


Policy for Sponsorship and Joint Working between BLMK ICB and the Pharmaceutical Industry and other non-NHS organisations

Document Status:

This is a controlled document. Any printed or downloaded copies are not controlled. The version of this document published on the Bedfordshire, Luton & Milton Keynes Integrated Care Board website is the controlled copy
www.befordshirelutonandmiltonkeynes.icb.nhs.uk

Sustainable Development - Environmental

 Do you really need to print this document?

Please consider the environment before you print this document and where possible copies should be printed double-sided. Please also consider setting the page range in the print properties, when relevant to do so, to avoid printing the document in its entirety.

Document Control	
Document Owner:	Chief of Primary Care
Document Author(s):	Associate Director Pharmacy and Medicines Optimisation
Directorate:	Primary Care
Approved By:	Operational Group
Date of Approval:	15-04-2024
Date of Next Review:	This policy will be reviewed in the light of new guidance from the Department of Health or by 15-4-2026
Effective Date:	15-04-2024

Version Control			
Version	Date	Reviewer(s)	Revision Description
Final v1.0	June 2022	Operational Group	Approved by BLMK ICB Prescribing Committee June 2022
Final v1.0	01-07-2022		The Board of the Integrated Care Board adopted the policy as approved following Operational Group
Amendments made to V1.0:			
Job titles updated - ICS changed to ICB (as the policy is an ICB policy for the ICS) - Reference to Scriptswitch deleted – Section 3.5 amended wording re reference to rebate policy - Updated to reflect the ICB’s Corporate Gifts and Hospitality register - Email addresses updated - Out of date hyperlinks replaced - Governance route post Prescribing Committee changed to System Quality Group.			
Final V2.0	Feb 2024	Approved by BLMK ICB Prescribing Committee February 2024	
Final V2.0	15-04-2024	Operational Group	

Implementation Plan

Development and Consultation:	<p>The following individuals were consulted and involved in the development of this document:</p> <ul style="list-style-type: none"> ▪ BLMK ICB prescribing Committee Members ▪ BLMK ICB Medicines Optimisation team ▪ BLMK ICB Long Term Conditions groups
Dissemination:	<p>Staff can access this document via the website and will be notified of new / revised versions via the staff briefing.</p> <p>This document will be included in the organisation's Publication Scheme in compliance with the Freedom of Information Act 2000.</p>
Training:	<p>The following training will be provided to make sure compliance with this document is understood:</p> <ul style="list-style-type: none"> ▪ Mandatory training for all Medicines Optimisation team members
Monitoring:	<p>Monitoring and compliance of this document will be carried out via:</p> <ul style="list-style-type: none"> ▪ All proposals for sponsorship in Primary Care will be considered by the BLMK ICB Prescribing Committee in line with this policy and decisions documented in the minutes
Review:	<p>The Document Owner will ensure this document is reviewed in accordance with the review date on page 2.</p>
Equality, Diversity and Privacy:	<p>Appendix 1 - Equality Impact Assessment Appendix 2 - Data Protection Impact Assessment</p>
Associated Documents:	<p>The following documents must be read in conjunction with this document:</p> <ul style="list-style-type: none"> • Conflicts of Interest & Standards of Business Conduct Policy
References:	<p>The following articles were accessed and used to inform the development of this document:</p> <ul style="list-style-type: none"> • NHSE guidance on Managing conflicts of Interest in the NHS 2017 https://www.england.nhs.uk/wp-content/uploads/2017/02/guidance-managing-conflicts-of-interest-nhs.pdf • Code of Practice for the Pharmaceutical Industry. Prescription Medicines Code of Practice Authority and the ABPI. 2016.

	<ul style="list-style-type: none">• The House of Commons Health Committee - Report on the Influence of the Pharmaceutical Industry. March 2005.• Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry. Available from the National Archive website: http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_119052.pdf• ABPI list of companies https://www.abpi.org.uk/member-representation/abpi-members-list/
--	---

Table of Contents

1.0	Introduction.....	6
2.0	Scope	7
3.0	Definitions.....	7
4.0	Policy Statement	9
5.0	Roles and Responsibilities	9
6.0	Processes and Procedures	10
	Appendix 1 - Equality Impact Assessment Initial Screening.....	18
	Appendix 2 - Data Protection Impact Assessment Initial Screening.....	20
	Appendix 3 - Process Flow diagram.....	21
	Appendix 4 - Sponsorship Form.....	22
	Appendix 5 - BLMK Initial Checklist for Assessment of Collaborative Working with the Pharmaceutical Industry or their Agents or Affiliated Companies.....	23
	Appendix 6 - BLMK ICB Agreement for Joint Working	25
	Appendix 7 - BLMK ICB SPONSORSHIP FOR PROFESSIONAL OR SCIENTIFIC MEETINGS	26
	Appendix 8 - Process for Pharmaceutical Representatives.....	27
	Appendix 9 - The 7 Principles of Public Life (The Nolan Principles).....	28

1.0 Introduction

- 1.1 NHS Bedfordshire, Luton, and Milton Keynes Integrated Care Board (ICB) aims to ensure robust governance through its formal written procedural documents, such as this document, which communicate standard organisational ways of working. These documents help clarify operational requirements and consistency within day-to-day practice. They can improve the quality of work, increase the successful achievement of objectives and support patient safety, quality and experience. The ICB aims to ensure its procedural documents are user friendly, up-to-date and easily accessible.
- 1.2 The ICB must design and implement procedural documents that meet the diverse needs of our service and workforce, ensuring that none is placed at a disadvantage over others, in accordance with the Equality Act 2010. The Equality Impact Assessment initial screening, which was used to determine the potential impact this policy might have with respect to the individual protected characteristics is incorporated at Appendix 1.
- 1.3 A Data Protection Impact Assessment is a process which helps assess privacy risks to individuals in the collection, use and disclosure of personal information. The Data Protection Impact Assessment initial screening, which was used to determine the potential impact this policy might have with respect to an individual's privacy is incorporated at Appendix 2.
- 1.4 Pharmaceutical companies, and other companies that provide products to the NHS, wish to work with ICBs through offering sponsorship or joint working initiatives, in line with their company objectives.
- 1.5 Good governance within the public sector is based upon the seven 'Nolan principles' (See Appendix 3). It is important that all employees of Bedfordshire, Luton and Milton Keynes Integrated Care Board (BLMK ICB) understand these principles and embed them in their working practices and behaviours, so that the public and patients we serve have confidence and trust in the organisation. Joint working with industry and receiving hospitality from industry are key areas where ICB employees should apply the 'man in the street' test as perception of an action can be as significant as the factors involved.
- 1.6 This Policy translates the Nolan principles into a protocol to support staff working with industry, particularly the pharmaceutical industry, and incorporates updated statutory guidance to ICBs on Managing Conflicts of Interest.
- 1.7 The purpose of this Policy is to provide a framework within which the ICB can develop sponsorship arrangements or joint working with pharmaceutical and other health related companies such that assurance is provided to the Integrated Care Board, to clinicians, and to the public, that any agreements made do not adversely influence prescribing advice or choice of products. These decisions should always be based on

