



HPFT

Working with the Pharmaceutical Industry Policy

This policy provides a framework to assist HPFT staff in determining when commercial sponsorship from the pharmaceutical industry or a joint working agreement is appropriate and managing any visits from pharmaceutical representatives

HPFT Policy

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|-----------------|---|
| Version | 1 |
| Executive Lead | Executive Director – Quality & Medical Leadership |
| Lead Author | Deputy Chief Pharmacist |
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Document on a Page

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| Title of document | Working with the Pharmaceutical Industry Policy | | |
| Document Type | Policy | | |
| Ratifying Committee | Drug and Therapeutics Committee | | |
| Version | Issue Date | Review Date | Lead Author |
| 1 | 13/02/2018 | 13/02/2021 | Deputy Chief Pharmacist |
| Staff need to know about this policy | This policy sets out the principles and standards which should be adhered to in order to ensure that commercial sponsorship from the pharmaceutical industry or a joint working agreement is appropriate whilst maintaining an impartial and honest approach to putting service users first. | | |
| Staff are encouraged to read the whole policy but I (the Author) have chosen three key messages from the document to share: | <ol style="list-style-type: none"> 1. The importance of the Drug and Therapeutics Committee members to complete a declaration of conflict of interests form when necessary 2. The conduct of the pharmaceutical representatives. 3. All collaborative working should be in the interests of service users. | | |
| Summary of significant changes from previous version are: | New policy | | |

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1. Introduction

- 1.1 The Trust acknowledges the role which the pharmaceutical industry has to play in aiding healthcare professionals in the provision of treatments that are safe and cost effective for service users in their care.
- 1.2 Pharmaceutical representatives can be a useful resource for healthcare professionals and joint working with pharmaceutical industry can help create innovative new services to benefit service users.
- 1.3 This policy provides a framework to assist HPFT staff in determining when commercial sponsorship from the pharmaceutical industry or a joint working agreement is appropriate whilst maintaining an impartial and honest approach to putting service users' interests first.
- 1.4 The Association of the British Pharmaceutical Industry (ABPI) Code of Practice 2016 has been referred to in the creation of this document.
<http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf>
- 1.5 The Trusts' Standards of Business Conduct policy has also been referred to throughout this policy
<http://trustspace/InformationCentre/TrustPolicies/Lists/Policies/Attachments/230/Standards%20of%20Business%20Conduct%20Policy%20v5.1.pdf>.

2. Summary

- 2.1 The purpose of this policy is not intended to prohibit HPFT staff from working with the Pharmaceutical Industry however the policy does require staff to declare those interests.
- 2.2 The policy aims to provide clarity on when and how staff may work with the Pharmaceutical Industry, and what documentation is required to ensure transparency of such arrangements.
- 2.3 The Trust is a public body and as such is subject to public scrutiny and is accountable for all its actions. The Trust therefore has a duty to ensure that all its business is conducted to the highest possible standards of openness, honesty and probity. It is the responsibility of all employees to ensure that they are accountable and are not placed in a position which risks, or appears to risk conflict between their private interests and their NHS duties.
- 2.4 Staff must ensure the interests of service users remain paramount at all times.
- 2.5 Staff must be impartial and honest in the conduct of their official business.
- 2.6 Staff who are in doubt about a particular situation should seek advice from their line manager.
- 2.7 Failure to adhere to this policy could constitute the criminal offence of fraud and the staff could be subject to both disciplinary action and a criminal investigation

3. Objectives

- 3.1 To set out the principles and standards which should be applied when HPFT staff engage with the Pharmaceutical Industry.
- 3.2 To provide consistency across the Trust when dealing with the pharmaceutical industry.

4. Scope

4.1 This policy applies to all staff within the Trust who may deal with the Pharmaceutical Industry.

5. Definitions

5.1 **Commercial sponsorship** is defined as including NHS funding from an external source e.g. funding of all or part of the costs of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs (including trips abroad), provision of free services (speakers), buildings or premises.

