Essex Partnership University
NHS Foundation Trust

POLICY ON HOSPITALITY, GIFTS AND SPONSORSHIP PROVIDED BY THE PHARMACEUTICAL INDUSTRY AND RELATED SUPPLY COMPANIES, AND CONTACT WITH COMPANY REPRESENTATIVES

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POLICY SUMMARY

The Trust will ensure that information relating to individual patients and the business of the Trust remains confidential. This can be achieved by ensuring that appropriate authorisation has been obtained for each pharmaceutical representative whilst undertaking projects on Trust property

The Trust monitors the implementation of and compliance with this policy in the following ways;

Services	Applicable	Comments
Trustwide	✓	

The Director responsible for monitoring and reviewing this policy is Executive Medical Director

ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

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ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST

POLICY ON HOSPITALITY AND SPONSORSHIP PROVIDED BY THE PHARMACEUTICAL INDUSTRY, AND CONTACT WITH REPRESENTATIVES

Assurance Statement

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1.0 INTRODUCTION

1.1. Contact between the pharmaceutical industry and NHS professionals previously revolved around the purchase and/or promotion of specific medicines or wound management products. More recently the industry has focused on enhancing links with the NHS, and many companies have developed internal structures to encourage closer liaison with both primary and secondary care. National guidance places an obligation on those providing health services to work together with other agencies in order to improve the health of the population that they serve and the services for that population.

1.2. Working in partnership with the pharmaceutical industry can have a number of benefits, which may include the provision of information, educational activities, project support and the provision of resources/materials. However, it must be remembered that pharmaceutical companies are commercial businesses whose primary activity is to sell their products and maximise the returns on their substantial investment in product development. An important part of such joint working is that any hospitality and sponsorship should be transparent, and to the mutual advantage of both the NHS and the commercial partner, whilst avoiding potential conflicts of interest.

2.0 PURPOSE

2.1 The purpose of this policy is to provide guidance to all employees of the Trust when entering into collaborative partnerships with pharmaceutical companies.

2.2 This policy aims to ensure that the Trust and its staff respond consistently to approaches from the pharmaceutical industry and that the interests of service users, carers, the public and the Trust are maintained at all times. The policy aims to ensure that all arrangements for commercial sponsorship are transparent and devoid of any current or potential conflicts of interest.

2.3 The policy summarises NHS guidance contained within *Managing Conflicts of Interest in the NHS* (NHS England, 2017). Reference has also been made to the document published by the Royal College of Psychiatrists on commercial sponsorship (CR202: *Good Psychiatric Practice: relationships with pharmaceutical and other related organisation)* and the Department of Health

'*Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations*'.

3.0 SCOPE

3.1 This policy applies to all employees of the Essex Partnership University NHS Foundation Trust. It is of particular significance to medical and nursing staff, non-medical prescribers and pharmacists. It should be read in conjunction with the Trust procedural guidelines '*Code of Conduct for Members of the Board of Directors*' (CP15).

3.2 Staff should also refer to their own professional code of conduct and any specific guidance from their professional body when interacting with the pharmaceutical industry.

3.3 The standard NHS contract includes a requirement that NHS organisations ensure that staff declare any actual or potential conflicts of interest and offers of gifts or hospitality.

3.4 Commercial sponsorship is defined as NHS funding from an external source. This policy deals primarily with commercial sponsorship, including funding of all or part of the cost of e.g. staff training, meeting rooms and costs associated with meetings and conferences, meals, hotel and transport costs (including transport abroad), provision of free services (speakers, facilitators, audits and research), sponsored posts, equipment.

4.0 HOSPITALITY AND MEETINGS

4.1 Guiding principles on hospitality are set out in the Trust Conflict of Interests, Gifts and Hospitality Policy and Procedure and should be adhered to.

4.2 All members of the Trust Medicines Management Groups should report the details of any hospitality they have received under the standing agenda item for Declarations of Interest, including fees received for speaking or attendance at conferences paid by the pharmaceutical company.

4.3 Staff should not ask for or accept hospitality that may affect, or be seen to affect, their professional judgement. Hospitality must only be accepted where there is a legitimate business reason and it is proportional to the nature and purpose of the event.

4.4 Meals and refreshments:

- under a value of £25 may be accepted and need not be declared.
- of a value between £25 and £75[*] may be accepted and must be declared.
- over a value of £75 should be refused unless (in exceptional circumstances) senior approval is given. A clear reason should be recorded as to why it was permissible to accept.

[*] Based on guidance issued in the ABPI: Code of Practice for the Pharmaceutical Industry, 2019

4.5 Offers of modest travel and accommodation costs related to attendance at events may be accepted and must be declared. Offers which go beyond modest, (for example, business class or first class travel; foreign travel), must only be accepted in exceptional circumstances, and must be declared.

