) and any other duality of interest to an appropriate committee and this be placed on public record.
4. All drug delivery, SAS, compassionate use supplies or PFPs must be accompanied by an official Pharmacy purchase order and must be delivered directly to the Pharmacy Department and dispensed by the Pharmacy Department.

In circumstances where there is a duality of interest relating to an application for drugs to be included in the hospital drug formulary, the staff member should declare these. The group must

decide whether a conflict exists and if action needs to be taken, what form this should take, including withdrawal from discussion of that particular drug or therapeutic area. NSW TAG has produced a DTC template for formulary submissions that includes provision for declaration of conflict of interest (<http://www.ciap.health.nsw.gov.au/nswtag/evaluatingnewdrugs.html>).

Drug samples/starter packs

In general, acceptance of drug samples from pharmaceutical representatives is usually inappropriate. There are exceptions and these are set out by the Royal Australasian College of Physicians in their 'Guidelines for ethical relationships between physicians and the industry'¹. Hospital staff should refer to and observe their own hospital policy on the provision and use of samples/starter packs. Consideration of the following points is suggested in the preparation of hospital policy regarding acceptance of samples/starter packs.

1. All drug samples must be delivered directly to the Pharmacy Department and dispensed by the Pharmacy Department.
2. Requests and receipt of supply of samples must be documented in accordance with the Code of Conduct of Medicines Australia (i.e. there must be an appropriate signed request/receipt of supply).
3. Samples are not to be left in clinics, patient care areas, offices or elsewhere on hospital premises for the purpose of being issued to hospital patients.
4. Medical or nursing staff must not accept samples for the use in the treatment of patients within the hospital.

Product Familiarisation Programs

Hospital staff should refer to and observe their hospital policy or guidelines on Product Familiarisation Programs (PFPs). The Joint Therapeutics Advisory Groups has published recent guidelines for PFPs in Australian public hospitals (<http://www.ciap.health.nsw.gov.au/nswtag/publications/guidelines/jtagsPFP.pdf>).

Pharmaceutical industry sponsored research projects and clinical trials

1. Sponsored research projects and clinical trials involving patients in hospitals require Clinical Drug Trials Committee and Human Research Ethics Committee (HREC) approval. These expert committees with formal terms of reference must assess these trials for adequate study design and objectives.
2. The Pharmacy Department should be provided with information on any drug trial being carried out at the hospital. Such information should include data on efficacy, toxicity and protocol for use. Ideally, the Pharmacy department would receive details of study design and objectives as supplied for approval in point 1(above).
3. The HREC must be made aware of financial arrangements for clinical trials, including proposed payments to researchers and research participants and the provision of other resources required to carry out the study. The requirements are detailed and the process for management requires rigorous scrutiny.
4. Funds should be deposited into an appropriate 'special purpose' account. This account must be open to scrutiny and have strict principles for management of funds and clearly state the purposes of those funds.
5. Funds may be used for payment for the time and expertise of the staff involved and other activities directly related to the study or to broader activities of the research group. The amount of compensation should be administered under a formal contractual arrangement with the pharmaceutical industry which is open to scrutiny.
6. Payments to research participants should reasonably relate to income or time lost but should not be so large as to constitute an inducement to participate in the project or trial. This situation is unlikely to arise as the HREC should not approve a study where inducements or coercion (financial or otherwise) are evident.

Provision of staff or equipment

1. Donations of equipment, or funds for the purchase of equipment, should be made to the institution and not to an individual staff member.
2. Donations of equipment should be made public in the hospital's public communications.
3. Donated equipment becomes the property of the hospital and is subject to the hospital's receipt and handling policies.
4. Funds may be provided to employ staff for specific service functions; however, dualities and potential conflicts of interests should be declared and managed as described.

Ex-gratia payments and 'special purpose' accounts

1. Any *ex-gratia* payments received by divisions or units should be paid into a separate 'special purpose' account administered by the hospital. The management of such an account must be transparent and clearly defined to avoid simple laundering of money.
2. *Ex-gratia* payments should only be used for approved corporate purposes (e.g. support of professional visitors, research fellowships, staff continuing education or other such purposes).
3. A 'special purpose' account is a departmental account set up with clear rules of management which are open to scrutiny. A 'special purpose' account is essential for staff members acting as consultants, staff members presenting at meetings, travel sponsorship, funds for the provision of staff or equipment, and *ex-gratia* payments. The handling of these funds is an essential part of managing the conflict of interest process.