evidence of value for money, safety and efficacy, and it should be demonstrable that the governance surrounding such decisions is independent from sponsorship and joint working arrangements with industry.

- 1.8 The policy aims to provide BLMK ICB staff with a set of principles and guidelines to follow when entering into a sponsorship or joint working agreement with pharmaceutical companies or other non-NHS organisations who supply medicines, medical devices, diagnostic agents, dressings, appliances, or reagents (all referred to as pharmaceutical companies throughout this document). It does not aim to inhibit sponsorship or joint working as it is recognised that such arrangements can be mutually beneficial.
- 1.9 The policy aims to provide the BLMK ICB and clinicians with assurances that decisions on prescribing and sponsorship or joint working which give mutual advantage are made within a framework of probity.
- 1.10 The policy aims to provide pharmaceutical companies with an understanding of the limits of BLMK ICB jurisdiction and to state positively that BLMK ICB, regardless of the prescribing practice of individual practitioners, does not endorse specific products as a result of sponsorship or joint working agreements.

2.0 Scope

- 2.1 This policy applies to all ICB staff members, including Ordinary Members of the Board of the ICB, involved in policy-making processes, whether permanent, temporary or contracted-in under a contract for service (either as an individual or through a third-party supplier).
- 2.2 This policy applies, as appropriate, to all staff members employed by the ICB including seconded and sessional staff, and temporary staff such as agency staff and interims.
- 2.3 Member practices and their employees when undertaking duties on behalf of the ICB. This includes clinicians undertaking roles with the ICB, e.g., clinical directors and clinical leads, and any other roles where a clinician from a member practice undertakes duties on behalf of the ICB.
- 2.4 Third parties acting on behalf of the ICB and services contracted by the ICB, e.g., commissioning support services.

3.0 Definitions

- 3.1 For the purposes of the Policy the term **commercial sponsorship** is defined as including any funding to the NHS from an external source, including funding 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, provision of free services including guest speakers, buildings or premises. In sponsorship arrangements, pharmaceutical companies simply provide funds for a specific event or work programme. Where hospitality is involved, reference should also be made to the ICB's 'Conflict of Interest Policy' for further guidance and for details of how to declare a Conflict of Interest or to declare Hospitality.

- 3.2 **Joint working** is defined as including 'situations where, for the benefit of patients, the NHS and industry organisations pool skills, experience and resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery'. Joint working is a more complex arrangement and ICB staff should refer to the Department of Health document on best practice guidance for joint working between the NHS and the pharmaceutical industry, published in February 2008 and the toolkit, 'Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry' for further background information. Sponsorship for these more complex initiatives may also be handled through a third party who provide resources such as staff to undertake audits or perform review clinics. The third party would obtain the funds from the pharmaceutical companies directly without involving the ICB. This is often referred to as a Medical and Educational Goods and Services (MEGS) agreement and is a preferred model for more involved complex initiatives. Where collaborative partnerships involve a pharmaceutical company, the proposed arrangements must comply fully with the Medicines (Advertising) Regulations 1994 (regulation 21 'inducements and hospitality').
- 3.3 **Secondary employment** is a term used to describe any employment additional to the work with the ICB. The ICB takes all reasonable steps to ensure that employees, committee members, contractors and others engaged under contract with them are aware of the requirement to inform the ICB if they are employed or engaged in, or wish to be employed or engaged in, any employment or consultancy work in addition to their work with the ICB. The purpose of this is to ensure that the ICB is aware of any potential conflict of interest.
- 3.3.1 Examples of work which may conflict with the business of the ICB, including part-time, temporary, and fixed term contract work, include:
- Employment with another NHS body
 - Employment or carrying out duties with another organisation which might be in a position to supply goods/services to the ICB
 - Directorship for GP federation; and
 - Self-employment, including private practice, in a capacity which might conflict with the work of the ICB or might be in a position to supply goods/services to the ICB
- 3.3.2 The ICB requires that all individuals obtain prior written permission to engage in secondary employment and reserves the right to refuse permission where it believes a conflict will arise which cannot be effectively managed. Consideration of the implications of secondary employment may be relevant when sponsorship or joint working agreements are proposed. In particular it is unacceptable for pharmacy

advisers or other advisers, employees or consultants to the ICB on matters of procurement for themselves to be in receipt of payments from pharmaceutical or other industry suppliers.

- 3.4 BLMK ICB welcomes appropriate sponsorship and joint working with pharmaceutical companies when these initiatives are aligned with the National Institute for Health and Care Excellence (NICE) guidance, BLMK ICB formulary (including OptimiseRx®) or prescribing recommendations made by the BLMK Area Prescribing Committee (APC). However, NHS funding sources should have been investigated first and found not to be available or practical before entering into an agreement. Where possible and practical and particularly for large projects, this should be across the industry as a whole rather than with single companies.
- 3.5 Pharmaceutical rebate schemes are not within the scope of this policy; however, due to the potential for overlap and for clarity, the ICB follows the good practice principles in relation to the assessment and uptake of rebates schemes as set out in the BLMK ICB Pharmaceutical Industry Rebate Process.
- 3.6 This policy should be used by BLMK ICB staff when offered meetings, sponsorship or joint working initiatives with pharmaceutical companies. It should be read alongside the BLMK ICB *Standards of Business Conduct Policy* which outlines the principles that staff should follow when offered gifts, sponsorship or hospitality from non-NHS organisations.
- 3.7 In all cases, the ICB and its employees must publicly declare sponsorship/joint working, or any commercial relationship linked to the supply of goods or services and be held to account for it, even if a sponsored activity occurred in an employee's own time.