5.0 'TRANSFERS OF VALUE' FROM THE PHARMACEUTICAL INDUSTRY

5.1 As part of the pharmaceutical industry's move towards greater transparency, benefits that they give in cash or kind (termed 'transfers of value') to individual healthcare professionals, other relevant decision makers and healthcare organisations are publically available as part of a searchable database held by the Association of the British Pharmaceutical Industry (ABPI).

5.2 Examples or 'transfers of value' include, but are not restricted to, the following:

- Payment of registration fees and expenses for an individual to attend a conference or event
- Payment of travel and accommodation for an individual to attend a conference or event
- Payment of fees or expenses for consultancy services
- Joint-working projects between the NHS and one or more pharmaceutical companies
- Provision of equipment
- Donations, grants and other benefits in kind
- Contributions towards the cost of meetings, which may include provision of food
- Provision of medical and educational goods and services.

5.3 All 'transfers of value' received by individuals or the Trust must be disclosed in line with this policy, and declared in relevant meetings, such as the Medicines Management Group, especially if they result in a conflict of interest in relation to an agenda item.

5.4 Further information about the Disclosure UK initiative can be found on the ABPI website.

6.0 COMMERCIAL SPONSORSHIP

6.1 For the purpose of this policy, commercial sponsorship is defined as:

> "*NHS funding from an external source, including 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, gifts, hotel and transport costs (including trips abroad), provision of educational goods and services (e.g. speakers), buildings or premises*."

6.2 The pharmaceutical industry often wishes to have close involvement with the NHS. Sometimes this may be to mutual advantage, but both partners should assess and understand the costs and benefits of any such agreements. The important principle is that there should be no actual or apparent conflict of interest created by any gifts, hospitality or sponsorship sought or accepted by, or on behalf of, Trust employees or contractors. It is necessary to avoid any set of conditions whereby professional judgment concerning a primary interest, e.g. patients' welfare or validity of research, might be unduly influenced by a secondary interest (such as financial gain).

6.3 Where collaborative partnerships involve a pharmaceutical company the proposed arrangements must comply fully with the Medicines (Advertising) Regulations 1994 (Regulation 21 'Inducements and Hospitality') and the ABPI Code of Practice for the Pharmaceutical Industry.

6.4 Prior to entering into any sponsorship arrangement (as defined in paragraph 6.1), Trust staff should seek approval in accordance with Section 7 of this policy. The only exceptions to this requirement are as follows:

- Gifts from suppliers of less than £6[†] in value, e.g. promotional aids such as notebooks, pens and pencils for use at *bona fide* meetings and conferences etc. Such items can be accepted and do not have to be declared. However, gifts should be declared on the 'Gifts and Hospitality Register' if several small items worth a total of over £50 are received from the same or closely related sources in a 12-month period.

- Income generation schemes.

- Discounts on the purchase of pharmaceuticals.

6.5 Offers of sponsorship from the pharmaceutical industry which could possibly breach this policy or the ABPI Code of Practice should be reported to the Chief Pharmacist.

6.6 Where meetings, conferences, etc. are supported by external funding, the names of the companies providing the sponsorship must be disclosed in the papers relating to the meeting and in any published proceedings.

[†] Based on guidance issued by the ABPI: Code of Practice for the Pharmaceutical Industry, 2019

6.7 Any Trust publications that have been supported with external funding should include a declaration of the names of the companies who have provided sponsorship.

7.0 PROCEDURE FOR THE APPROVAL OF COMMERCIAL SPONSORSHIP ARRANGEMENTS

7.1 As a general rule, sponsorship should be at a corporate, rather than individual level. The principles set out in the *Managing Conflict of Interest in the NHS* guidance and the Trust's *Declarations of Interests, Gifts & Hospitality Policy* should be adhered to. Sponsorship should only be approved if a reasonable person would conclude that the arrangement will result in clear benefit for the Trust and the NHS.

7.2 Offers of sponsorship less than £500

A 'Sponsorship Checklist and Approval Form' (see Appendix 1) should be completed and then passed to the line manager for assessment/approval. When approval has been granted, the line manager should forward a copy of the completed form to the Trust Secretary for information.

7.3 Offers of sponsorship greater than £500 but less than £1000

A 'Major Sponsorship Form' (see Appendix 2) should be completed by the lead person involved in the sponsorship arrangement. This form should be checked and approved by the line manager, and then passed to the appropriate Clinical Director or Service Director for final approval before the arrangement can proceed. A copy of the completed form should be passed to the Trust Secretary for information.