Financial and other interests

All cases of financial interests in pharmaceutical industry by staff or close family of staff members should be declared to the hospital's administration and on any other relevant occasion. These may include stocks and shares ownership, paid employment or consultancy.

As a matter of principle, important non-pecuniary interests must also be declared, i.e. factors of a non-financial kind which could influence an individual's judgements or decisions. Non-pecuniary interests could include: unpaid consultancies, nomination as an expert advocate in industry publications or at meetings, strong religious beliefs, and interests relating to professional advancement and stature. It is recognised that identification of non-pecuniary interests is often difficult, as a result of which it is important that both individuals and institutions adopt a sensible and balanced approach to this matter.

Breaches of these guidelines

Where a breach of the guidelines has occurred, a complaint should be submitted to the Chair of the Drug and Therapeutics Committee. The complainant should outline the details of the breach, the pharmaceutical company concerned and the name of the individual concerned e.g. pharmaceutical representative and staff member(s). The 'Conflict of Interest Committee' or similar will have established processes for ensuring adequate and transparent guidelines are in place to deal with any contentious issues. In all cases the Chair of the DTC should pass the complaint directly to the nominated committee. The nominated committee for this process is often, but does not necessarily need to be, the DTC. Such a committee ensures that such issues are dealt with at 'arm's length' in a fair and transparent manner. Referral to a single individual for decision making should be avoided to protect such an individual and the hospital. The committee can provide independent guidance with consideration of all processes and ultimately decide whether a formal warning is required.

In the case of the pharmaceutical industry:

1. If it is deemed that a formal warning is to be given, the pharmaceutical company employee should be contacted personally and given a formal request letter to meet with

- relevant personnel at the hospital. The principles of natural justice must be followed – i.e. the pharmaceutical employee must be afforded a fair hearing and the opportunity to respond to the complaint, which may be unjustified or malicious.
2. If there is a further complaint in writing, the pharmaceutical employee should be warned by the committee handling the breach, and the relevant Divisional Director and the Executive Director of Medical Services should be informed of this action. A formal warning in writing should also be sent to the relevant pharmaceutical company. Pharmaceutical industry employees should adhere to Medicines Australia Code of Conduct and the complaints committee of Medicines Australia should be informed of any potential breach of the Code.
 3. If breach of the guidelines continues following a fair process for hearing evidence and deciding a breach has occurred then the relevant pharmaceutical company should be notified and the matter referred to them for resolution with a recommendation that they prohibit the employee from attending the hospital. Further infringement may jeopardise future business dealings with the hospital and will be addressed via professional channels.

In the case of hospital staff members:

1. Hospital staff are required to observe the Code of Conduct for New South Wales Public Sector Employees (pdf available at www.health.nsw.gov.au/policies/pd/2005/PD2005_626.html. Accessed 4 December 2007).
2. Any staff member who fails to observe these guidelines will be reminded of the hospital policy and requested to comply. Further infringement will be dealt with via the hospital disciplinary policy and may be punishable under law.
3. If staff become aware of a breach of conduct either by themselves or other staff members the matter should be reported to a supervisor immediately.

Evidence

Guidelines, codes and duality of interest

Doctors and allied health professionals are faced with ethical dilemmas when interacting with the pharmaceutical industry. At its worst, duality leading to conflict of interest has led to significant legal scandals involving practices such as kickbacks, sham consulting, continuing medical education (CME), and payment for prescribing drugs under the guise of a clinical trial.^{2,3} Assistance in dealing with conflict of interest has been provided by way of guidelines and codes of practice produced by professional societies and organisations within Australia and internationally.⁴⁻⁹ Their aim is to minimise the potential for conflict of interest that may arise when drug marketing occurs overtly by way of obvious drug promotion or more subtly under the guise of educational activities or in clinical trials. To maintain their integrity, the Australian pharmaceutical industry has a code of conduct for its members.¹⁰ Specifically, employees of NSW Health are bound by their own Code of Conduct, provided in Policy Directive 2005_626.¹¹

The relationship between health professionals and industry is complex and open to exploitation; however, an advocate for continuing and improving relationships with the pharmaceutical industry has said that, if employed judiciously, doctor-industry interaction may enhance clinical practice.¹² The conclusion of a survey in Canada was that doctors should be given more training on how to interact with industry.^{10,13} A bioethics article in the Canadian Medical Association Journal stated that “there is nothing inherently unethical in finding oneself in a conflict of interest. Rather, the key questions are whether one recognises the conflict and how one deals with it. Strategies include disclosing the conflict, establishing a system of review and authorisation, and prohibiting the activities that lead to the conflict.”¹⁴ Tattersall and Kerridge (both University of Sydney), in a Medical Journal of Australia (MJA) editorial, said that the pharmaceutical industry itself is not the issue, rather it is to prevent, assess and manage conflict of interest, and to maintain public trust in doctors, which may all be substantially assisted by greater transparency through disclosure of relationships with the pharmaceutical industry.¹⁵