4.0 Policy Statement

- 4.1 The ICB is committed to meeting the obligations, standards and requirements as laid out in this policy.

5.0 Roles and Responsibilities

- 5.1 The following have specific responsibilities in relation to this policy.
- BLMK Prescribing Committee
 - Associate Director and Head of Medicines optimisation
 - Medicines optimisation team members
 - All ICB employed staff

6.0 Processes and Procedures

6.1 Context

- 6.1.1 There is an obligation on NHS bodies to work together, and in collaboration with other agencies, to improve the health of the population they serve, and the health services provided for that population.
- 6.1.2 Pharmaceutical companies, and other companies that provide products to the NHS, wish to work with ICBs through offering sponsorship or joint working initiatives, in line with their company objectives. There is a national imperative for NHS organisations to work with industry as this can be mutually beneficial and may introduce innovation into practice. The ICB acknowledges and recognises the interdependent relationship between the NHS and industry, and their need to promote medicines and other products to maintain their profitability.
- 6.1.3 There is a national remit for ICBs to develop mature working relationships with pharmaceutical companies. Collaborative partnerships with industry can have a number of benefits in the context of this obligation. However, BLMK ICB acknowledges the interdependent relationship between the pharmaceutical industry and the NHS and their need to maintain profitability and promote specific drugs. It is important to have a transparent approach to any sponsorship/joint working proposed to the ICB and for the ICB to consider fully the implications of a proposed sponsorship/joint working deal before entering into any arrangement so that the Board and clinicians are assured that such sponsorship agreements or joint working initiatives do not adversely influence prescribing advice which should be based on evidence, value for money, safety and equity.
- 6.1.4 If any such partnership is to work, there must be trust and reasonable contact between the sponsoring company and the NHS. Such relationships, if properly managed, can be of mutual benefit to the organisations concerned. However, it is essential that pharmaceutical companies or other suppliers cannot influence, or be perceived to influence, ICB decision making. Whatever type of agreement is entered, a clinician's judgement must always be based upon clinical evidence that the product is the best for their patients.
- 6.1.5 The House of Commons Health Committee Report on the Influence of the Pharmaceutical Industry acknowledges that the UK pharmaceutical industry conducts much excellent research, produces products that contribute to health, and is of great economic importance, but its influence is such that it dominates clinical practice. This is in line with available literature which shows that the more doctors rely on commercial sources of information, the less appropriate and less cost-effective are their prescribing decisions.

6.1.6 Pharmaceutical companies also promote their products or therapeutic area to BLMK ICB staff, many of whom will be supplementary or independent prescribers or have the ability to influence prescribing decisions. BLMK ICB staff should be aware that pharmaceutical companies see promotion of their products as important in influencing prescribing behaviour and continue to spend much of their revenue on this activity.

6.1.7 The Association of the British Pharmaceutical Industry (ABPI) Code of Practice 2016 sets out the principles which pharmaceutical companies should follow when promoting their medicines. This includes sponsorship and hospitality. The ABPI is a voluntary organisation, but most pharmaceutical companies are members. BLMK ICB staff should seek assurances that the company follows good practice principles in relation to the promotion of medicines, medical devices, diagnostic agents, dressings, appliances or reagents if they are not members of the ABPI.

6.2 A. Pharmaceutical Sponsorship from non-NHS Organisations

Pharmaceutical companies may approach BLMK ICB staff with offers of sponsorship or joint working. Similarly, BLMK ICB staff may wish to approach pharmaceutical companies to sponsor or work with them on projects. This policy covers both of these scenarios and outlines general principles and guidelines for BLMK ICB staff to work within.

6.2.1 A1. General Principles

Before entering into any sponsorship agreement the ICB will:

- Satisfy itself, with reference to information available, that there are no potential irregularities that may affect a company's ability to meet the conditions of the agreement or impact on it in any way, for example checking financial standing by referring to company accounts.
- Assess the costs and benefits in relation to alternative options where applicable, and to ensure that the decision-making process is transparent and defensible.
- Ensure that legal and ethical restrictions on the disclosure of confidential patient information, or data derived from such information, are complied with; no information should be supplied to a company for their commercial gain. As a general rule, information which is not in the public domain should not normally be supplied.
- Determine how clinical and financial outcomes will be monitored.
- Ensure that the sponsorship/joint working agreement has break clauses built in to enable the ICB to terminate the agreement if it becomes clear that it is not providing expected value for money and/or clinical outcomes.
- Make clear that acceptance of commercial sponsorship will not in any way compromise commissioning decisions of the ICB or be dependent on the purchase

or supply of goods and services. Sponsors should not have any influence over the content of an event, meeting, seminar, publication or training event. Sponsorship arrangements do not imply that the ICB endorse individual companies or their products.

