Guidance Document
for
Western Australian Public Hospitals and Health Services and their Staff on Liaison with the Pharmaceutical Industry

September 2010
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Acknowledgement: This document has been adapted for WA Hospitals and Health Services from the SATAG Guidance Document on The Relationship Between the Pharmaceutical Industry and South Australian Public Hospitals, September 2008 and the NSW TAG Position Statement on Pharmaceutical Industry and Hospital Staff Liaison in Public Hospitals, July 2008. WATAG acknowledges SATAG and NSW TAG for permission to adapt these guidelines for use in WA.
**Purpose**

The purpose of this document is to provide Western Australian public health services with guidelines for ethical interactions between the pharmaceutical industry, Western Australian public hospitals and health services and their staff, including but not limited to medical, pharmacy and nursing staff.

These guidelines aim to ensure that the primary objective of professional interactions with pharmaceutical industries is the advancement of the health and well being of the patient.

Additionally, the purpose of these guidelines is to protect:
- I. The well-being of the individual patient
- II. The fiduciary nature of the physician-patient relationship
- III. The legal interests of the hospital or health service

**Background**

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

The relationship between the pharmaceutical industry and hospital or health service staff should be maintained at the highest professional standard to ensure patient care takes precedence. Hospital and health service 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 and health service employees are likely to have a promotional intent.

The provision of patient care requires independence of judgement, unbiased prescribing of pharmaceuticals, and unbiased product selection and acquisition of pharmaceuticals.

**Guidance**

1. **Pharmaceutical Industry Representatives**

Pharmaceutical industry representatives are expected to abide by the Code of Conduct of Medicines Australia in all interactions with hospital and health service employees. Attendance of pharmaceutical industry representatives at Western Australian public hospitals and health services should comply with the following guidelines:

1.1 Appropriate identification indicating the pharmaceutical industry representative’s name and company should be worn at all times while at the hospital or health service.

1.2 Prior to making initial contact with any hospital or health service staff member, a new pharmaceutical representative should first arrange a meeting with the Director of Pharmacy.
1.3 Attendance at the hospital or health service should be by appointment only and should occur at a time and place that is not likely to interfere with the staff member’s usual work or patient care.

1.4 Patient care areas, including clinics and emergency departments must not be used for interviews between representatives and hospital and health service staff.

1.5 Non-patient care areas on wards or staff facilities may be used for interviews provided that prior arrangements have been made with the relevant hospital or health service staff.

1.6 Appointments with individual members of staff:

I. Medical Staff

In general, appointments for individual meetings should not be made with medical staff in their first three postgraduate years, except with the permission of the Head of Unit, for each appointment. Please note that within individual functional Units, there may be specific guidelines for medical staff liaison with pharmaceutical representatives. Pharmaceutical representatives and medical staff should ensure that they are familiar with any individual Unit guidelines.

II. Pharmacy Staff

Appointments for individual meetings may only be made after authorisation has first been obtained from the Director of Pharmacy.

III. Nursing Staff

Appointments for individual meetings with nursing staff should only be made after arrangement with the Director of Nursing of the relevant area.

1.7 Indications that have not been registered by the Therapeutics Goods Administration should not be promoted or disseminated in any printed form.

2. Public Hospital and Health Service Staff

Public hospital and health service staff are employees of the Western Australian Government and are required to observe the Western Australian Public Sector Code of Ethics, Conduct Guide and WA Health Code of Conduct. WA Health staff must also observe the requirements of relevant Operational Directives pertaining at the time, for example OD 0264/10 Conflict of Interest Policy and Guidelines, 29 December 2009; OD 0266/10, Sponsorship Policy, 22 January 2010; OD 0046/07 Fraud and Corruption Control Plan, 23 April 2007 and OD 0086/07 Attendance at Functions and the Acceptance of Gifts, Prizes or Inducements, 29 November 2007. Hospital and health service staff are additionally expected to abide by the Code of Professional Conduct of their registration authority and by the policy of their employer.