5.2 **Hospitality** is defined as the receipt of entertainment, gifts or cash (or equivalent) for personal use or benefit which has no direct benefit to service user care or the business of HPFT.

5.3 **Joint working** describes situations where, for the benefit of service users, organisations pool skills, experience and / or resources for the joint development and implementation of service user centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner. <http://www.abpi.org.uk/about-us/resources/publications-library/joint-working-handbook>

6. Duties and Responsibilities

6.1 **The Chief Executive** is responsible for ensuring the Trust employs a comprehensive strategy to support the management of risk, including clinical risks associated with service users' mental ill health.

6.2 **The Executive Directors** are responsible for ensuring the Trust has robust policies and procedures for the management of clinical risk. They are also responsible for the strategic and operational delivery of a high quality of service provision and ensure that learning is applied following any adverse incidents.

6.3 **Service Line Directors, Assistant Directors and Services Managers:** are responsible for ensuring that all staff within their service lines receives regular supervision, are properly supported and receive their mandatory training.

6.4 **The Trust's Chief Pharmacist** has the overall responsibility for the establishment, maintenance and monitoring of the system for medicines optimisation and management across the Trust. This is in consultation with appropriate senior medical and nursing staff, and other relevant healthcare professionals.

6.5 **The ward / service manager** is ultimately accountable for ensuring adequate systems are in place to control all the medicines in his/her ward or unit and that these systems are followed at all times. They are also responsible for ensuring that staff have access to this policy and have working knowledge of its contents.

6.6 All **staff** (especially those involved in organising hospitality meetings, seeking sponsorship or who are involved in any other form of collaborative working with the pharmaceutical industry) are responsible for ensuring they are familiar with the contents of this policy and adhere to it.

7. Process

7.1 Code of Conduct

7.1.1 All Trust staff including independent contractors working in the NHS should follow existing professional codes of conduct and the Trusts' Values and Behaviour framework. All employees and those who are not covered by such a professional code are expected at all times (including during leave) to:

- Act impartially in all their work;
- Refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgement or integrity, and to avoid seeking to exert influence to obtain preferential consideration. All such gifts should be returned and hospitality refused;
- Declare and register gifts, benefits, or sponsorship of any kind in accordance with time limits agreed locally (HPFT - 28 days) whether refused or accepted. In addition gifts should be declared if several small gifts worth a total of over £20 are received from the same or closely related source in a 12-month period. The Declaration of Conflict of Interest form must be completed, see Appendix 1;
- Declare and record financial or personal interest (e.g. company shares, research grant) in any organisation with which they or a close relative have to deal with, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgement is not influenced by such considerations. The Declaration of Outside Business Interest form must be completed, see Appendix 2;
- Make it a matter of policy that offers of sponsorship that could possibly breach the Code be reported to the Board, allowing the Board to make the decision on whether the sponsorship should be accepted or declined;
- Not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others;
- Ensure professional registration (if applicable) and/or status are not used in the promotion of commercial products or services;
- Beware of bias generated through sponsorship, where this might impinge on professional judgement and impartiality;
- Neither agrees to practise under any conditions, which compromise professional independence or judgement, nor imposes such conditions on other professionals.

7.2 Declaration of Conflict of Interest

- The following publication was consulted for this section - NHS England - Managing Conflicts of Interest in the NHS: Guidance for staff and organisations, published in February 2017. <https://www.england.nhs.uk/wp-content/uploads/2017/02/guidance-managing-conflicts-of-interest-nhs.pdf>
- For the purposes of this policy a 'conflict of interest' is defined as: "A set of circumstances by which a reasonable person would consider that an individual's ability to apply judgement or act, in the context of delivering, commissioning, or assuring taxpayer funded health and care services is, or could be, impaired or influenced by another interest they hold."
- All Trust staff who are members of strategic decision making groups should be asked to complete a "Conflict of Interest" form (see Appendix 1) at the beginning of each meeting should they need to make a declaration.

