Guidelines in regard to pharmaceutical company representatives and sponsorship

Medicines Policy

<table>
<thead>
<tr>
<th>Version Number</th>
<th>1</th>
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</thead>
<tbody>
<tr>
<td>Name of Originator/Author:</td>
<td>Chief Pharmacist</td>
</tr>
<tr>
<td>Name of Responsible Committee:</td>
<td>Medicines Management Committee</td>
</tr>
<tr>
<td>Name of Executive Lead:</td>
<td>Medical Director</td>
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<tr>
<td>Date V1 issued:</td>
<td>May 2010</td>
</tr>
<tr>
<td>Last Reviewed:</td>
<td>March 2015</td>
</tr>
<tr>
<td>Next Review date:</td>
<td>March 2018</td>
</tr>
<tr>
<td>Scope:</td>
<td>Trustwide including HMP Manchester</td>
</tr>
<tr>
<td>MMHSCT Document Code:</td>
<td>This to be completed by Quality Administrator</td>
</tr>
</tbody>
</table>
Type of Procedural Document: Guideline  
Specific Category / Directorate: Governance  
Document Purpose: Guideline for pharmaceutical representatives concerning joint working relating to prescribing or new products.

Consultation: Medicines Management Team Guidelines Committee  
Approving Committee: Medicines Management Committee  
Approval Date: March 2015  
Ratification and Date: Lead Executive  
Date of Ratification: March 2015

Procedural Documents to be read in conjunction with this document:  

Training Needs Analysis Impact: There are training requirements for this procedural document - see the Mandatory Training matrix.  
Financial Resource Impact: There are no financial resource impacts.

Document Change History: Changes to this document in different versions must be detailed below. Rationale for the change should also be given.

<table>
<thead>
<tr>
<th>Version Number / Name of procedural document this supersedes</th>
<th>Type of Change i.e. Review / Legislation / Claim / Complaint</th>
<th>Date</th>
<th>Details of Change and approving group or Executive Lead (if done outside of the formal revision process)</th>
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<tbody>
<tr>
<td>Version 1</td>
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Please ensure that any external references used in the creation of this document are entered as the final section of this procedural document.

External References have been included in the body of the Procedural Document: YES

Privacy Impact Assessment submitted?: Please ensure this is completed at each consultation stage:  
- Any issues? See Medicines Policy

Fraud Proofing submitted?: Please ensure this is completed at each consultation stage:  
- Any issues? See Medicines Policy

Policy authors are asked to consider each of the nine protected characteristics under the Equality Act 2010. We expect you to demonstrate that throughout the policy process you have had regard to the aims of the Equality Duty:

1. Eliminate unlawful discrimination, harassment and victimisation and any other conduct prohibited by the Act;
2. Advance equality of opportunity between people who share a protected characteristic and people who do not share it; and
3. Foster good relations between people who share a protected characteristic and people who do not share it.

Please provide a brief account of how you have done this, further work to be completed and any support you have had in considering the aims and working in compliance with the Equality Duty.

If you are unclear on how to do this or would like further advice and support then you may contact quality.admin@mhsc.nhs.uk.

It is the responsibility of the approving Committee/group/meetings to ensure this statement reflects the Trusts objectives and position with compliance as set out within the NHS Equality Delivery System.
Please confirm that the statement below is correct. If not please indicate why?  YES

This procedural document is broad and the scope is Trustwide so complies with the Trust’s Equality Delivery Service

| In line with the Trust values can this Procedural Document be published on the Trust’s External Website. | YES | X | NO |

It is the Authors responsibility to ensure all procedural documents comply with the Trust values

If you are unclear on any of the requirements in the document control sheet then please email quality.admin@mhsct.nhs.uk before proceeding
Monitoring and Compliance Requirements Sheet (This section **MUST** be completed by the Author without exception). This section demonstrates the Trust’s commitment to Continuous Improvement and Lessons Learned from Incidents, Reports from the Coroner or other External Agencies and will be submitted as evidence as required.