2.1 Medical Staff

Medical Board of Western Australia, The Duties Of A Medical Practitioner Registered With The Medical Board Of Western Australia, August 2003.
2.2 **Pharmacy Staff**


2.3 **Nursing Staff**


2.4 All hospital and health service staff are bound by privacy principles and must not divulge patient details to individuals not involved in patient care.

3. **Sponsored Meetings and Events**

Hospital and health services 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.

3.1 Pharmaceutical industry sponsored meetings, promotional events or exhibits for medical, nursing or pharmacy staff should be arranged in consultation with an appropriate senior member of the professional staff.

3.2 Pharmaceutical industry sponsorship should be explicitly declared and acknowledged.

3.3 With the exception of in-service training on a specific product, functions should address general topics and not be orientated towards one product.

3.4 The cost of bringing invited speakers to present at scientific meetings should be defrayed by the pharmaceutical industry.

3.5 Discussion should be based on sound published evidence.

3.6 There should be an opportunity for staff to express independent views relating to the meeting topic.

3.7 Materials provided at functions should be educational rather than promotional in nature and useful to hospital or health service staff for the care and treatment of patients.

3.8 Product promotion at hospital or health service meetings and events should not be permitted.

3.9 Meetings should not be used as a forum to provide samples.

3.10 In-service training should not be undertaken without prior approval from an appropriate senior staff member, such as the Director of Nursing or Director of Pharmacy.

4. **Drug Acquisition**

Management of pharmaceutical products at Western Australian public hospitals and health services is by use of a drug formulary. The WA Drug Evaluation Panel, hospital or health service Drug and Therapeutics Committee, or other delegated person or body, evaluates drugs for inclusion in the formulary following consideration of applications from senior hospital and health service medical staff. Formulary approval is made following consideration of multiple factors including clinical and scientific evidence, equity of access, cost-effectiveness and affordability.
4.1 The Director of Pharmacy must have 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).

4.2 Appropriate consultation with clinical units or users should take place.

4.3 Individual staff members, departments, or the health service 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 or health service drug formulary.

4.4 All drug delivery, SAS, compassionate use supplies or PFPs should be accompanied by an official Pharmacy purchase order and must be delivered directly to the Pharmacy Department and dispensed by the Pharmacy Department.

5. Drug Samples/Starter Packs

Hospital and health service staff should refer to and observe their hospital or health service policy on the provision and use of samples/starter packs.

5.1 All drug samples should be delivered directly to the Pharmacy Department and dispensed by the Pharmacy Department.

5.2 Requests and receipt of supply of samples should be documented in accordance with the Medicines Australia Code of Conduct (i.e. there must be an appropriate signed request/receipt of supply).

5.3 Drug samples should not to be left in clinics, patient care areas, offices or elsewhere on hospital or health service premises for the purpose of being issued to patients.

5.4 Hospital and health service staff should not accept drug samples for the treatment of patients within the service unit, except where dispensed by the Pharmacy Department.

6. Product Familiarisation Programs

Hospital and health service staff should refer to and observe approved processes and guidelines for Product Familiarisation Programs (PFPs). WATAG guidelines on PFPs are based on recommendations of the Council of Australian Therapeutics Advisory Groups (CATAG).

7. Pharmaceutical Industry Sponsored Research Projects and Clinical Trials

7.1 Sponsored research projects and clinical trials require the Clinical Drug Trials Committee and Human Research Ethics Committee approval.

7.2 The Pharmacy Department should be provided with information on any drug trial being carried out at the hospital or health service. Such information should include data on efficacy, toxicity and protocol for use.

7.3 The Human Research Ethics Committee should 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. This would include details of travel to investigators’ meetings.
7.4 Funds should be deposited into an appropriate ‘special purpose’ account managed by the hospital or health service.

7.5 Funds provided should be for the conduct of the project and not involve direct personal payment to individual staff members.

7.6 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.

7.7 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.

8. Travel Sponsorship

8.1 Hospital and health service employees should be encouraged not to accept travel sponsored by pharmaceutical industries unless it is related to the need for research and educational activities related to the staff member’s professional speciality or sponsorship is to attend a meeting at which the staff member is making a formal contribution.

