



Corporate	ICBP006 Commercial sponsorship and joint working with the pharmaceutical, medical appliance and health technology industry Policy
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EQUALITY IMPACT ASSESSMENT

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February 2023	None

POLICY VALIDITY STATEMENT

Policy users should ensure that they are consulting the currently valid version of the documentation. The policy will remain valid, including during its period of review. However, the policy must be reviewed at least once in every 3-year period.

ACCESSIBLE INFORMATION STANDARDS

If you require this document in an alternative format, such as easy read, large text, braille, or an alternative language please contact NECSU.comms@nhs.net

Version Control

Version	Release Date	Author	Update comments
1	July 2022	Clinical Services Manager, NECS	Not Applicable
2	April 2023	Director of Medicines and Pharmacy, NENC ICB and Clinical Services Manager, NECS	To include medical appliances and devices. Minor wording amendments.

Approval

Role	Name	Date
Version 1	ICB Executive Committee	July 2022
Version 2	ICB Executive Committee	April 2023

Contents

1. Introduction	4
2. Definitions	6
3. Standards of Business Conduct, Sponsorship and Joint Working	7
4. Implementation	18
5. Training Implications	19
6. Documentation	19
7. Monitoring, Review and Archiving	20
Appendix 1 Duties and Responsibilities	21
Appendix 2 Advice for ICB Commissioned Primary Care Providers regarding support provided by the Pharmaceutical, Medical Appliance or Health Technology Industry	22
Appendix 3 Framework for joint working between the NHS and pharmaceutical, medical appliance or health technology industry	26
Appendix 4 Equality Impact Assessment	27

1. Introduction

This policy is intended for the Integrated Care Board (hereafter refer to as the ICB) and its staff who are involved in working with the pharmaceutical, medical appliances and health technology industries. It is intended to complement the ICB Policy on Standards of Business Conduct and Conflicts of Interest. It should also act as a guide for commissioning support staff who are responsible for working alongside the ICB in delivering effective partnering and conduct with the pharmaceutical, medical appliances and health technology industries.

The ICB recognises that primary care providers are providers in their own right but would encourage them to adopt the policy, in particular the advice contained in Appendix 1, Advice regarding support provided by the Pharmaceutical Industry, Medical Appliance Industry or Health Technology Industry.

In the past, contacts between the pharmaceutical industry, medical appliance industry, health technology industry and primary health care professionals have revolved around the purchase or promotion of specific products and the provision of sponsorship e.g., to support educational events or training.

More recently, industry has begun to focus on enhancing its links with the NHS in an effort to support improving the value from the NHS investment in medicines, medical appliances, and health technology.

Department of Health (DH) Guidance encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical, medical appliance and health technology industries, where the benefits that this could bring to patient care and the difference it can make to their health and well-being are clearly advantageous. Such advantages are to be clearly stated and evidence presented to support such claims. The pharmaceutical industry, medical appliance industry and the health technology industry are also expected to be transparent about anticipated commercial gain of such initiatives.

Increasing financial pressures and a growing improvement agenda make it more important for the NHS to consider strategic partnerships that will enable it to achieve national and local targets.

It is important to recognise that a partnership already exists between the NHS and the pharmaceutical, medical appliance and health technology industries. Many parts of the healthcare system already undertake collaborative work with drug companies, medical appliance companies and health technology companies to work on specific projects. ICBs are keen to engage in collaborative working to facilitate service re-design. Clear guidance is required to ensure that such arrangements are fully transparent and deliver maximum benefits for patients and the health economy. Positively engaging with companies and primary care providers may lead to larger, longer-term collaborations that meet the needs of all parties including pharmaceutical, medical appliance and health technology industries.