<table>
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<tr>
<th>Minimum Requirement/Standard/Indicator to be monitored and Section of Document it appears</th>
<th>Process for monitoring</th>
<th>Responsible Individual</th>
<th>Frequency of Monitoring</th>
<th>Responsible Committee/Group/meeting for review of results / action plan approval / implementation</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>1 Please state how different aspects (standards) of the effectiveness of this Procedural Document will be monitored. If more than one standard, please enter the details in the rows below (as appropriate)</td>
<td>Audit or review or reports to committees or meetings</td>
<td>Please enter the title of the person(s) who will be undertaking this task.</td>
<td>Please enter how often e.g. monthly or 6 monthly or annually</td>
<td>This will normally be the Integrated Risk Management and Clinical Governance Committee. If it is different specify.</td>
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</tr>
<tr>
<td>2 Compliance as part of the Medicines Policy</td>
<td>Annual Report</td>
<td>Chief Pharmacist</td>
<td>Annually</td>
<td>Integrated Risk Management and Clinical Governance Committee</td>
<td></td>
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<tr>
<td>3 Incidents Reported</td>
<td>DATIX Reports</td>
<td>Chief Pharmacist</td>
<td>Quarterly</td>
<td>Medicines Management Team</td>
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NB: If you have selected audit you should complete the required audit registration form and standards document and submit these with your expected timescales for completing the audit to quality.admin@mhsc.nhs.uk as soon as possible and no later than 4 weeks prior to the audit commencing.

The Group / Committee should also ensure the monitoring work is added to their yearly schedule of monitoring and action logs as appropriate.
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1. Introduction

This guideline aims to provide guidance and clarification to all members of the Trust regarding business conduct and accountability in relation to commercial sponsorship and dealings with the Pharmaceutical Industry (PI). The guideline will:

- Ensure that the work of the organisation is not compromised in any way
- Establish a mechanism to protect service users, carers and members
- Establish ways that all parties can work constructively with the pharmaceutical industry
- Provide a means of monitoring development in this area

It is intended to supplement and provide practical advice in addition to Health Service Guidance HSG (93) 5: Standards of Business Conduct for NHS Staff which includes the Prevention of Corruption Acts 1906-1916 and the Trust’s ‘Standards of business conduct for NHS staff and declaration of interest policy’.

The guidelines are intended to address the potential conflict when engaging with the Pharmaceutical Industry. It also addresses the conflict that could occur between a member of staff’s employment with the Trust and paid employment they undertake or may wish to undertake outside the Trust. It is recognised that some employees will work for more than one organisation and as such will have to consider the governance arrangements covering the area that they are working within when undertaking any paid employment. Further advice should be taken through supervision if ambiguous.

They are also designed to avoid confusion and safeguard the interests of the service and public.

If you have any doubts on any part, then please contact your manager / supervisor who will be able to advise you.

2. Summary of principles

All staff must:

- Remain impartial and honest in the conduct of their business.
- Not accept gifts.
- Ensure they do not abuse their official position for personal gain.
- Ensure they do not seek to advantage any private business or other interests in the course of their duties.
- Register any interest outside the work place, with the Trust, that could be construed as affecting any aspect of their work with the Trust.

3. Code of conduct for Pharmaceutical Industry representatives visiting the Trust

a. Company representatives should not visit clinical areas without prior agreement from the relevant manager. This is to preserve confidentiality for our service users.
b. The relevant manager approving the visit should ensure that this and other guidelines listed above are followed and that the reason for a PI visit is legitimate and necessary.

c. Reps must see the consultant first by making an appointment and must ask permission before seeing junior medical staff. Likewise prior permission from ward manager is needed before seeing ward nurses.

d. Opportunistic visits by company representatives will not be accepted.

e. PI representatives will wear a name badge at all times and sign in at the relevant reception point. If there is no reception point for the area they are visiting they should sign in at the nearest point. e.g. Park House if visiting the Sir Sidney Hamburger Unit or Medical Education Centre.

f. Company representatives may only discuss products which are listed within current Trust prescribing guidelines / formularies

g. Company representatives will be expected to provide information relating to the company’s products as well as any supporting literature and independent clinical data.

h. If company representatives are found to deviate from this protocol then future access will be denied for a period to be notified to the representative and his / her manager by the authorising manager in conjunction with the chief pharmacist.

i. PI representatives should follow the Association of the British Pharmaceutical Industry (ABPI) code of conduct or their own company code at all times if not ABPI affiliated.