8.2 Staff members should ensure the transparency of the arrangements and should declare the nature of the sponsorship to their Executive Director, so that determination can be made as to whether any conflict of interest exists.

8.3 Acceptance of travel sponsorship should be clearly linked to education and there must be no loss of professional independence.

8.4 Staff members’ cost of travel should be paid from ‘special purpose’ accounts, the income of which may be partly or wholly derived from payments by the pharmaceutical industry.

8.5 Accepting travel sponsorship from a pharmaceutical company for a spouse or partner cannot be justified under any circumstance in accordance with the Medicines Australia Code of Conduct.

9. Ex Gratia Payments

9.1 Any ex gratia payments received by divisions or units should be paid into a separate ‘special purpose’ account administered by the hospital or health service.

9.2 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.

10. Provision of Staff or Equipment

10.1 Donations of equipment, or funds for the purchase of equipment, should be made to the institution and not to an individual staff member.

10.2 Donations of equipment should be made public in the hospital or health service’s public communications.

10.3 Donated equipment becomes the property of the health service and is subject to the hospital or health service’s receipt and handling policies.
10.4 Funds may be provided to employ staff for specific service functions but should be transparent, open to scrutiny and accountable and should not bestow competitive advantage to the sponsoring organisations.

The sponsorship must not to be tied to the purchase of specific products or supply from particular sources.

Agreement to any sponsorship must be based on the best clinical practice and clinical evidence that the product is in the best for the patient and does not preclude alternative therapies from other pharmaceutical companies.

Associated staff must declare any pecuniary interest such as company shares or receipt of a research grant with the sponsoring organisation, which may have the potential to influence funding decisions.

Any submission or request for a commercially sponsored nurse or allied health position must be discussed and approved by the hospital or health service executive and comply with any policy governing this matter.

11. **Staff Members Acting as Consultants**

11.1 Staff members who act as pharmaceutical industry consultants should openly declare their involvement to avoid conflict of interests relating to applications for research studies or drug formulary applications.

11.2 Staff members who act as consultants are encouraged to pay any honoraria into a ‘special purpose’ fund managed by the hospital, health service or affiliated university and not receive these as personal payments.

12. **Financial Interests**

12.1 All cases of financial interests in pharmaceutical industry by staff or close family of staff members should be declared to the hospital or health service’s administration and on any other relevant occasion.

12.2 Staff should ensure that financial interests in pharmaceutical industries do not influence professional judgement.

12.3 In circumstances where there is a conflict of interest relating to an application for drugs to be included in the hospital or health service drug formulary, the staff member should withdraw from any discussions about the drugs.

13. **Breaches of Hospital or Health Service Guidelines**

13.1 Where a breach of the guidelines has occurred, a complaint should be submitted to the Chair of the hospital or health service Drug and Therapeutics Committee. The complainant should outline the details of the breach, the Pharmaceutical Company and the name of the representative. The Chair should have discretion, after discussion with the reporter, as to whether a formal warning is required.

If it is deemed that a formal warning is to be given, the pharmaceutical representative should be contacted personally and a formal letter sent to them requesting meeting with the relevant personnel at the hospital or health service. The principles of natural justice must be followed, i.e. the pharmaceutical representative should be afforded a fair hearing and the opportunity to respond to the complaint.
Following a further complaint in writing, the pharmaceutical representative is warned by the Chair of the Drug and Therapeutics Committee, the relevant Divisional Director and Executive Director of Medical Services. A formal warning in writing should be sent to the relevant pharmaceutical company.

If a third breach occurs, the relevant pharmaceutical company is notified and the matter is referred to them for resolution with a recommendation that they prohibit the representative from attending the hospital or health service. Further infringement may jeopardise future business dealings with the hospital or health service and should be addressed via professional channels.

13.2 Any hospital or health service staff member who fails to observe their hospital or health service guidelines should be reminded of the local policy and requested to comply. Further infringement should be dealt with via the hospital or health service disciplinary policy.