The benefits of greater collaboration must be weighed against any potential risks. It is essential that all projects are subject to the highest scrutiny to enable potential pitfalls to be highlighted at an early stage. It is vital to ensure that the business priorities of commercial organisations do not lead to a distortion of local priorities or investment. Upfront disclosure of expected commercial return will help negate this risk. Where a return on investment is expected by the pharmaceutical industry, medical appliance industry or health technology industry to be as a result of product sales this must be in line with the ICB prescribing policies and investment priorities as well as the [Association of British Pharmaceutical Industry \(ABPI\) Code of Practice](#), [Surgical Dressing Manufacturers Association \(SDMA\) Code of Practice](#) or [Association of British HealthTech Industries \(ABHI\) Code of Ethical Business Practice](#) respectively. *(It should be noted that the same principles should also apply to other commercial organisations that provide products and services).*

1.1 Status

This policy is a corporate policy.

1.2 Purpose and scope

The purpose of this policy is to:

- assist the ICB in achieving its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical, medical appliance and health technology industries
- ensure that the ICB and its staff respond consistently to approaches from the pharmaceutical, medical appliance and health technology industries and that the interests of patients, the public and the ICB are maintained
- ensure staff comply with ICB commercial sponsorship the pharmaceutical, medical appliance and health technology industry policy and working with standards and their own professional codes of conduct, and that representatives of the pharmaceutical industry comply with the [ABPI Code of Practice for the Pharmaceutical Industry](#) representatives of the medical appliance industry comply with the [Surgical Dressing Manufacturers](#)

- [Association \(SDMA\) Code of Practice](#) and representatives of the health technology industry comply with the [Association of British HealthTech Industries \(ABHI\) Code of Ethical Business Practice](#)
- inform and advise staff of their main responsibilities when entering into joint working arrangements with the pharmaceutical, medical appliance or health technology industries. Specifically, it aims to:
 - assist NHS employers and staff in maintaining appropriate ethical standards in the conduct of NHS business
 - highlight that NHS staff are accountable for achieving the best possible health care within the resources available
 - highlight that NHS staff may be vulnerable to marketing techniques that may attempt to show some pharmaceutical companies, medical appliance companies or health technology companies in a more favorable light than is appropriate.

For the purposes of this policy, the term ‘staff’ refers to all employees of the ICB and those personnel not directly employed by the ICB but who sit on the ICB Board, its Committees/sub-committees and includes Commissioning Support staff.

2. Definitions

The following terms are used in this document:

- **Commercial sponsorship** is defined as including

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, medical appliances, health technology 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.

- **Joint working** is defined as

Situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

- **Medical and Educational Goods and Services (MEGS) grants** defined as:

Grants for a legitimate health or educational purpose with no expectation of anything in return for providing the support. They are provided to healthcare organisations to either benefit patients or benefit the NHS, whilst maintaining patient care. Medical Educational Goods and Services (MEGS) grants must relate to either: continuing professional education, patient or community education or community projects that promote better healthcare (e.g., disease screening programmes).

3. Standards of Business Conduct, Sponsorship and Joint Working

3.1 Standards of Business Conduct

NB This section should be read in conjunction with the ICB Standards of Business Conduct and Declarations of Interest Policy.

3.1.1 Casual Gifts and Hospitality

All gifts and hospitality should be declared by all ICB staff and recorded on the Gifts and Hospitality register, regardless of whether they are accepted / refused. Where gifts and hospitality offers are received, all ICB staff are required to complete the declaration of interest form and return it to their line manager for initial approval. These will then be sent to the governance lead promptly so that the details can be recorded on the central register.

Where required by the ICB Standards of Business Conduct and Declarations of Interest Policy, paragraph 6.4, the completed form should be sent to the Director of Corporate Governance and Involvement or their deputy for final approval and recording in the gifts, hospitality and sponsorship register. In cases of doubt, advice should be sought from the line manager/ Governance Lead or Director of Corporate Governance and Involvement

3.1.1.1 Overarching Principles (Gifts)

Employees of the ICB, Board and Committee/Sub committee members and individuals acting on behalf of the ICB must not accept any fee or reward for work done whilst on ICB duty other than that agreed under their terms and conditions of employment.