Examples of such groups include committees, panels and groups that make key strategic decisions about things such as:

- Entering into (or renewing) large scale contracts
- Awarding grants
- Making procurement decisions
- Selection of medicines, equipment, and devices

This includes all **members of the Drug and Therapeutics Committee (DTC)**. Completed forms by DTC members should be given to the Chief Pharmacist, who will pass these on to the HPFT Company Secretary.

- Some common situations which can give rise to risk of conflicts of interest, includes:
 - Gifts
 - Hospitality
 - Outside employment
 - Shareholdings and other ownership interests
 - Patents
 - Loyalty interests
 - Donations
 - Sponsored events
 - Sponsored research
 - Sponsored posts
 - Payment for speaking at meetings
 - Participation in sponsored clinical trials
 - Clinical private practice
- The Trusts Company Secretary is responsible for maintaining an up to date register of interests. An interest should remain on the register for a minimum of 6 months after the interest has expired. The trust should retain a private record of historic interests for a minimum of 6 years after the date on which it expired.
- In order to ensure that service users and others have confidence in the relationship between the pharmaceutical industry and healthcare professionals and healthcare organisations, the pharmaceutical industry discloses details of payments and other benefits in kind made by the industry to staff and the organisation.

This information is published on the database – Disclosure UK.
<http://www.abpi.org.uk/ethics/ethical-responsibility/disclosure-uk/> .

This database will be checked by the DTC annually to ensure it matches with the relevant declaration of conflict of interest forms.

7.3 Pharmaceutical Representatives

- Visits to the hospital should be made only to keep an agreed appointment, or to make an appointment;
- New representatives should contact the Chief Pharmacist and/or Chair of DTC to introduce themselves and acquaint themselves with relevant Trust procedures;
- Only senior members of staff e.g. Consultants, SPRs (CT4-6), Senior Non-Medical Prescribers, Senior Nurses and Pharmacy leads should see pharmaceutical representatives and this should be by a pre-arranged appointment. Junior staff are not permitted to see pharmaceutical representatives or to provide them with information;
- Representatives **MUST** have photographic identification, which clearly states their name, company and job title;
- Representatives must not promote a new product until the Chief Pharmacist and Chair of DTC have been contacted;

- Representatives are not allowed to tour the hospital looking for staff, and are not to enter clinical areas without prior appointment with a senior member of staff;
- Representatives must not talk to service users;
- Representatives must not present or ask for information on competitor products and prices;
- Meetings with representatives should not take place in public places such as corridors, waiting rooms or canteens;
- Representatives are expected to adhere to the APBI Code of Practice;
- Meetings for staff/teams are permitted but should be educational and therefore arranged via the medical education team for doctors, Director of Nursing for nurses and Heads of Department/Service for all other staff. Meetings must be arranged via email and be recorded using the form found in appendix 3. **The form must be sent by the Trust Lead to the Pharmacy Data Analyst at MedsManagement@hpft.nhs.uk two weeks before the meeting.**
- Representatives should respect their position as visitors to the Trust and recognise that the interests and priorities of the trust may be different from their own.

7.4 Gifts

- No gifts may be received by HPFT staff from the pharmaceutical representatives promoting or endorsing medicines.
- This does not include publications made available to healthcare professionals which are to be passed on to service users and which are part of a service user support programme.
- Articles of low intrinsic value, such as calendars, pens and diaries, may be accepted.

7.5 Samples

- Product samples may be shown and demonstrated but must not be left with staff unless they are placebo.