6.2.2 A2. The ICB will apply the following principles:

- Purchasing decisions, including those concerning pharmaceutical and appliances, will always be taken on the basis of best clinical practice and value for money. Such decisions will take into account their impact on other parts of the health care system, for example, products dispensed in hospital which are likely to be required by patients regularly at home.
- When making purchasing decisions on products which originate from NHS intellectual property, ethical standards will ensure that the standard is based on best clinical practice and not on whether royalties will accrue to an NHS body.
- Arrangements whereby sponsorship/joint working is linked to the purchase of particular products, or to supply from particular source, will not be allowed, unless as a result of a transparent tender for a defined package of goods and services.
- Patient information attracts a legal duty of confidentiality and is treated as particularly sensitive under Data Protection legislation. Professional codes of conduct also include clear confidentiality requirements. The ICB will assure itself taking advice when necessary, that sponsorship/joint working arrangements are both lawful and meet appropriate standards.
- Where a sponsorship/joint working arrangement permitting access to patient information appears to be legally and ethically sound (for example, where the pharmaceutical company is to carry out or support NHS functions, where patients have explicitly consented), a contract will be drawn up which draws attention to obligations of confidentiality, specifies security standards that should be applied, limits use of the information to purposes specified in the contract and makes it clear that the contract will be terminated if the conditions are not met. This must comply with the current legal position concerning sharing of Patient Identifiable Data (PID). Guidance must be sought from the ICB's Senior Information Risk Officer.
- Where the major incentive to entering into a sponsorship/joint working arrangement is the generation of income rather than other benefits, then the scheme should be properly governed by income generation principles rather than sponsorship arrangements. Such schemes should be managed in accordance with income generation requirements, i.e. they must not interfere with the duties or obligations of the ICB. A memorandum trading account should be kept for all

income generation schemes and the Finance Department must be involved in making and conducting the agreement.

- Sponsorship/joint working arrangements involving the ICB will be at a corporate, rather than individual level, even if the activities concerned are to take place in an employee's own time.
- If publications are sponsored by a commercial organisation, that organisation should have no influence over the content of the publication. The company logo can be displayed on the publication, but no further advertising or promotional information should be displayed. The publication should contain a disclaimer which states that sponsorship of the publication does not imply that the ICB endorses any of the company's products or services.
- All ICB employees should discuss the implications, with their manager, before accepting an invitation to speak at a meeting organised by a pharmaceutical or other company. The company should have no influence over the content of any presentation made by the ICB employee. It should be made clear that the employee's presence does not imply that the ICB endorses any of the company's products or services. This also applies to interviews with ICB employees given live or published.
- The ICB will ensure that all sponsorship/joint working deals are documented through the use of a Gifts and Hospitality register, which can be audited as appropriate. In order to demonstrate openness, the Register will be available on request to the public.
- In order to provide a robust framework to support successful implementation of this policy any proposals for sponsorship/joint working by the Pharmaceutical Industry, whether direct or indirect through an intermediary, should be reviewed and commented on by the BLMK ICB Primary Care Prescribing Committee. This process is encapsulated in the Pharmaceutical Industry Sponsorship/Joint Working Proposal Process Flow Diagram (Appendix 3).
- Checklists 1&2 (Appendices C & D) should be populated by the appropriate lead usually the strategic implementation lead or work stream lead and submitted to the Medicines Optimisation Coordinator. The proposal is then considered at the ICB Prescribing Committee. The Prescribing Committee issue a recommendation on the proposal. Assurance is through the System Quality Group.
- Point of contact for Pharmaceutical industry to BLMK ICB: blmkicb.medsopt@nhs.net

6.3 B. Meeting with Pharmaceutical Company or other non-NHS Representatives

6.3.1 **B1. Principles** The principles that staff should follow when offered gifts, sponsorship or hospitality from non-NHS organisations are set out in the BLMK ICB *Standards of Business Conduct Policy* and these should be referred to in conjunction with this policy.

- BLMK ICB welcomes appropriate sponsorship and joint working with pharmaceutical companies when these initiatives are aligned with the NICE guidance, BLMK ICB formulary (including OptimiseRx®) or prescribing recommendations made by the BLMK Area Prescribing Committee (APC).
- BLMK ICB will not endorse specific products as a direct result of sponsorship or joint working agreements with pharmaceutical companies.
- Any sponsorship or joint working initiative should demonstrate clear benefits to patients. Clinical decisions must always be made in the best interest of patients. No agreements are acceptable which compromise clinical judgement.
- Pharmaceutical companies that offer sponsorship or joint working with BLMK ICB should agree to abide by the principles set out in the ABPI Code of Practice. If the company is not a member of the ABPI, BLMK ICB staff should seek assurances that the company follows good practice principles in relation to the promotion of medicines, medical devices, diagnostic agents, dressings, appliances or reagents.
- Any sponsorship or joint working initiatives should be transparent, open to scrutiny and be a matter of public record.
- BLMK ICB NHS funding or resources should be sought first and found not to be available or ruled out before considering sponsorship or joint working with pharmaceutical companies.
- All BLMK ICB staff should be aware of the influence of pharmaceutical promotion on prescribing decisions and seek advice from the Medicines Optimisation Team.

6.3.2 **B2. Guidelines for BLMK ICB staff when meeting with pharmaceutical company representatives**

6.3.2.1 Pharmaceutical company representatives may legitimately approach BLMK ICB staff to request meetings to discuss sponsorship or joint working initiatives. BLMK ICB staff may also proactively seek meetings with pharmaceutical company representatives. In both cases, staff should be aware of their line manager or directorate / Primary Care Network (PCN) position on meeting with pharmaceutical company representatives.

6.3.2.2 Pharmaceutical companies promote their products or therapeutic area to ICB staff, many of whom will be supplementary or independent prescribers or have the ability to influence prescribing decisions. BLMK ICB staff should be aware that pharmaceutical companies see promotion of their products as important in influencing prescribing

behaviour and continue to spend much of their revenue on this activity. And so, only products either currently on local formularies or having positive guidance from NICE or the BLMK Area Prescribing Committee may be promoted. Requests to discuss new products or products not currently on BLMK ICB or hospital formulary should be directed to the nominated representative of the Medicines Optimisation Team. Representatives must not approach members of BLMK ICB Prescribing Groups in order to 'lobby' for decisions to be made in favour of their products.

6.3.2.3 Staff should only meet with representatives by prior appointment, to reduce unnecessary interruptions, to clarify who will be attending the meeting and that the objectives of the meeting are mutually beneficial. Ad hoc meetings with other staff whilst representatives are in the office should be discouraged. The Medicines Optimisation team will use the form in Appendix 7 to agree meetings with representative. For the purpose of this policy, "meet" applies to face to face meetings, virtual meetings and also phone calls, web chats etc

6.3.2.4 During meetings, staff should not provide BLMK ICB prescribing data or medicine usage information that is not already in the public domain unless permission to do so has been given by their line manager or the BLMK ICB Prescribing Committee.