Situations where the acceptance of gifts could give rise to conflicts of interest should be avoided. ICB staff and members should be mindful that even gifts of a small value may give rise to perceptions of impropriety and might influence behaviour if not handled in an appropriate way.

ICB staff should not accept gifts that may affect, or be seen to affect, their professional judgement. This overarching principle should apply in all circumstances.

Any personal gift of cash or cash equivalents (e.g., vouchers, tokens, offers of remuneration to attend meetings whilst in a capacity working for or representing the ICB) must always be declined, whatever their value and whatever their source, and the offer which has been declined must be declared to the ICB governance lead who has designated responsibility for maintaining the register of gifts and hospitality and recorded on the register.

Any offers of gifts, hospitality or sponsorship shall be recorded.

3.1.1.2 Overarching Principles (Hospitality)

ICB staff should not ask for or accept hospitality that may affect, or be seen to affect, their professional judgement.

Hospitality must only be accepted when there is a legitimate business-reason, and it is proportionate to the nature and purpose of the event. 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.

Caution should be exercised when hospitality is offered by actual or potential suppliers or contractors. These can be accepted if modest and reasonable, but individuals should always obtain approval from the Director of Corporate Governance and Involvement or nominated ICB governance lead and declare these.

Further information regarding registration and a copy of the relevant documentation to register gifts and hospitality is contained within the ICB Standards of Business Conduct and Declarations of Interest Policy.

3.1.2 Meeting with Representatives

Representatives of the pharmaceutical, medical appliance and health technology industries request meetings to discuss products and services. If a topic is of interest, staff should ask for information to be sent to them, prior to scheduling of meeting, to determine appropriateness and relevance. They should critically evaluate the information sent and not rely on it as their sole source of information.

The ICB Medicines Optimisation team has access to independent sources of evaluated information and can provide advice and meet representatives on behalf of the ICB as necessary.

If commissioners or service leads wish to meet with pharmaceutical, medical appliance or health technology industry representatives it is recommended that the following guidelines are followed:

- Staff should have a clear agenda from a pharmaceutical, medical appliance or health technology industry representative before agreeing to a meeting, which should be by appointment for a specified time and duration.
- If other personnel arrive for the meeting other than those agreed in advance, then staff are at liberty to decide the optimal numbers for the meeting and should use their discretion as to whether it is in the interests of the ICB and therefore appropriate to see the additional personnel.
- Further meetings should not be arranged if the representative was unhelpful or unethical in any respect or if the meeting did not produce expected outcomes, such as relevant information on a new drug, product or device.
- If a member of staff feels uncomfortable with an approach or offer from a company, then they should discuss it with their line manager in the first instance. Advice should then be sought from an appropriate service manager or the ICB Medicines Optimisation team.
- A record of the visit should be made.
- This policy supports the facilitation of joint meetings between the ICB, Primary Care providers and pharmaceutical, medical appliance and health technology companies where these meetings conform to this policy. Such joint meetings will enable a variety of industry proposals for joint working to be considered by the ICB and Primary Care providers in conjunction with the priorities of the ICB.
- Any behaviour by pharmaceutical, medical appliance or health technology industry personnel felt to be inappropriate should be reported to the ICB Medicines Optimisation team and, in the first instance, this will be taken up with the representative's line manager. If no satisfactory outcome is achieved, then a complaint will be made an Executive Director to the Association of British Pharmaceutical Industries (ABPI), Surgical Dressing Manufactures Association (SDMA) or Association of British HealthTech Industries (ABHI) as appropriate.
- Should staff feel uncomfortable or compromised in any way they should end the meeting immediately and report their concerns to their line manager, in the first instance.

3.1.3 Outside Work Activity

ICB staff must declare to the ICB in writing any financial interest or relationship they may have with a pharmaceutical, medical appliance or health technology company or other agency which may affect (or be considered to affect the ICB's policies or decisions in line with the *ICB Standards of Business Conduct and Declaration of Interest policy*.