It has been argued that it is of primary importance that pharmaceutical industry interaction does not damage the doctor-patient relationship, that trust is maintained with the public and that drug choice is not influenced.¹⁶ Disentanglement was the theme of several notable editorials in the British Medical Journal.¹⁷⁻¹⁹ In an MJA editorial, Breen suggested several steps including choosing not to see drug representatives and the development of policies by hospitals, colleges and professional associations to make their staff or members more independent of industry (e.g. hospital funding of catering to provide CME, reducing financial reliance on industry, dealing with conflict of interest).²⁰ A policy was presented in the Journal of the American Medical Association from US academic medical centres, which proposed that they should take the lead in eliminating conflicts of interest, and they suggested prohibition or regulation of current interactions with industry that may harm clinical care.²¹ Interestingly, a survey of residents in Ontario found that the presence of guidelines didn't seem to affect their interaction with the pharmaceutical industry.²² A survey of clinical practice guidelines produced by North American and European societies found that an average of 81% of the authors had had interaction with the pharmaceutical industry.²³ The authors recommended that appropriate disclosure of financial conflicts of interest should be made for any clinical practice guidelines that are developed.

Kerridge et al. surveyed Australian medical organisations to find out the extent of pharmaceutical industry support they received for their CME or accreditation.²⁴ A majority of the organisations received pharmaceutical industry support for items such as conferences, CME, research grants, travel and library purchases. Whilst most had policies in place, the authors concluded it was unclear if these were effective in preventing conflict of interest and maintaining public trust. In an accompanying editorial, Komesaroff stated significant changes were required to ensure medical practice was independent and critical, yet able to work with a productive and creative

pharmaceutical industry, and serving the needs of the community.²⁵ This concurs with a US observation that rapid and effective dissemination of drug information into clinical practice requires collaboration between academic medicine and industry; however, CME must be clearly separated from drug marketing.²⁶

Recognising the marketing

Most clinical trials are funded by the pharmaceutical industry, which results in a publication bias.^{14, 27} This is compounded by further reworking of data in promotional events and publications. A US survey of promotional brochures found that data was selectively reported in favour of the company's drug.²⁸ Significant pharmaceutical industry budgets are spent on marketing and administration with the aim of influencing prescriber behaviour and inclusion of drugs in formularies.²⁷ The activity involved in such marketing includes advertising, detailing, gifts, free samples, travel subsidy and entertainment. As well as the obvious drug company representatives, key opinion leaders are recruited in an attempt to impart messages more subtly. It has been estimated that the Australian pharmaceutical industry spends about \$21000/year/doctor on drug promotion.²⁹

Various groups attempt to provide unbiased information by analysing the studies and providing evidence-based information. Examples include the Cochrane Collaboration as well as the Australian-specific endeavours of the National Prescribing Service (aimed at GPs) and state-based TAGs, which assist hospitals in their drug decision-making.

Interactions with drug companies

The assertion that promotional activities of drug companies adversely affect patient care and therapeutic costs, has been challenged.³⁰ An argument is that a productive and ethical relationship between the pharmaceutical industry and health professionals can foster significant drug discovery and improve healthcare.^{31, 32} The advantages of interacting with the pharmaceutical industry may include the following: new product information and training, free samples, funding for conferences, support for professional and social activities, and opportunities to meet with peers.¹⁶ The pharmaceutical industry may also sponsor medical education in grand rounds and specialty postgraduate training. The question is how much all of this interaction influences subsequent drug prescribing. Editorials exist that state evidence for duality of interest having a negative effect on patient care is lacking and warning against strictly limiting or severing ties with industry.³³