4. New Products (see appendix 1)

a. New products will be evaluated by the Medicines Management Committee

b. Representatives will only be able to promote new products approved via the Medicines Management Committee route.

c. Product samples will not be used under any circumstances and should never be offered or supplied

d. Representatives are not permitted to use MMHSCT guidelines for promotional purposes outside Trust

5. Sponsorship

5.1 Meetings

a. Agreement between the Trust and the PI shall only be considered having taken full account of HSG(93)5 – ‘Standards of business conduct for NHS staff’ and EL(94)40 – ‘Codes of conduct and accountability’ and the ABPI code of conduct.

b. Sponsorship is only permitted of education events agreed by the relevant manager with advice as necessary from the medicines management team.

c. Educational events should link into Trust and operational priorities and should support improved clinical or evidence based practice.

d. Sponsorship of purely social events is not permitted at any point.
e. The Trust will not agree to any ‘linked deals’ whereby sponsorship is linked to purchase of particular products or to supply from particular sources.

f. The Trust will accept sponsorship only in the spirit of co-operating with the other parties interested in improving the quality of healthcare for the people of Manchester.

g. Where sponsorship is accepted, the relevant clinician or department must ensure the sponsor is aware that:
   - commissioning decisions will not be influenced by the sponsor
   - monitoring systems will be put in place to audit the impact of the sponsor
   - sponsorship will be withdrawn, subject to the above not being agreed by both parties.

h. Acknowledgement of sponsorship may be made where appropriate but not in a promotional way, i.e. specific drug names will not be used.

i. The Trust will not allow information to be given to the PI by its employees, which will identify individual patients within the Trust.

5.2 Conferences

a. Pharmaceutical industry sponsorship of educational meetings should be compatible with the Association of the British Pharmaceutical Industry (ABPI) code of ethics if the sponsor is a member. This states that each company should have a policy that covers meetings with healthcare staff. Wherever practical sponsorship of meetings, particularly in the case of large meetings / conferences will be from several companies, by mutual agreement.

b. Pharmaceutical Industry representatives must leave the room during the meeting to limit inadvertent access to confidential information.

5.3 Posts / Research and Audit

a. The Trust Chief Pharmacist and medicines management committee should be made aware of and be in agreement with any post sponsored by the pharmaceutical industry

b. Departments should not enter into agreements with commercial companies to carry out audits or research within a clinical area where an external nurse has access to patient information without explicit agreement, which must comply with the trust’s policies on confidentiality and on service audit. Departments offered such support should discuss this with the Chief Pharmacist. The Trust Medicines Management Committee, Effectiveness team and pharmacists may be able to provide support similar to that offered.

c. The Trust will not allow PI sponsored posts to work with its service users unless agreed through the medicines management and clinical governance structures.

d. All information generated as a result of commercial sponsorship activity or research and subsequent reports remain the property and copyright of the party that entered into the sponsorship. They must not be disclosed to commercial companies. The Trust must receive copies of all information collected if requested.
5.4 Financial arrangements

a. The Trust is committed to openness in respect of sponsorship and sponsorship income. The sources of sponsorship and use of income shall be identified separately in all accounts and independently audited as required. Further advice can be sought from the finance department.

b. Sponsorship income will be paid to the Trust. Under no circumstances will sponsorship monies be paid directly to an individual member of staff unless this is for work undertaken in their own time.