Examples may include:

- Holding shares in a pharmaceutical, medical appliance, health technology or medical supplies company, where the shareholder is a direct beneficiary - If shares are held through a third party (e.g., a pension fund or an ISA) and there is no direct benefit gained, then a declaration is not needed.
- Consultancy work
- Speaking at meetings
- Attendance at advisory boards

It is expected that staff should seek prior approval from their line manager and ICB Director of Corporate Governance & Involvement or nominated governance lead, before taking on any outside work for the pharmaceutical, medical appliance or health technology industry. If the work is carried out in NHS time, i.e., during the normal working day, without the member of staff taking annual leave, the fee should either be refused, or, if accepted, be paid to an ICB budget agreed with the line manager in advance of undertaking the activity.

A fee that is in line with fair market value can be accepted for work carried out in the staff member's own time, but this should be approved by their line manager and the Director of Corporate Governance and Involvement or nominated governance lead in advance of undertaking the activity. All payments and fees paid by the pharmaceutical industry will be disclosed by the company and made publicly available.

Medical appliance companies must also ensure that a written agreement is in place signed by all parties and clearly describes the service provided, remuneration and expenses to be paid. Health technology companies must also ensure they fully comply with all applicable national laws, regulations and professional codes of conduct requiring disclosure of payments made and transparency of any interactions between industry representatives and healthcare professionals or healthcare organisations.

Any information shared with industry must be compliant with ICB Information Governance policies, where this involves the sharing of personal identifiable information there may be information governance requirements to consider; please consult the information governance service for advice

3.1.4 Research and Development

Those undertaking sponsored research or post-marketing surveillance must be guided only by their patients' best interests and not be influenced by any sponsorship. All such research must be approved by the Medicines Sub Committee or the Executive Committee in accordance with the Scheme of Reservation and Delegation and the Financial Limits and follow ICB research and development guidelines.

The employee should complete the ICB declaration of interest for stating that they are undertaking sponsored research or post-marketing surveillance. All completed forms should be sent to Director of Corporate Governance and Involvement for approval and management of the conflict of interest (potential or actual).

3.2 Sponsorship

3.2.1 Conferences and Courses Attended by Staff

Staff must seek approval in advance from their line manager and the Director of Corporate Governance & Involvement or nominated governance lead, before accepting commercial sponsorship to attend relevant courses and conferences. Managers must be satisfied that acceptance will not compromise purchasing or commissioning decision or influence prescribing. A record should be made of all sponsorship in the organisation's Gifts and Hospitality Register.

3.2.2 Educational Meetings and Training Arranged by the ICB

Industry representatives organising meetings are permitted to provide appropriate hospitality and/or meet any reasonable, actual costs, which may have been incurred.

Hospitality must be secondary to the purpose of the meeting. The level of hospitality offered must be appropriate and not out of proportion to the occasion; the costs involved must not exceed that level which the recipients would normally adopt when paying for themselves, or that which could be reciprocated by the NHS. It should not extend beyond those whose role makes it appropriate for them to attend the meeting.

Where meetings are sponsored by external sources, that fact must be disclosed in the papers relating to the meeting and in any published proceedings.

Where an educational event is being considered and sponsorship is being sought then all relevant manufacturers (i.e., those manufacturing products that appear in ICB adopted or approved guidelines) should be approached, to avoid any suggestion of preferential treatment towards one manufacturer. There should be prior agreement about the content of educational / clinical meetings, training course, identity of speakers and nature of displayed promotional material.

Where industry personnel are directly providing training the ICB organiser must be satisfied that the training complies with the ABPI code of conduct, SDMA Code of Practice or ABHI Code of Ethical Business Practice, all guidance complies with current evidence base and NHS and local guidance and the training could not be construed as an incentive to prescribe, use, or dispense a particular pharmaceutical, medical appliance, or health technology product.

It must be clear that sponsorship does not imply the ICB endorsement of any product or company, and there should be no promotion of products apart from that agreed in writing in advance.

The company cannot promote its products through the work it is supporting by direct advertisement, except by operating a promotional stand, as appropriate, at sponsored meetings during the registration period only preferably in a separate area to that of the main meeting. Sponsorship should not compromise purchasing, commissioning decisions or prescribing advice.