6.3.2.5 Samples of products or supplies may be offered during meetings, but these should not be accepted by BLMK ICB staff unless prior approval has been given by their line manager or BLMK ICB Prescribing Committee. Placebo or dummy devices may be accepted for educational or training purposes.

6.3.2.6 Sponsorship of educational meetings held under ICB auspices by pharmaceutical companies should not be accepted if the products concerned are not in line with the ICB's approach to rational prescribing. ICB run Protected Learning Events will be funded by the ICB.

6.3.2.7 Sponsorship of nurse or other health professional staff training by pharmaceutical or other companies should only be accepted if such training is demonstrated to be impartial and broadly in line with the prescribing advice strategy or other guidance on clinical and cost effectiveness, and with the training needs assessment.

6.3.2.8 Hospitality provided in relation to any meeting must be secondary to the purpose of the meeting. The level of hospitality must be appropriate and not out of proportion to the occasion, and the costs must not exceed that which could be reciprocated by the ICB or which the recipients would normally adopt if paying for themselves. Hospitality in association with formal public meetings of boards is not appropriate. Where meetings are sponsored by external sources, this must be disclosed in the papers relating to the meeting and in any published proceedings.

6.3.2.9 Promotional messages should not be included in any patient information or health promotion material supplied by the ICB.

6.3.2.10 BLMK ICB staff should follow the *Standards of Business Conduct Policy* and also be aware that the *Association of the British Pharmaceutical Industry (ABPI) Code of Practice 2016* sets out the principles which pharmaceutical companies should follow when promoting their medicines including sponsorship and hospitality (<http://www.abpi.org.uk>). The ABPI is a voluntary organisation, but most pharmaceutical companies are members. Staff are encouraged to report any potential breach of the ABPI Code of Practice to a member of the Medicines Management Team, locality manager or BLMK ICB clinical governance lead.

6.3.3 **B3. Guidelines for considering pharmaceutical sponsorship for meetings, educational events and hospitality**

6.3.3.1 The principles that staff should follow when offered gifts, sponsorship or hospitality from non-NHS organisations are set out in the BLMK ICB's *Conflict of Interest Management and Standards of Business Conduct Policy*. These guidelines apply equally to funding received to support place based meetings, such as Board meetings, Protected Learning Zone meetings, or "in-house" educational meetings as well as BLMK ICB staff being funded to attend external educational meetings.

6.3.3.2 Should NHS funding be ruled out or not available and pharmaceutical sponsorship sought, BLMK ICB staff should contact the Medicine Management Team for advice on potential pharmaceutical company sponsors. The Medicine Management Team will keep a list of pharmaceutical companies who have expressed an interest in sponsoring and whose products are already approved for use within BLMK ICB. When BLMK ICB staff are offered pharmaceutical sponsorship, they should contact the Medicines Optimisation Team for advice before accepting this to ensure that the company would not be promoting a product that is not recommended within BLMK ICB.

6.3.3.3 A *Summary of Pharmaceutical Sponsorship Form* (Appendix 4) should be completed for the proposed sponsorship and sent to the Head of Medicines Optimisation. The Head of Medicines Optimisation or nominated Deputy may approve sponsorship forms without referral to the BLMK ICB Prescribing Committee if the sponsorship value is £300 or less. However, these should be declared retrospectively to the Committee. Values over £300 will be referred to the next BLMK ICB Prescribing Committee meeting for approval or otherwise. If approved, the Head of Medicines Optimisation will forward the approved form to the Corporate Services Manager for recording in the central register of gifts and hospitality and return a signed copy to the applicant for their records. If there is an issue with the proposed products to be promoted at the meeting or method of promotion, the Head of Medicines Optimisation will liaise with the applicant.

6.3.3.4 When completing the sponsorship form, it should be borne in mind that the method of promotion should be agreed prior to the meeting taking place and that representatives are not allowed to give presentations on their company's products at the meeting.

When promotional stands are used, these should normally be placed outside of the rooms where the event takes place, for example in a foyer, and then removed once the event has commenced. If the area outside the meeting room is open to the public and hence promotional stands cannot be displayed, then the stand may go in the meeting room as long as the material is removed prior to the start of the meeting.

6.3.3.5 Pharmaceutical company representatives are not allowed to be delegates at sponsored events unless this has been declared and approved on the sponsorship form.

6.3.3.6 If a pharmaceutical company sponsors a speaker at the event, they may not insist on a particular speaker who may favour their products but should instead allow BLMK ICB to choose the speaker.

6.3.3.7 The form in Appendix 6 should be used to confirm arrangements with the company.

6.4 Guidelines for projects involving joint working with pharmaceutical companies

6.4.1 Joint working is a more complex arrangement than simple sponsorship of an event or programme. As such, a fuller written agreement is required which clearly specifies the benefits to the NHS, BLMK ICB and its' patients arising from any project involving joint working. The benefits to the pharmaceutical company must also be explicit.

6.4.2 The forms in Appendix 3 and 4 *BLMK ICB Agreement for Joint Working and Checklist* should be completed and forwarded to the Head of Medicines Optimisation. If approved by the BLMK ICB Prescribing Committee, the Head of Medicines Optimisation will forward the approved form to the Corporate Services Manager for recording in the central register of gifts and hospitality and return a signed copy to the applicant for their records. If there is an issue with the proposed products to be promoted at the meeting, method of promotion or joint working arrangement, the Head of Medicines Optimisation will liaise with the applicant. Joint working projects should not commence until approval from the BLMK ICB Prescribing Committee has been given.