In one Canadian survey, the more money and promotional items a physician-in-training had received, the more likely he or she believed that discussions with representatives did not affect prescribing.¹³ Most doctors do not recognise or deny that their prescribing is being affected by their contact with the pharmaceutical industry, but this has been contradicted by objective research.^{27, 34} In a qualitative analysis of the relationship between doctors and industry representatives in the US, it was found that doctors used a variety of denials and rationalisations to cope with duality of interest and their favourable views of the doctor-detailer exchange.³⁵ Wazana's review of published articles on the subject found that doctors' interactions with the pharmaceutical industry began in medical school and persisted in practice with requests for adding their drugs to hospital formularies and changes in prescribing practice.³⁶ It was recommended that the extent of doctor-industry interactions should be further addressed at the level of policy and education. In a nested case-control study in a US university hospital, requests by doctors to have drugs added to the hospital formulary were strongly and specifically associated with the extent of the doctor's interactions with the company that marketed the drug.³⁷

A survey at one US medical school showed their students were exposed to extensive pharmaceutical industry marketing during training.³⁸ The authors recommended formal instruction was required on how to critically assess pharmaceutical industry contacts. This was also the conclusion of a literature review on the subject.³⁹ Examples of the development, implementation

and evaluation of curricula to address doctor-industry interactions have been published.^{40, 41} Other suggestions have been that medical schools must address potential conflict of interest, teach students how to scrutinise their own professional behaviour and industry practises and that policies covering student-industry interactions must be put in place.^{42, 43} A survey in another US medical centre found that the majority of residents and faculty wanted lecturers to report all financial relationships with industry.⁴⁴ Rogers et al. commented that medical educators in Australia have a duty of care to protect medical students from pharmaceutical industry influence.⁴⁵

One medical historian commented that teaching hospitals should proscribe drug company sponsorship of lunches, conferences, and travel for house staff and make it clear that gifts or food and drink off-the-premises violates the ethical norms of the profession.⁴⁶ Brennan et al. put forward a policy for all US medical centres in an attempt to remove overt pharmaceutical industry influence on prescribing.²¹ In Australia, Komesaroff and Kerridge put it simply: that the values of clinical medicine must prevail over commercial imperatives. They made key recommendations with regard to pharmaceutical industry interaction, as follows:

- conflict of interest must be declared
- accept minimal or no gifts
- entertainment should not be lavish
- travel support is appropriate for meeting contributors only
- meetings should be organised by independent committees
- participate in research and publications that have clinical value rather than just commercial bias.⁴⁷

Similar themes were incorporated into residency program guidelines developed at McMaster University in Canada for interaction with the pharmaceutical industry.⁴⁸ Subsequent analysis found that the attitude towards pharmaceutical industry information was less favourable among doctors who had trained under the guidelines than where no guidelines were in place.⁴⁹

Recommendations for improving education for health professionals about drug and device promotion have been published by four organisations concerned with this issue (www.amsa.org, www.healthyskepticism.org, www.nofreelunch.uk, www.pharmaware.co.uk).⁵⁰ They recommend the following:

- the need to be educated explicitly about decision making and the evaluation of evidence and promotion
- realise there is no proven method to gain more benefit than harm from promotion
- be aware of a responsibility to avoid drug and device promotion
- know the most reliable sources of information.

Payments and gifts

The Medicines Australia Code of Conduct aims to prohibit giving doctors payments and excessive gifts or hospitality that might induce them to prescribe their drugs.

The Wazana review of published studies found that most doctors denied that gifts influenced their prescribing. However, in one of the reviewed studies, most of the internal medicine faculty and residents agreed high-value gifts compromised their clinical decision making.⁵¹ In a review of the psychology and social effect of industry gifts to doctors it was concluded that gifting did influence doctor's prescribing habits and clinical care.²¹ A population-based survey of US radiation oncologists at one US centre found that doctors thought they were immune to industry influence but their colleagues may not be and that doctors who were willing to accept high-value gifts were sympathetic towards this practice.⁵² When 823 medical specialists across Australia completed a survey questionnaire, it was revealed 96% received offers of food, 94% items for the office and 51% personal gifts. A high proportion of these were accepted. 41 respondents received personal gifts unrelated to their profession and in breach of the current guidelines suggesting the guidelines should be expressed in more rigorous terms.⁵³ From the same survey 6.7% and 5.1%

of respondents indicated delayed publication and non-publication of key negative findings and for 2.2 % concealment of findings: All breaches of clinical research integrity.⁵⁴