3.2.3 Development of Guidelines

It is legitimate for a company to support the development and implementation of NHS or other accepted clinical guidelines provided the company is open and transparent about its involvement in the guideline's development process.

Where representatives from industry may be involved in the development of clinical guidelines / protocols e.g., as part of a multidisciplinary steering group this contribution must be managed as follows:

- Clinical aspects must always be under local control. The development of guidelines or protocols will be through a local group, although they may decide to use or adapt information produced elsewhere. (See appendix 3 for further guidance)
- The development of guidelines should preferably be undertaken with the involvement of secondary care professionals, where appropriate.
- Equitable access and opportunity for comment will be offered to all companies with interests in each therapeutic area.
- All suggested comments and amendments by industry will be in writing and supported by necessary evidence.
- Responses to comments will be documented and supported with an explanation of the decision where necessary.
- The pharmaceutical, medical appliance or health technology industries will undertake not to lobby or influence members of any steering group or panel out with the official processes.
- The final decision to approve a guideline will be made through designated ICB approval processes and will be independent of any consideration of financial or other support.
- In entering partnership arrangements, participants should ensure that they are not conditional on the use of the sponsor's product in preference to other more clinically appropriate products or services. In addition, they must be in keeping with local guidelines and formularies.
- The ICB, and its employees, must not be seen to be endorsing any individual company or products through such agreements.
- It should be clear through appropriate governance processes that the pharmaceutical, medical appliance or health technology company is not inappropriately influencing decisions about the prescription, supply administration and recommendation of its products.

3.3 Joint Working

The key requirements of joint working are twofold:

1. Joint working must be foremost for the benefit of patients and preserve patient care. Any joint working between the NHS and the pharmaceutical, medical appliance or health technology industries should be conducted in an open and transparent manner.

Arrangements should be of mutual benefit, the principal beneficiary being the patient. The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined before entering any joint working.

The aims that the pharmaceutical, medical appliance or health technology industry partner(s) wishes to gain from the initiative should be transparent. It should also be made clear what the NHS and industry partners are contributing to the joint working agreement e.g., financial support, project management, data analysis.

2. Given the significant governance and administrative requirements involved in setting up proper joint working arrangements it is likely that most joint working projects will be of a significant size and duration generally involving resources (manpower, materials, funding etc.).

3.3.1 Principles of Joint Working

The following principles will also apply to joint working:

- All joint working projects should be conducted through an open and transparent process.
- Staff should be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct as described in extant NHS guidance.
- Contract negotiations will be negotiated in line with NHS values.
- Confidentiality of information received in the course of duty must be respected and never used outside the scope of the specific project.
- Joint working arrangements should take place at a corporate, rather than an individual level.
- Clinical and financial outcomes will be assessed through a process of risk assessment.
- Projects should address local priorities and preferred service balance.
- All collaborative projects will maintain the freedom of all clinicians to prescribe the most clinically appropriate and effective treatment for individual patients in line with locally approved guidelines and formulary.

- Clinical and prescribing policies or guidelines will always be based upon principles of evidence-based medicine and cost effectiveness. These will be consistent with national recommendations and expert bodies specifically the National Institute for Health and Care Excellence (NICE).
- A whole-systems approach will be taken to developing collaborations.
- This will ensure that only arrangements that benefit the whole NHS are approved. Those that lead to higher costs or a reduction in quality in other areas of the NHS or shift the balance of investment in service in a manner not consistent with local priorities, are not acceptable.
- Collaborative projects that focus on broader areas are to be preferred to those which focus on specific drugs or products. Projects that encourage the preferential prescribing or use of one product may be viewed as a financial incentive to prescribe or use and may contravene national guidance.
- Multi partner collaborations are desirable although this may sometimes be difficult to achieve due to differences in organisational governance policies. Documentation of multi company projects will need careful consideration and the involvement with company compliance teams at an early stage in planning to avoid unnecessary delays. If the ICB is approached by one company as a matter of course, all companies providing products consistent with local policies should be invited to contribute to the partnership.
- Where products are deemed equally clinically effective, assessment of cost-effectiveness may include the package of additional resources and support for each product.