6.4.3 Staff should note that all agreements must include:

- A 'break' clause, enabling the termination of the agreement at short notice. This should outline the repercussions of a non-NHS organisation breaking the terms of the signed agreement.
- That the identity of any patient or other confidential information will not be made available to the pharmaceutical company except as listed in the signed written agreement
- That reports or information cannot be used elsewhere without the permission of BLMK ICB

Appendix 1 - Equality Impact Assessment Initial Screening

Please answer the questions against each of the protected characteristic and inclusion health groups. If there are significant impacts and issues identified a full Equality / Quality Impact Assessment (EQIA) must be undertaken. It is against the law to discriminate against someone because of these protected characteristics. For support and advice on undertaking EQIAs please contact: agcsu.equality@nhs.net

Name of Policy:	Policy for Sponsorship and Joint Working between BLMK ICB and the Pharmaceutical Industry and other non-NHS organisations
Date of assessment:	08/02/2024
Screening undertaken by:	Associate Director and Head of Medicines Optimisation

Protected characteristic and inclusion health groups. Find out more about the Equality Act 2010, which provides the legal framework to tackle disadvantage and discrimination: https://www.equalityhumanrights.com/en/equality-act/protected-characteristics	Could the policy create a disadvantage for some groups in application or access? (Give brief summary)	If Yes - are there any mechanisms already in place to mitigate the potential adverse impacts identified? If not, please detail additional actions that could help. If this is not possible, please explain why
Age A person belonging to a particular age (for example 32 year olds) or range of ages (for example 18 to 30 year olds).	No	
Disability A person has a disability if she or he has a physical or mental impairment which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities.	No	
Gender reassignment The process of transitioning from one gender to another.	No	
Marriage and civil partnership Marriage is a union between a man and a woman or between a same-sex couple. Same-sex couples can also have their relationships legally recognised as 'civil partnerships'.	No	
Pregnancy and maternity Pregnancy is the condition of being pregnant or expecting a baby. Maternity refers to the period after the birth and is linked to maternity leave in the employment context. In the non-work context, protection against maternity discrimination is for 26 weeks after giving birth, and this includes treating a woman	No	

unfavourably because she is breastfeeding.		
Race Refers to the protected characteristic of race. It refers to a group of people defined by their race, colour and nationality (including citizenship) ethnic or national origins.	No	
Religion or belief Religion refers to any religion, including a lack of religion. Belief refers to any religious or philosophical belief and includes a lack of belief. Generally, a belief should affect your life choices or the way you live for it to be included in the definition.	No	
Sex A man or a woman.	No	
Sexual orientation Whether a person's sexual attraction is towards their own sex, the opposite sex, to both sexes or none.	No	
Carers Individuals within the ICB which may have carer responsibilities.	No	
Please summarise the improvements which this policy offers compared to the previous version or position.		
None – re-formatting of existing BLMK policy		
Has potential disadvantage for some groups been identified which require mitigation?		
No – (If there are significant impacts and issues identified a full Equality / Quality Impact Assessment (EQIA) must be undertaken.)		

Appendix 2 - Data Protection Impact Assessment Initial Screening

Data protection is the fair and proper use of information about people. Before completing this form, please refer to the Data Protection Impact Assessment (DPIA) Guidance in the Information Governance (IG) section on the staff Intranet or contact the Data Protection Officer for support via blmklCB.ig@nhs.net. A DPIA is a process to help you identify and minimise the data protection risks. You must do a DPIA for processing that is likely to result in a high risk to individuals. You can use our screening checklist below to help you decide when to do one. If you have answered 'Yes' to any of the 10 screening questions, you must then carry out a full DPIA using the Stage 2 form, which is also available on the Intranet in the IG section.

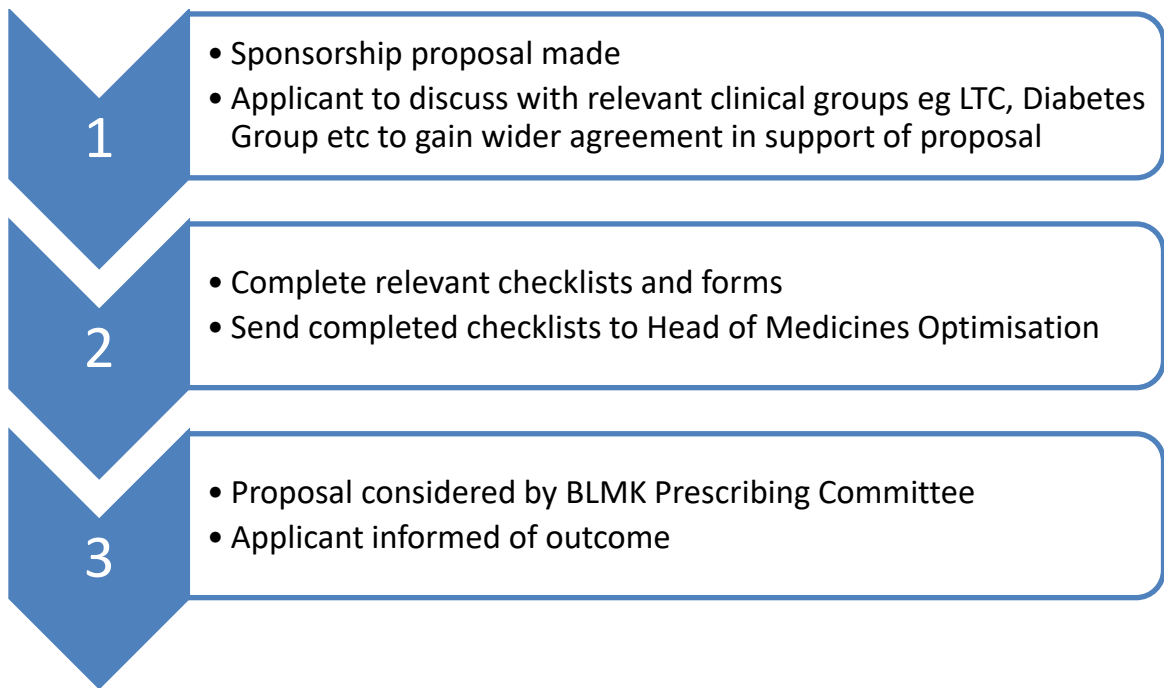
Name of Policy:	Policy for Sponsorship and Joint Working between BLMK ICB and the Pharmaceutical Industry and other non-NHS organisations
Date of assessment:	08/02/2024
Screening undertaken by:	Associate Director and Head of Medicines Optimisation