6. Trust Employee Recommendations

a. Staff should not accept gifts of entertainment other than modest hospitality when this is provided as sponsorship of an educational meeting. Staff must not approach pharmaceutical industry representatives for sponsorship of non-educational events e.g. birthday or leaving celebrations.

b. Where Trust employees carry out consultancy work or give lectures for the pharmaceutical industry, this will be in the employee’s own time and carried out with the permission of their manager. Wherever possible, this should not be of a promotional nature.

c. Where employees carry out work in Trust time payment will be to the Trust.

d. Offers of support for sponsorship for study leave must be approved by the line manager. Managers are welcome to contact the Chief Pharmacist to discuss these offers.

e. A record should be made in the Trust register of interests of any gifts, payments for consultancy work or educational conferences or courses where the value is greater than £25. The form to register interests, gifts or hospitality is included in Appendix 2.

7. Monitoring procedures

The effectiveness of this policy will be maintained by regular evaluation, review and development. This will be the responsibility of the Chief Pharmacist and the Medical Director via the Medicines Management and Integrated Risk & Governance Committee.
Meetings with pharmaceutical representatives concerning joint working relating to prescribing or new products

1. Representatives wishing to discuss service development / joint working related to prescribing within the trust, should discuss their proposals with the Chief Pharmacist who will then pass on any relevant information to other appropriate members of the trust staff.

2. New medicines will be evaluated by the medicines management committee which includes members from NHS Manchester to allow decisions to be made across the health economy.

3. Visits by senior representatives of the pharmaceutical industry e.g. regional managers, are encouraged to ensure that the full range of product information is available. Pharmaceutical companies should provide one point of contact to ensure consistent communication.

4. Representatives wishing to make an appointment should contact the Chief Pharmacist outlining the information they wish to discuss.

5. Following receipt of the information, the Chief Pharmacist will contact the representative if they wish to discuss the product / service development further. Some queries may be dealt with over the telephone, whilst others may require an appointment.

6. If the Chief Pharmacist does not contact the representative following receipt of the information, then the representative should assume that no further contact is required at this point in time.

7. The Chief Pharmacist will provide feedback on significant developments in drug therapy through the Medicines Management Committee and they will decide if any information needs to be more widely distributed. Individual prescribers are welcome to seek the Chief Pharmacist’s opinion on the information they have received on specific products or to request 'neutral' information on a drug.

8. Significant drug issues affecting the Trust as a whole will continue to be monitored via the Medicines Management Committee.
Appendix 2

DECLARATION OF INTERESTS FORM

Employees are required to make a Declaration of Interests / Declaration of gifts and Hospitality / Declaration of Commercial Sponsorship in accordance with the Care Trust’s Standards of Business conduct for NHS Staff and Declaration of Interest Policy. This form should be returned to the Trust Board Secretary and a copy sent to your Service Director or equivalent senior manager.

Name: ________________________________________________________________

Job Title: ______________________________________________________________

Department/ Ward: ______________________________________________________

Telephone number: ______________________________________________________

Please outline below the nature of the interest / gifts / hospitality / commercial sponsorship to be declared:

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

Approximate value (if appropriate): __________________________

Employee’s signature: ________________________________________________

Date: __________________________________________________________________
### Register of Gifts, Gratuities, Sponsorship and Hospitality

<table>
<thead>
<tr>
<th>Name of person making the declaration</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>Designation / role:</td>
<td>--</td>
</tr>
<tr>
<td>Name &amp; designation of person the gift or hospitality given to <em>(if different from above)</em></td>
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</tr>
<tr>
<td>Work Base</td>
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<tr>
<td>Date Received</td>
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<tr>
<td>Received from</td>
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<tr>
<td>Purpose</td>
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<tr>
<td>Details of Benefit</td>
<td></td>
</tr>
<tr>
<td>Value <em>(if known)</em></td>
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Completed forms to be forwarded to:

**Mrs M Hughes**  
**Trust Board Secretary**  
Manchester Mental Health & Social Care NHS Trust

Address:  **70 Manchester Road, Chorlton cum Hardy, Manchester M21 9UN**  
Email:  **michelle.hughes@mhsc.nhs.uk**  
Tel:  **0161 882 1366**  
Fax:  **0161 882 1090**