The Department of Health and the ABPI have jointly produced a [toolkit](#) to support joint working.

The following sections are based on the Department of Health and the [ABPI toolkit](#) and are applicable to working with medical appliance and health technology industries also. Staff in the ICB wishing to enter into joint working arrangements are recommended to use the [toolkit](#) in conjunction with the recommendations below.

3.3.2 Mechanism for Monitoring Joint Working Arrangements

A joint working arrangement framework proforma should be completed for all proposed collaborations. (Appendix 3) considering the principles outlined in Appendix 2. This should be submitted to Northern Technology Appraisal Group (NTAG) for assessment. If NTAG recommends approval it will then be submitted to the Medicines Sub Committee or the Executive Committee in accordance with the Scheme of Reservation and Delegation and the Financial Limits for approval.

All projects should be managed by a named nominated ICB representative and NTAG with clear terms of reference. Any decisions arising through the management of the project must be referred to the the Medicines Sub Committee or the Executive Committee in accordance with the Scheme of Reservation and Delegation and the Financial Limits for decision. NTAG must not make decisions on behalf of the ICB. A

named ICB lead may make decisions on the management of the project if this is within their remit (job description) and any financial limits.

A project plan should be developed and be subject to regular review, sufficient to ensure successful progress for all parties. In entering such agreements all parties will give a commitment to maintain this input.

All meetings connected to the development or delivery of a collaborative project will be formally minuted and recorded, with any conflicts of interest transparently recorded.

Collaboration should be based on explicit written agreements between the ICB and the company, which define the precise nature of the support provided. There should be a written contract or business agreement authorised by an appropriate ICB representative consistent with the SORD and Financial Limits for all joint working agreements. An example of such a contract is available in the DH Toolkit.

All proposals will specify sufficient report arrangements to enable progress to be monitored by the relevant ICB committee or sub committee, consistent with the Scheme of Reservation and Delegation via NTAG.

The outcomes of every joint working project should be measured. Dependent on the project, a set of baseline measurements should be established at the outset of the project to track and measure the success of the project aims, particularly patient outcomes.

A mutually agreed and effective exit strategy will be in place at the outset of any joint working arrangement detailing the responsibilities of each party and capable of dealing with a situation where premature termination may become necessary.

Where the joint working project involves the commissioning of new services from an external provider or the provision of additional services from an existing provider a business case and service specification should be developed which details:

- Services to be provided
- How these will be procured
- Payments / costs for services
- Who will be responsible for monitoring service quality / performance management of service in line with ICB commissioning guidelines?

3.3.3 Clinical Accountability

Clinical aspects of projects must always be under local control. Development of prescribing or clinical guidelines and protocols will be developed in accordance with usual procedures in conjunction with the relevant prescribing and clinical governance groups, seeking approval from the Quality & Safety Committee (as per its terms of reference).

The ICB will preferentially pursue collaboration with 'natural partners' i.e., those companies that produce products that are consistent with locally developed independent policies.

The ICB may decide that advice or guidelines developed by the pharmaceutical, medical appliance or health technology industry are consistent with the ICB policies and suitable for local distribution.

3.3.4 Financial Arrangements

All financial arrangements must comply with ICB standing financial instructions. To ensure probity all funding must be held by the finance team for the ICB.

The ICB project lead will receive a budget statement for the project on a monthly basis in order to manage the costs of the project within the funding available. Project costs will routinely be monitored by the NTAG, as part of the overall project monitoring and report to the Medicines Sub Committee as appropriate.

3.3.5 Communications

All communications, both verbal and written will be recorded and available for public scrutiny.

Any learning or products (protocols, guidelines, etc) developed through sponsored projects may be shared with other NHS organisations.

The ICB will consider supporting the dissemination of lessons learned from the set projects but retains the right of approval of associated literature and material.