In an editorial in the *Annals of Internal Medicine*, it was suggested that it might be acceptable to take modest gifts that advance medical practice but it wouldn't be appropriate to accept gifts that obligate the doctor to reciprocate in some way.⁵⁵ However, social science researchers state that even small gifts are surprisingly influential in affecting how the recipient evaluates claims made by the gift giver, and they argue that policies of limiting gift size are unlikely to eliminate bias.⁵⁶ One industry representative (turned anthropologist) found that offering free coffee made him the "drug rep of choice" at one hospital and improved his sales targets.⁵⁷ Some leading US academic institutions limit or prohibit pens and pads in an attempt to thwart potential influences on clinical decision making.^{10, 58} Codes of conduct exist to limit extravagant hospitality and funding of travel by the pharmaceutical industry. The British Thoracic Society suggested its members ask themselves if they would be happy for their patients, employers and the local press to witness their hospitality.⁵⁹

Sponsored meetings and events

Educational events sponsored by the pharmaceutical industry are nearly always associated with a free lunch or dinner. Free lunch has been described as one of the most effective sales techniques ever devised and drug companies spend enormous amounts of money on this activity.⁶⁰ In a US survey, 83% of doctors (specialists and GPs) accepted pharmaceutical industry food in the workplace. An early pharmaceutical industry publication suggested that promotional dinners resulted in an 80% increase in sales of the promoted drug.⁶¹ A study in Canada showed that industry-sponsored education or paid attendance at symposia influenced the prescribing patterns of doctors.⁶² Orłowski and Wateska found that use of two intravenous drugs increased significantly at a hospital after a large group of doctors attended an all-expenses paid trip to a medical conference sponsored by the drug companies that marketed the drugs.⁶³ Wazana found that attendance at sponsored CME events was associated with increased prescribing of the sponsor's product and that attending presentations given by pharmaceutical representative speakers was also associated with nonrational prescribing.³⁶ Retrospective analyses at US hospitals found that the increase in prescriptions for particular drugs was linked to grand rounds sponsored by the manufacturers of the drugs.^{64, 65} A questionnaire among US pharmacy residents found they thought industry-sponsored educational events enhanced their knowledge and half said it influenced their thinking.⁶⁶

A survey by the Hunter Postgraduate Medical Institute in Newcastle found that the majority of local doctors (GPs and specialists) regularly attended industry meetings (55% of responding doctors attended three or more meetings/year) and believed they were of good to excellent quality.⁶⁷ Topic, speaker and time of the meeting were seen as more important than CME points or venue and the actual sponsor was regarded as least important to them. Industry-funded but independent CME was supported by a majority of respondents. An accompanying editorial emphasised that, in Australia, there is increasing reliance on industry support for CME and that sponsorship should be provided through independent committees.⁶⁸

Brennan et al. recommend that US academic medical centres should create a central fund for educational and research activities in an attempt to reduce direct influences by the pharmaceutical industry.²¹ A perspective from the pharmaceutical industry is that they are expected to provide CME for new drugs.⁶⁹ In the same article, the author argued that it isn't surprising for prescriptions to increase after a CME activity (that presents compelling clinical data) because of participants' inclination to try it.

Samples and familiarisation programs

Samples offer a convenient way for doctors to initiate prescribing of new drugs; however, they also allow pharmaceutical industry representatives to make contact with doctors and other health

professionals. In a US national survey, 78% of doctors (specialists and GPs) admitted to receiving samples.⁷⁰ A cross-sectional survey at a US academic medical centre found that doctors used samples primarily to avoid cost to their patients but this also led to them prescribe drugs which weren't their preferred drug choice.⁷¹ This was also found in a more recent study among obstetrician-gynaecologists.⁷² Brennan et al. said that samples are a powerful inducement for doctors to prescribe expensive drugs that may not necessarily be better than what is already available and they cited studies where drug prescriptions were shown to increase as a result of accepting samples.²¹ They advocated that academic medical centres should not accept samples from drug representatives. However, the editor of the American Journal of Therapeutics argued they assist with drug initiation and titration.³⁰

Product familiarisation programs enable patients and medical staff in public hospitals to access newly approved drugs prior to possible inclusion on the PBS. Such programs need to ensure ongoing availability of the drug for patients without unanticipated costs to hospitals. Guidelines need to be put in place to ensure such programs are approved by Directors of Pharmacy and Drug and Therapeutics Committees. The Victorian Therapeutics Advisory Group has published guidelines⁷³ and more recent Joint TAGs guidelines are now available (<http://www.ciap.health.nsw.gov.au/nswtag/publications/guidelines/jttagPFP.pdf>) .

