PHARMACEUTICAL REPRESENTATIVES - POLICIES AND PROCEDURES

(Adapted from the Position Statement of the NSW Therapeutic Advisory Group July 2008 - http://www.ciap.health.nsw.gov.au/nswtag/documents/publications/position-statements/pharma-liaison-july-2008.pdf)

Overview

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.

Identify any duality or conflict of interest

Disclosure is appropriate in all circumstances. 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.

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

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.

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.

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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.
   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 required to observe the Code of Conduct for New South Wales Public Sector Employees. In addition, they are expected to abide by the Code of Professional Conduct of their registration authority.

- Medical Staff: New South Wales Medical Board, Code of Professional Conduct, July 2005.
- Pharmacy Staff: Pharmaceutical Society of Australia, Code of Professional Conduct, March 1998.
- Nursing Staff: Australian Nursing and Midwifery Council, Code of Professional Conduct for Nurses in Australia, January 2003.

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.

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

- Accept minimal or no gifts. As a general rule, health professionals should not accept gifts, or at most only token items.
- Avoid the use of free samples. Free drug samples must not be used for the treatment of patients within the hospital. Acceptance of drug samples from pharmaceutical representatives is inappropriate except in circumstances approved by the Drug and Therapeutics Committee. All such drug samples must be delivered directly to the Pharmacy Department and dispensed by the Pharmacy Department.
- Entertainment should not be lavish
- Travel support is appropriate for meeting contributors only. 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
- Pharmaceutical industry sponsored research projects and clinical trials. Studies sponsored by the pharmaceutical industry are more likely to have outcomes favouring the sponsor than studies funded by other sources. Publication bias occurs because most clinical trials are funded by the pharmaceutical industry and multiple and selective publication of studies occurs. 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.

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Product Familiarisation Programs
Hospital staff should refer to the Joint Therapeutics Advisory Groups guidelines for PFPs in Australian public hospitals.

Provision of staff or equipment
Donations of equipment, or funds for the purchase of equipment, should be made to the institution and not to an individual staff member. Donations of equipment should be made public in the hospital's public communications. Donated equipment becomes the property of the hospital and is subject to the hospital's receipt and handling policies. 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.

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.

Breaches of these guidelines
Where a breach of the guidelines has occurred, a complaint should be submitted to the Chair of the Therapeutic and Drug Utlisation 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). All cases should be discussed at the Therapeutic and Drug Utilisation Committee and dealt with at 'arm's length' in a fair and transparent manner. The committee can provide independent guidance with consideration of all processes and ultimately decide whether a formal warning is required.

Risk rating: Low. Review in 5 years

REVISION & APPROVAL HISTORY
Reviewed and endorsed Therapeutic & Drug Utilisation Committee 11/8/15
Approved Quality & Patient Safety Committee 18/8/11
Therapeutic & Drug Utilisation Committee 14/6/11
Approved Quality Council 21/7/03

FOR REVIEW : AUGUST 2020