Stage 1 – DPIA form

please answer 'Yes' or 'No'

1. Will the policy result in the processing of personal identifiable information / data? This includes information about living or deceased individuals, including their name, address postcode, email address, telephone number, payroll number etc.	No
2. Will the policy result in the processing of sensitive information / data? This includes for living or deceased individuals, including their physical health, mental health, sexuality, sexual orientation, religious belief, National Insurance No., political interest etc.	No
3. Will the policy involve the sharing of identifiers which are unique to an individual or household? e.g., Hospital Number, NHS Number, National Insurance Number, Payroll Number etc.	No
4. Will the policy result in the processing of pseudonymised information by organisations who have the key / ability to reidentify the information? Pseudonymised data - where all identifiers have been removed and replaced with alternative identifiers that do not identify any individual. Re-identification can only be achieved with knowledge of the re-identification key. Anonymised data - data where all identifiers have been removed and data left does not identify any patients. Re-identification is remotely possible, but very unlikely.	No
5. Will the policy result in organisations or people having access to information they do not currently have access to?	No
6. Will the policy result in an organisation using information it already holds or has access to, but for a different purpose?	No
7. Does the policy result in the use of technology which might be perceived as being privacy intruding? e.g., biometrics, facial recognition, CCTV, audio recording etc.	No
8. Will the policy result in decisions being made or action being taken against individuals in ways which could have a significant impact on them? Including profiling and automated decision making. (This is automated processing of personal data to evaluate certain things about an individual i.e., diagnosis and then making a decision solely by automated means - without any human involvement)	No
9. Will the policy result in the collection of additional information about individuals in addition to what is already collected / held?	No
10. Will the policy require individuals to be contacted in ways which they may not be aware of and may find intrusive? e.g., personal email, text message etc.	No

Appendix 3 - Process Flow diagram



Appendix 4 - Sponsorship Form

Please complete all parts and then forward to the Associate Director Pharmacy and Medicines Optimisation, by e-mail: blmkicb.medsopt@nhs.net

Who is receiving sponsorship?	
Company providing sponsorship	
Is the pharmaceutical company a member of the ABPI? (List available at: https://www.abpi.org.uk/member-representation/abpi-members-list/)	Yes / No If no, what assurances have you been given that the company follows good practice principles in relation to promotion of medicines, dressings, and diagnostics?
Details of sponsorship i.e. purpose and aims of event /meeting, number of attendees anticipated, date, venue	
Value (If >£300 form will be referred to the BLMK ICB Prescribing Committee)	
Clinical area(s) being covered at the meeting or event	
Product (s) to be promoted	
Method of promotion eg Leaflets, stand and products on display, expert speaker	
Will the pharmaceutical company be presenting at the event?	
Product endorsement (Medicines Optimisation Team can advise if needed)	On ICB Formulary Yes / No / N/A APC or NICE positive endorsement Yes / No / N/A Other (please specify).....
Benefit to organisation of the meeting /event	
Completed by Signed Date	Name Position

Now forward the form to the Head of Medicines Optimisation.

To be completed by Head of Medicines Optimisation on behalf of the BLMK ICB Prescribing Committee	
Approved by Medicine Management Lead / BLMK ICB Prescribing Committee (delete as appropriate)	Yes / No
If NO reason for rejection:	
Signed	Date

Date form sent to applicant (if not approved) or Head of Governance (if approved):

Appendix 5 - BLMK Initial Checklist for Assessment of Collaborative Working with the Pharmaceutical Industry or their Agents or Affiliated Companies

If any responses to the following are **No**, the agreement will contravene the policy. Further advice must be sought from the Head of Medicines Optimisation before proceeding.

GENERAL

- ❖ Has ICB funding or other NHS resources been considered first and found not to be available or ruled out?
Y/N
- ❖ Is the agreement in the best interests of patients
Y/N
- ❖ Is the offer independent of purchasing or prescribing decisions?
Y/N
- ❖ Is professional judgement unaffected
Y/N
- ❖ Is patient and NHS data confidentiality maintained Y/N
- ❖ Is the company a member of the ABPI or do they follow good practice in promoting pharmaceuticals? Or are you satisfied with your knowledge of the sponsoring organisation(s) (i.e. is there evidence of audited accounts, is the organisation and its ownership known, is it capable of being independently audited?) Y/N
- ❖ Is the agreement upright and honest and free from conflict of interest?
Y/N

CONTRACTUAL

- ❖ Does a contractual agreement or service agreement exist (to include the aims and objectives of the collaborative working; an outline of the accountability framework within which the provider will operate; the protocols to be used on the programme, including a full description of the service(s) to be provided and the names and details of personnel to be involved; the procedure to be followed in the event of adverse incidents; any professional indemnity and liability arrangements that the service provider has in place; the option to modify or suspend the programme in the light of any assessments, evaluations or adverse events; the option for either party to withdraw, with agreed and clearly defined notice periods on both sides
Y/N
- ❖ Are the skills, competencies, professional status and qualifications of the named individuals who will be directly involved with the programme of a sufficient level to provide the aims and objectives effectively, efficiently and reliably?
Y/N
- ❖ Is the agreement lawful
Y/N
- ❖ Is there no reason to suspect the company will be unable to fulfil obligations
Y/N
- ❖ Have all appropriate parties discussed the proposed offer? Y/N
- ❖ Are lines of accountability clear – clinical, professional, managerial?
Y/N

CLINICAL EVIDENCE

- ❖ Is the agreement evidence based (The Medicines Optimisation team is available to give assessments of available evidence)
Y/N

- ❖ Does the agreement represent best clinical practice
Y/N
- ❖ Is the agreement compatible with national and local arrangements for prescribing Y/N