Sponsored clinical trials

Health professionals are responsible for ensuring they participate in clinical research that is of significant value and ethically conducted. They need to be careful about committing to participation in industry-sponsored trials if it is likely to cause a conflict of interest. Clinical trial design is important. Investigators should carefully define study limits within current clinical practice and an ethical framework and not be swayed to serve only marketing or licensing purposes.^{3, 74} A systematic review found that studies sponsored by pharmaceutical industry were four times more likely to have outcomes favouring the sponsor than studies funded by other sources.⁷⁵ Multiple and selective publication of studies have also been reported.^{76, 77} From an Australian questionnaire survey of medical specialists, delayed publication or non-publication of negative findings were reported by 6.7% and 5.1% of respondents.⁵⁴ A survey among US research-intensive universities found that research-related industry gifts (e.g., funding, equipment, travel) were given conditionally and the authors recommended awareness of potential conflict of interest.⁷⁸ Studies have shown that involvement in clinical trials led to requests for addition of the trial drugs into formularies and lowered the barrier for adoption of semi-innovative drugs in hospitals.^{37, 79} Similarly, clinical investigators were found to be early adopters of new drugs and influenced the prescribing behaviour of their peers.⁸⁰

Acting as a consultant

Most drug companies retain "opinion leaders" on advisory boards to provide insight into the clinical use of drugs. A US survey found that 28% of doctors received payments for consulting, giving lectures or enrolling patients in trials.⁷⁰ Conflict of interest may occur because payment for this service introduces the perception of bias when the consultant endorses a product.^{3, 81} Documents that became available after the litigation concerning the promotion of gabapentin in the US showed that advisory boards, consultant meetings and CME events were used to deliver promotional messages with augmentation by recruitment of local key opinion leaders who were used to further communicate promotional messages.⁷⁶ A Lancet editorial warned against the many temptations of the research-minded clinician, such as negotiating a lecture fee before agreeing to the subject matter, using material provided by the drug company, or becoming entangled in ghost-written publications and drug launches.⁸² A no-payment policy has been advocated or increased transparency of the doctor-industry relationship.⁵⁸

Conclusion

The pharmaceutical industry provides information and training about new products, funding for conferences, support for professional and social activities, and opportunities to meet with peers. Guidelines and codes of practice from professional bodies, societies and hospitals exist in an attempt to ensure this interaction does not breach conflict of interest. Some researchers have argued that pharmaceutical industry contact should be more limited and certain activities prohibited; however, there is a general expectation that the pharmaceutical industry will fund certain items. It is important that all health professionals who interact with the pharmaceutical industry can critically assess the contact, evaluate the evidence and recognise drug promotion, and know where to find the most reliable sources of information. Whilst there may not be anything inherently unethical in a duality of interest, the key is to recognise the duality and any potential conflict and know how to deal with it. Strategies include disclosing the duality, establishing a system of review and authorisation, and limiting or prohibiting the activities that lead to any conflict.

It is unrealistic to prohibit all contact with the pharmaceutical industry. Some activities may enhance clinical practice but others are potentially damaging to doctor-patient relationships. Suggested steps to minimise potential conflict include choosing not to obtain medical education via drug companies and to make full use of independent sources of evidence-based medicine. The development of policies by hospitals, colleges and professional associations to make their staff or members more independent of industry is also another way to limit potential conflict.

Disclosure is appropriate in circumstances where pharmaceutical company interaction may compromise decisions such as the preparation of clinical practice guidelines or suggesting additions to a drug formulary. High-value gifts may influence clinical decision making but even small gifts may be persuasive in forging bonds with the pharmaceutical industry. Free drug samples can allow doctors to initiate prescribing of new drugs but they may also lead to long-term prescribing of non-preferred and more costly drugs. With regard to continuing education, “free lunch” is a most effective sales technique and has been linked to increased sales of promoted drugs. Similarly, paid attendance at symposia appears to influence the prescribing patterns of doctors and is only appropriate for meeting contributors. Whilst there is continuing reliance on industry support for CME, another approach might be to allow sponsorship only through independent committees.

Clinical research is also not immune to promotional bias and investigators must ensure research is based on sound clinical practice and complies with all ethical requirements. Studies sponsored by the pharmaceutical industry are more likely to have outcomes favouring the sponsor than studies funded by other sources. Research-related industry gifts may be given conditionally with the goal of getting trial drugs into formularies. Publication bias occurs because most clinical trials are funded by the pharmaceutical industry and multiple and selective publication of studies occurs. Other temptations for research-based clinicians to beware of include negotiating a lecture fee before agreeing to the subject matter, using material provided by the drug company, or becoming entangled in ghost-written publications and drug launches.

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Conflict of Interest

None declared.

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