7.4 Offers of sponsorship exceeding £1000

A 'Major Sponsorship Form' (see Appendix 2) should be completed by the lead person and approved by their line manager as for (b) above. The completed form should then be forwarded to the relevant Trust Medicines Management Group via the Chief Pharmacist for discussion/approval before the sponsorship arrangement can proceed. Once approval has been granted by the Group, the lead person will be notified and a copy of the completed form passed to the Trust Secretary for information.

7.5 Chairman's action may be sought from the Chairman of the Medicines Management Group if a sponsorship arrangement exceeding £1000 in value needs to start as a matter of urgency. The Chairman will inform the Medicines Management Group of any sponsorship that has been approved by Chair's action.

7.6 Before entering into any sponsorship agreement, the Trust, its staff or officers, should:

7.6.1 Satisfy themselves, with reference to the information available, that there are no potential irregularities that may affect the company's ability

to meet the conditions of the agreement or impact on it in any way, e.g. by checking financial standing by referring to company accounts.

7.6.2 Assess the costs and benefits in relation to alternative options and to ensure that the decision making process is transparent and defensible.

7.6.3 Ensure that legal and ethical restrictions on the disclosure of confidential patient information, or data derived from such information, are complied with. Additionally, disclosure for research purposes should not take place without the approval of the appropriate Research Ethics Committee and the Trust's Research Governance Group.

7.6.4 Determine how clinical and financial outcomes will be monitored, by whom and when.

7.6.5 Ensure that the sponsorship agreement has get-out clauses built in to enable the Trust to terminate the agreement if it becomes clear that it is not providing expected value for money, or if unanticipated conflicts of interest arise.

7.7 Trust staff and board members therefore need to ensure that:

7.7.1 Purchasing decisions, including those concerning pharmaceuticals, devices and appliances, should always be taken on the basis of best clinical practice and value for money. They should take into account the impact on other parts of the health care system, for example, products dispensed in a hospital which are likely to be required by patients at home, or selection of devices that restrict the options or increase costs to others in the health system.

7.7.2 Staff must ensure that ongoing and future purchasing decisions are not influenced by sponsoring companies. Potential sponsors should be informed that any sponsorship arrangement would have no effect on purchasing decisions within the Trust.

7.7.3 Deals whereby sponsorship is linked to the purchase of particular products, or to supply from particular sources, are not allowed, unless as a result of a transparent competitive tender for a defined package of goods and services.

7.7.4 Deals that require staff to recommend to patients that they use the sponsor's products or services, in preference to other options open to them, should be avoided.

7.7.5 The supply of 'free' goods or services, including the provision of training that is implicitly or explicitly linked to the use of one or more specific product is not acceptable.

7.7.6 Arrangements entered into should be through an open and transparent process with no potential for fraud, and should be recorded as detailed in Section 6.

7.7.7 What appears to be advantageous to one person or one part of the organisation should not cause problems, either financial or legal, for other parts of the Trust or wider NHS.

7.8 Sponsorship of a post should only happen where there is written confirmation that the arrangements will have no effect on purchasing, prescribing or dispensing decisions.

7.9 Breaches will be dealt with in line with section 8 of the Trust's *Declarations of Interests, Gifts & Hospitality Policy.*

8.0 CONTACTS WITH PHARMACEUTICAL REPRESENTATIVES

8.1 The Trust recognises the role of pharmaceutical industry representatives in promoting and providing information on their products to the NHS. This policy seeks to ensure that the relationships between industry representatives and members of the Trust are conducted on a sound and professional basis.

8.2 There is an expectation that representatives will have adequate training and skills to present information responsibly and accurately, and that they will follow the guidance set out in this policy. It is also expected that pharmaceutical representatives will comply with all relevant sections of the ABPI Code of Practice, which can be accessed at the Prescription Medicines Code of Practice Authority website (www.pmcpa.org.uk). Concerns about the conduct of pharmaceutical representatives should be discussed with the Trust's Chief Pharmacist who will advise on whether further action is required.

8.3 Visits and appointments

8.3.1 Visits by representatives to Trust premises should be made only to keep agreed appointments. Prior to any visit, contact must be made with the relevant consultant, operational director, or team/ward manager to outline the purpose of the visit and arrange an appointment.

8.3.2 Staff should have a clear agenda from a pharmaceutical industry representative before agreeing to a meeting, which should be by appointment at a specific time and of a specific duration.

8.3.3 If pharmaceutical industry personnel other than those agreed in advance arrive for the meeting, then staff are at liberty to decline to see the additional personnel.

8.3.4 Ad-hoc contacts are forbidden, and representatives are not permitted to tour Trust premises looking for staff. Representatives are not permitted to enter clinical areas without a prior appointment agreed with a consultant, operational director or team/ward manager.

8.3.5 On each visit to Trust premises, including attendance at meetings, a representative must ensure that copies of the Summary of Product Characteristics (SPC) and other relevant prescribing information are available for the products to be discussed.