FINANCIAL

- ❖ Does the agreement represent value for money
Y/N
- ❖ If the agreement is linked to the purchase of a particular product, has there been a competitive tender process in line with ICB SFIs?
Y/N
- ❖ Have costs and benefits been assessed in relation to alternative options
Y/N
- ❖ Is there provision within the agreement for financial audit
Y/N
- ❖ Have the future potential implications of the agreement been considered
Y/N
(e.g. continuing cost of treatment initiated during a trial) and are on-going and future purchasing decisions unaffected by the agreement

AUDIT

- ❖ Is there provision within the agreement for financial audit
Y/N

OUTCOME MEASURES

- ❖ Does the agreement include monitoring of clinical/ financial measures
Y/N
- ❖ Is there provision for break clauses for the ICB to terminate the agreement if outcomes are not satisfactory
Y/N

The answers to the following **MUST** be **NO** otherwise the agreement may contravene the policy

EXCLUSIONS

- ❖ Is there any reason to suspect the company will be unable to fulfil obligations?
Y/N
 - ❖ Are there any purchasing decisions affected by the agreement?
Y/N
 - ❖ Is the NHS expected to pick up recurrent costs of the scheme?
Y/N
- If the answer is yes then it needs to be considered as a Business Development.

Assessment undertaken by

Signature

Designation

Date of assessment

Appendix 6 - BLMK ICB Agreement for Joint Working

Please complete all parts of this form plus the initial checklist and then forward to the Head of Medicines Optimisation, by email to blmkicb.medsopt@nhs.net

FUNDING OF: Please enter brief details eg funding for an asthma course for practice nurses

BY: Enter name of company

TYPE OF COMPANY: (Usually but not exclusively a pharmaceutical company)

Application for funding of: £ State amount agreed

Please complete on a separate sheet:

Basis for the Work: Justification for the work, brief background, purpose and objectives of the work to be funded. To include the contribution from BLMK ICB, if any, defining the work and audit / training / meetings to be held.

Description of the Work and Personnel involved: Overall and detailed objectives, personnel / organisations involved, expected benefits and outcomes.

Project Action Plan: Detailed description of the project to show how funding will be used and timescales.

Joint working is accepted on the basis that:

- 1) The Sponsor agrees to abide by the Integrated Care Board sponsorship policy for working with Non-NHS organisations. The Sponsor may only be involved to the extent defined in this agreement, consistent with the policy.
- 3) Any reports resulting from the work may acknowledge The Sponsor's contribution. The Sponsor cannot use any reports or information from this work without explicit permission from BLMK ICB.

The Sponsor knows of no potential embarrassment that would accrue to BLMK ICB as a result of this agreement. The Sponsor shall not use the name of the ICB including logos or its employees or services to infer endorsements of products or activities without explicit agreement.

BLMK ICB should hold copies of all Service Agreements.

Name of BLMK Manager requesting sponsorship	Signature, designation, date and contact number
Name of non-NHS organisation representative	Signature, designation, organisation name, date and contact number

The following will be considered by the BLMK Prescribing Committee:

1. Does the proposal on offer align with current views on evidence-based clinical practice?
2. Is the proposal on offer consistent with ICB priorities?
3. Have all offers of sponsorship including gifts or hospitality accepted (greater than £25) been registered in the ICB's gifts and hospitality register?

Approved by BLMK Prescribing Committee (yes or no) Date:

Appendix 7 - BLMK ICB SPONSORSHIP FOR PROFESSIONAL OR SCIENTIFIC MEETINGS

To
Of (State Company)
Thank you for agreeing to sponsor the meeting on Venue:
Title of Meeting

Sponsorship is accepted on the understanding that:-

- The Sponsor agrees to abide by the BLMK ICB sponsorship policy for working with the Pharmaceutical industry and other Non-NHS organisations
- The meeting organiser retains overall control of the event and the content of the event
- The sponsor does not have the automatic right to present teaching or promotional material
- Where the organiser considers additional value may be gained from a presentation by the sponsor, that the content of the material is agreed in advance.
- The sponsor does not use the ICB contact to promote products outside the meeting.
- Any stand the sponsor uses to promote products is to be outside the main meeting room, where this is possible.
- Attendance at the meeting by the sponsor is at the discretion of the course organiser.
- Where course material is provided by a pharmaceutical company there is no promotion of specific products (the name of the company supporting the meeting is acceptable)
- Any reports resulting from the work may acknowledge The Sponsor's contribution.
- The Sponsor cannot use any reports or information from this work without explicit permission from BLMK.
- **The Sponsor knows of no potential embarrassment that would accrue to BLMK ICB as a result of this agreement. The Sponsor shall not use the name of the ICB including logos or its employees or services to infer endorsements of products or activities without explicit agreement.**

Please confirm that you accept the terms detailed above:

Signed:

Date:

Print Name:

Position/Company:

Signed on behalf of the ICB

Signed:

Date:

Print Name:

Position

Appendix 8 - Process for Pharmaceutical Representatives

If you wish to discuss a product with the Medicines Management Team please complete this form and email it back to the Medicines Management Team at blmkicb.medsopt@nhs.net

****Please note no appointments will be considered until we have received this information****

This form can also be filled out online at <https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/categories/formulary/pharmaceutical-reps/>

Your name:	
Job title	
Company name:	
Email address:	
Telephone number:	
What products does the pharmaceutical sales representative wish to discuss? (Please be specific)	
Is this product in our local formulary? Yes No (please circle/delete) Bedfordshire and Luton Formulary Wound Care Formulary (Beds & Luton) Milton Keynes formulary	
How is this product more effective than the current product in use? Include the clinical and quality benefits to the patients of Bedfordshire, Luton and Milton Keynes.	
How does the price compare with similar products?	
What addition information do you have to enable the team to make an informed decision? You may attach further information.	

Appendix 9 - The 7 Principles of Public Life (The Nolan Principles)

The Seven Principles of Public Life, known as the Nolan Principles, were defined by the Committee for Standards in Public Life. They are:

Selflessness Holders of public office should act solely in terms of the public interest. They should not do so in order to gain financial or other benefits for themselves, their family or their friends.

Integrity Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their official duties.

Objectivity In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands it.

Honesty Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

Leadership Holders of public office should promote and support these principles by leadership and example