7.6 Meetings, Hospitality and Sponsorship

- Delivery of services across the NHS relies on working with a wide range of partners (including industry and academia) in different places and, sometimes, outside of 'traditional' working hours. As a result, staff will sometimes appropriately receive hospitality. Staff receiving hospitality should always be prepared to justify why it has been accepted, and be mindful that even hospitality of a small value may give rise to perceptions of impropriety and might influence behaviour.
- Hospitality means offers of meals, refreshments, travel, accommodation, and other expenses in relation to attendance at meetings, conferences, education and training events, etc.
- Modest hospitality provided it is normal and reasonable in the circumstances - e.g. lunches in the course of working visits may be acceptable (no alcohol to be consumed by staff during work times).
- Hospitality must be secondary to the purpose of the meeting. The level of hospitality offered must not exceed that level which the recipients would normally adopt when paying for themselves or that which could be reciprocated by the Trust. It should not extend beyond those whose role makes it appropriate for them to attend the meeting.
- Pharmaceutical companies are permitted to sponsor Trust academic meetings provided they are arranged via senior members of staff. Meetings must be

arranged via email and be recorded using the form found in appendix 3. The form must be sent to the Pharmacy Data Analyst at MedsManagement@hpft.nhs.uk two weeks before the meeting.

- If a meeting is sponsored by a pharmaceutical company or companies, this fact must be disclosed in all of the papers relating to the meeting and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

7.7 Joint Working

- Joint working between one or more pharmaceutical companies and the NHS and others is acceptable provided that this is carried out in a manner compatible with the ABPI Code.
- The Department of Health and the ABPI have jointly issued Moving beyond sponsorship: interactive toolkit for joint working between the NHS and the pharmaceutical industry. This toolkit should be used to ensure that all aspects of joint working have been fully considered and is carried out in a structured way.
- Joint working must always benefit service users.
- A formal written agreement must be in place and an executive summary of the joint working agreement must be made publicly available before arrangements are implemented.
- Transfers of value made by companies in connection with joint working must be publicly disclosed.
- Joint working must not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell any medicine. It must therefore always be ensured that any and all of the benefits of joint working which are due to the NHS, go not to individuals or practices but to an NHS or other organisation.
- A joint working agreement can be based on the use of a particular medicine of a company party to the agreement, but only if the requirements below are complied with and only if the parties have satisfied themselves that the use of the medicine will enhance service user care.
- Goods and services provided by the company as part of the joint working agreement must be relevant to the medicines involved and the agreement as a whole must be fair and reasonable. Any goods and services provided by the company must themselves contribute to service user care.
- The written agreement must cover the following points:
 - The name of the joint working project, the parties to the agreement, the date and the term of the agreement
 - The expected benefits for service users, the NHS and the pharmaceutical company; service user benefits should always be stated first and service user outcomes should be measured
 - An outline of the financial arrangements
 - The roles and responsibilities of the NHS and the pharmaceutical company and how the success of the project will be measured, when and by whom; all aspects of input should be included
 - The planned publication of any data or outcomes
 - If a pharmaceutical company enters into a joint working agreement on the basis that its product is already included in an appropriate place on the local formulary, a clear reference to this should be included in the joint working agreement so that all the parties are clear as to what has been agreed

- Contingency arrangements to cover possible unforeseen circumstances such as changes to summaries of product characteristics and updated clinical guidance; agreements should include a dispute resolution clause and disengagement/exit criteria including an acknowledgement by the parties that the project might need to be amended or stopped if a breach of the Code is ruled
- Publication by the company of an executive summary of the joint working agreement, for example on a clearly defined website or section of a website, such as on the company's or companies' website; the NHS organisation should also be encouraged to publish this.

8. Training and Awareness

- There is no formal training course on this policy.
- Staff will be asked to familiarise themselves with this policy.
- A copy will be held in all clinical areas.
- A copy may be accessed through the Trust intranet.