The ICB recognises the need for ethical companies to promote their products to the NHS and has no wish to disadvantage those companies that engage in positive collaboration. In this context pharmaceutical, medical appliance and health technology companies and their agents will undertake not to seek to gain advantage in terms of access to staff or sales by reference to their participation in any collaboration other than with the written consent of the ICB.

Any publication produced with the support of a pharmaceutical, medical appliance or health technology company should contain a statement to the effect that sponsorship of the publication does not imply the endorsement of the company's products or services by the ICB. This should use a form of words such as "This document has been printed with the support of xxxx Ltd, who had no influence on its content".

3.3.6 Confidentiality and Data Protection

Where a project involves access to, or processing of patient sensitive data all staff will comply with the ICB Confidentiality and Data Protection Policy, advice should be sought from the Information Governance Lead or Data Protection Officer and Caldicott Guardian.

It may be beneficial for both parties to exchange commercially sensitive data such as sales figures. It may also be appropriate to exchange information regarding strategic direction, product development or marketing information. Where such exchange is advantageous it should be underpinned by signing an appropriate secrecy or confidentiality agreement.

3.3.7 Conflicts of Interest, Payments and Hospitality

All ICB staff must comply with the ICB Policy on Standards of Business Conduct and Declarations of Interest.

Clinical staff must also comply with their own professional codes of conduct.

Individuals employed as part of a collaborative project should be made aware that the post is supported by the pharmaceutical, medical appliance or health technology industry and of their obligation to act in a manner consistent with their own professional code of conduct independent of any influence by such a company.

Pharmaceutical companies are required to conduct themselves within the legal framework for the promotion of pharmaceutical products, the ethical code of the Association of British Pharmaceutical Industry (ABPI) and their internal regulations. This is irrespective of whether the company is a member of the ABPI. The Surgical Dressing Manufacturers Association (SDMA) has as members the majority of manufacturers of wound care products supplying the UK health care market and therefore largely represents this sector of the health care industry including some stoma appliance companies. Compliance with the SDMA Code of Practice is mandatory for members. The Association of British Health technology industry (APHI) member companies are required to comply with the legal framework for the promotion of health technology products, the ABHI, 2019. Code of Ethical Business Practice and the ABHI, 2021. [EU Medical Device Regulations \(MDR\) and local country medical device advertising guidelines](#). Although the EU MDR does not apply in the UK local restrictions apply and are detailed in this guidance.

Individuals involved in the development or consideration of proposals must declare any potential conflicts of interest they or their immediate family may have at the outset of the process.

3.3.8 Approval of Joint Working Arrangements

All joint working proforma should be submitted to NTAG for assessment. If NTAG recommend the scheme this will be submitted to the ICB Medicines Sub Committee or the Executive Committee as appropriate in line with the Scheme of Reservation and Delegation and Financial Limits. Once approved NTAG will maintain an overview of all projects.

Approval of joint working arrangements should be in line with ICB standing financial instructions and Standing Orders.

Approval of joint working arrangements must be confirmed by the pharmaceutical, medical appliance or health technology company's compliance panel/officer in conjunction with the ICB.

All ICB collaborations of any value involving ICB staff must be recorded on the ICB register of interests.

All proposals that may impact on prescribing either directly or indirectly must be referred to Medicines Sub Committee to ensure consistency with local and national prescribing guidance.

Where the main emphasis of collaboration is on education or training accountability lies with the relevant workstream group.

Where collaborations have a research element this must be consistent with the ICB's research governance policy and comply with the ICB research governance guidelines.

4. Implementation

This policy will be available to all staff for use in the circumstances described on the title page.

All managers are responsible for ensuring that relevant staff within the ICB have read and understood this document and are competent to carry out their duties in accordance with the procedures described.

5. Training Implications

The sponsoring director for this specific policy will ensure that the necessary training or education needs, and methods required to implement the policy or procedure(s) are identified and resourced or built into the delivery planning process. This may include identification of external training providers or development of an internal training process.