8.3.6 As such visits take place during working hours it would not normally be expected that a particular representative would visit a clinician or team more than annually.

8.3.7 Any behaviour by pharmaceutical industry personnel felt to be inappropriate should be reported to the Chief Pharmacist, and in the first instance will be taken up with the representative's line manager. If not satisfactorily resolved, a complaint may be made to the ABPI.

8.4 Samples

8.4.1 Representatives wishing to leave samples of medicines, dressings, devices or nutritional products for use within the Trust should be directed to the appropriate hospital pharmacy department. Pharmacy will usually only accept such samples if there has been a prior agreement to do so between a Trust clinician and the Chief Pharmacist. Samples should not be accepted by members of staff, and must not be left on wards, departments or in offices. (See also section 6.3 of the relevant Safe and Secure Handling of Medicines Procedure (CLPG13)

8.4.2 Samples of products requested for *private* use by Trust doctors should not be received whilst on Trust premises.

8.4.4 In accordance with the ABPI Code of Practice, samples of a product can only be provided in response to a written request, which has been signed and dated from a healthcare professional qualified to prescribe that product. No more than four samples of a particular medicine, dressing, device or nutritional product may be provided to an individual health professional during the course of one year, and any such samples much be provided in line with section 8.4.1.

8.5 Introduction of new drugs and wound dressings

8.5.1 The Trust has systems in place to manage the introduction of new drugs, and these are detailed in the Trust's Procedural Guidelines for the Safe and Secure Handling of Medicines. A request for a new drug to be made available for use within the Trust must be submitted to the Medicines Management Group by a consultant or healthcare practitioner, using the appropriate 'New Drug Request' form.

8.5.2 Representatives may provide information to clinicians to assist them in preparing a proposal for the introduction of a new drug, but may not complete the Trust 'New Drug Request' form on behalf of a Trust clinician. Any such forms received by the Medicines Management Group will be rejected.

8.6 Price information

8.6.1 Staff should not accept as correct any price comparisons provided by a representative. The cost of a drug within the Trust may vary considerably from the manufacturer's recommended price and prescribers may obtain accurate information from the pharmacy team.

8.6.2 No member of staff should disclose to a representative any information relating to the pricing or volume of products used within the Trust.

9.0 CLINICAL TRIALS, PRODUCT ASSESSMENT AND TRAINING

9.1 A clinical trial may be undertaken only after approval in line with the Research Conduct and Processes policy and procedure (CLP19). All trial material should be delivered from the company directly to the relevant pharmacy department, with which prior agreement must have been reached to support the clinical trial. The pharmacy department should be given full details of the protocol for the trial and necessary dispensing information.

9.2 Clinicians undertaking sponsored research or post-marketing surveillance must be guided by their patients' best interests and not influenced by any offer of sponsorship. All such research much be approved in line with the Trust policy and procedure.

9.3 Any study must not constitute an inducement to prescribe, supply, administer, recommend, buy, or sell any medicines, medical device, equipment or service.

9.4 A product assessment may be undertaken only if authorised by the relevant Medicines Management Group, at the request of a Consultant or appropriate senior healthcare professional / manager.

9.5 Training of staff by pharmaceutical representatives, or arranged by pharmaceutical representatives, should have the approval of the appropriate Director and Manager in order that patient confidentiality is maintained at all times. All pharmaceutical industry representatives must comply with the Trust's code of confidentiality.

9.6 Where a staff member of a pharmaceutical company is working with the Trust on a specific project, ongoing authorisation may be arranged at the discretion of the Team/Ward Manager for the duration of the project. Authorisation will be required for each new project that is undertaken.

10.0 POLICY REFERENCES / ASSOCIATED DOCUMENTATION

- ABPI Code of Practice for the Pharmaceutical Industry, 2019
- NHS Standard Contract 2019/20
- NHS England, *Managing Conflicts of Interest in the NHS*, 2017
- Royal College of Psychiatrists. CR202: *Good Psychiatric Practice: relationships with pharmaceutical and other related organisation,* 2017

11.0 REFERENCES TO OTHER TRUST POLICIES AND PROCEDURES

This policy should be read in conjunction with other policies / procedures that may be relevant. These include:

- Code of Conduct for the Members of the Board of Directors (CP15)
- Maintaining High Professional Standards Conduct and Capability Policy for Medical and Dental Staff (HR32)
- Policy for the Safe and Secure Handling of Medicines (CLP13)
- Procedural Guidelines for the Safe and Secure Handling of Medicines in Mental Health Services (CLPG13-MH)
- Procedural Guidelines for the Safe and Secure Handling of Medicines in Community Health Services (CLPG13-CHS)
- Procedural Guidelines for the Safe and Secure Handling of Medicines in Trust Nursing Homes (CLPG13-NH)

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