9. Process for monitoring compliance with this document

| Key process for which compliance or effectiveness is being monitored | Monitoring method (i.e. audit, report, on-going committee review, survey etc.) | Job title and department of person responsible for leading the monitoring | Frequency of the monitoring activity | Monitoring Committee responsible for receiving the monitoring report/audit results etc. | Committee responsible for ensuring that action plans are completed |
|--|--|---|--------------------------------------|---|--|
| 1) The Declaration of Conflict of Interest forms and Declaration of Outside Business Interest forms | Review of forms sent to Company Secretary | Company Secretary | Annually | Audit Committee | Audit Committee |
| 2) Declaration of arranged training and educational events by pharmaceutical companies / representatives within HPFT | Review of forms sent to Pharmacy Data Analyst | Chief Pharmacist | Annually | Drug and Therapeutics Committee (DTC) | DTC |
| 3) Disclosure UK database | Review of database | Chief Pharmacist | Annually | DTC | DTC |

10. Embedding a culture of equality and respect

The Trust promotes fairness and respect in relation to the treatment, care and support of service users, carers and staff.

Respect means ensuring that the particular needs of 'protected groups' are upheld at all times and individually assessed on entry to the service. This includes the needs of people based on their age, disability, ethnicity, gender, gender reassignment status, relationship

status, religion or belief, sexual orientation and in some instances, pregnancy and maternity.

Working in this way builds a culture where service users can flourish and be fully involved in their care and where staff and carers receive appropriate support. Where discrimination, inappropriate behaviour or some other barrier occurs, the Trust expects the full cooperation of staff in addressing and recording these issues through appropriate Trust processes.

Access to and provision of services must therefore take full account of needs relating to all protected groups listed above and care and support for service users, carers and staff should be planned that takes into account individual needs. Where staff need further information regarding these groups, they should speak to their manager or a member of the Trust Inclusion & Engagement team.

Where service users and carers experience barriers to accessing services, the Trust is required to take appropriate remedial action.

| | |
|--|---|
| Service user, carer and/or staff access needs (including disability) | The Trust does not discriminate against staff living with physical, mental and or/emotional disabilities under the Equality Act 2010. |
| Involvement | This policy does not apply to service users or carers. The policy applies to all staff employed by HPFT. A wide variety of clinical and operational leaders have been involved in the development of this policy to ensure safe and effective service delivery for our service users. |
| Relationships & Sexual Orientation | Discrimination based on sexual orientation is illegal under the Equality Act 2010. All staff must complete mandatory training Equality, Diversity & Culture, so are aware of needs and support services which may assist this process |
| Culture & Ethnicity | The Trust does not discriminate against race or ethnicity of all staff. All staff must complete mandatory training Equality, Diversity & Culture, so are aware of needs and support services which may assist this process. |
| Spirituality | The Trust does not discriminate against religions/beliefs of all staff. |
| Age | This policy applies to all staff regardless of their age, race or ethnic backgrounds |
| Gender & Gender Reassignment | Discrimination based on Gender is illegal under the Equality Act 2010. All staff must complete mandatory training Equality, Diversity & Culture, so are aware of needs and support services which may assist this process. |
| Advancing equality of opportunity | Offer equality of opportunity between different groups. Foster good relations between different groups via the good working practices of the Trust |

11. Version Control

Version control for the Procedural Document Management System

| Version | Date of Issue | Author | Status | Comment |
|---------|---------------|-------------------------|------------|---------|
| 1 | 13/02/2018 | Deputy Chief Pharmacist | New Policy | |

12. Relevant Standards

1. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice 2016 <http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf>
2. ABPI Joint Working with the Pharmaceutical Industry, November 2013 <http://www.abpi.org.uk/about-us/resources/publications-library/joint-working-with-the-pharma-industry-guide>
3. NHS England - Managing Conflicts of Interest in the NHS: Guidance for staff and organisations, published in February 2017. <https://www.england.nhs.uk/wp-content/uploads/2017/02/guidance-managing-conflicts-of-interest-nhs.pdf>
4. The Department of Health/ ABPI 2010 - Moving beyond sponsorship: interactive toolkit for joint working between the NHS and the pharmaceutical industry. [Download Moving beyond sponsorship toolkit \(revised August 2010\) \(PDF, 1753K\)](#)

13. Associated Trust Documents -

<http://trustspace/InformationCentre/TrustPolicies/Pages/AlphabeticalPolicies.aspx>

1. Standards of Business Conduct Policy
2. Anti-Bribery Policy
3. Counter Fraud Including Financial Redress Policy

14. Supporting References

1. North East London Foundation Trust (NELFT), Working with the Pharmaceutical Industry Policy, 2016.
2. Barnet, Enfield & Haringey NHS Mental Health Trust (BEH-MHT), Trust Policy on Working with the Pharmaceutical Industry, 2016.

15. Consultation

| |
|--|
| Job Title of person consulted |
| Pharmacy and Medicines Optimisation Team, HPFT |
| Drug and Therapeutics Committee |
| Heads of Nursing |
| Clinical Directors |
| HPFT Company Secretary |
| |



DECLARATION OF CONFLICT OF INTERESTS FORM FOR HPFT STAFF

A. Staff details

| | | | |
|-------------------------|--|----------------|--|
| Name of member of staff | | Department | |
| Job Title | | Email address | |
| Service Line | | Contact number | |

B. Description of Interest

(Please enter in box below – where relevant include details of occasion/event and sponsor/donor details and the type of benefit and value (£))

e.g. Hospitality received – £95 from Organisation Z to pay for travel to speak at conference on Safe and Secure Handling of medicines on 21/12/2017

C. Relevant Dates and Comments

(Include name of manager who approved attendance to event)

| Relevant Dates | | Comments |
|----------------|----|---|
| From | To | |
| | | <i>e.g. approval to attend event and accept hospitality given by Mary Baker, Chief Pharmacist</i> |

I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations must be notified to the Trust as soon as is practical and **no later than 28 days after the interest arises**. I am aware that if I do not make full, accurate and timely declarations then civil, criminal, internal disciplinary or professional regulatory action may result.

Staff signature: Date:

Members of Drug and Therapeutics Committee please return form to Chetan Shah (Chief Pharmacist) – Chetan.shah@hpft.nhs.uk who will then forward to the Company Secretary.

All other staff please return this form to HPFT Company Secretary -

Jonathan.Elwood@hpft.nhs.uk

Post to: HPFT Company Secretary, Corporate Services, The Colonnades, Beaconsfield Road, Hatfield, Hertfordshire, AL10 8YE



DECLARATION OF OUTSIDE BUSINESS INTERESTS

(A record of financial or personal interest (e.g. company shares, research grant) in any organisation with which you or close relative have an interest with)

A. Staff details

| | | | |
|-------------------------|--|----------------|--|
| Name of member of staff | | Department | |
| Job Title | | Email address | |
| Service Line | | Contact number | |

B. Nature of Outside Business Interest

(Please enter details in box below)

C. Employee's role in the Outside Business Interest

(Please enter details in box below)

I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations must be notified to the Trust as soon as is practical and **no later than 28 days after the outside business interest arises**. I am aware that if I do not make full, accurate and timely declarations then civil, criminal, internal disciplinary or professional regulatory action may result.

Staff signature: Date:

All staff please return this form to HPFT Company Secretary - Jonathan.Elwood@hpft.nhs.uk
 Post to: HPFT Company Secretary, Corporate Services, The Colonnades, Beaconsfield Road, Hatfield, Hertfordshire, AL10 8YE

| | <i>we are...</i> | <i>you feel...</i> |
|-------------------|---------------------|---------------------------|
| Our Values | Welcoming | ✔ Valued as an individual |
| | Kind | ✔ Cared for |
| | Positive | ✔ Supported and included |
| | Respectful | ✔ Listened to and heard |
| | Professional | ✔ Safe and confident |

Our  values
 Welcoming Kind Positive Respectful Professional