It has been determined that there are no specific training requirements associated with this policy/procedure.

6. Documentation

6.1 Other related policy documents

- Counter Fraud, Bribery and Corruption Policy
- Procurement Policy
- Standards of Business Conduct and Declarations of Interest Policy

6.2 Legislation and statutory requirements

- Contracts Regulations 2006 (as amended)
- Bribery Act 2010

6.3 Best practice recommendations

- Association of the British Pharmaceutical Industry, 2021. The Code of Practice for the Pharmaceutical Industry 2021.
<https://www.abpi.org.uk/publications/code-of-practice-for-the-pharmaceutical-industry-2021/>
- Department of Health/ Association of the British Pharmaceutical Industry, 2010. Moving beyond sponsorship: interactive toolkit for joint working between the NHS and the pharmaceutical industry.
<https://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/joint%20working%20toolkit%20dh.abpi.pdf>
- Surgical Dressing Manufacturers Association Code of Practice 2018, Association of British HealthTech Industries , 2019.Code of Ethical Business Practice
- Association of British HealthTech Industries, 2021. EU Medical Device Regulations (MDR) and local country medical device advertising guidelines.

7. Monitoring, Review and Archiving

7.1 Monitoring

The ICB Board will agree a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database.

7.2 Review

The ICB Board will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. No policy or procedure will remain operational for a period exceeding three years without a review taking place.

Staff who become aware of any change which may affect a policy should advise their line manager as soon as possible. The ICB Board will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

For ease of reference for reviewers or approval bodies, changes should be noted in the 'document history' table on the front page of this document.

NB: If the review consists of a change to an appendix or procedure document, approval may be given by the sponsor officer and a revised document may be issued. Review to the main body of the policy must always follow the original approval process.

7.3 Archiving

The ICB Board will ensure that archived copies of superseded policy documents are retained in accordance with Records Management: Code of Conduct for Health and Social Care.

Appendix 1

Duties and Responsibilities

ICB Board	The ICB Board has responsibility for setting the strategic context in which organisational process documents are developed, and for establishing a scheme of governance for the formal review and approval of such documents.
Accountable Officer (ICB Medical Director)	The accountable officer has overall responsibility for the strategic direction and operational management, including ensuring that ICB process documents comply with all legal, statutory, and good practice guidance requirements.
Executive Committee	Responsible for maintaining strategic oversight of all joint working arrangements with the industry and responsible for ratification of any joint working proposals.
All Staff	All staff, including temporary and agency staff, are responsible for: <ul style="list-style-type: none">• Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken.• Co-operating with the development and implementation of policies and procedures and as part of their normal duties and responsibilities.• Identifying the need for a change in policy or procedure as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly.• Identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager.• Attending training / awareness sessions when provided.

Appendix 2

Advice for ICB Commissioned Primary Care Providers regarding support provided by the Pharmaceutical, Medical Appliance or Health Technology Industry

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry 2021 ,the Surgical Dressings Manufacturers Association (SDMA) Code Of Practice 2018 and the Association of British HealthTech Industries (ABHI) Code of Ethical Business Practice 2019 allows for medical and educational goods and services (MEGS) to be provided by companies to healthcare organisations, such as GP surgeries and hospital departments, in order to enhance patient care and benefit the NHS. MEGS must not be provided to individuals or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

The ICB Medicines Optimisation team are frequently asked to advise on the possible benefits and risks of accepting offers of therapeutic review services from industry. The provision of such services is strictly regulated through the ABPI Code of Practice, SDMA Code of Practice and ABHI Code of Ethical Business Practice and the conditions under which companies can offer and provide these services is summarised below.

In addition to ensuring that the company and any sponsored healthcare professionals adhere to the ABPI Code of Practice, SDMA Code of Practice or ABHI Code of Ethical Business Practice as appropriate, primary care providers should also consider whether the service on offer will genuinely improve the care of their patients:

- Will the service in question help to address a clinical priority for the primary care provider or the ICB?
- What are the potential benefits and risks for patients and for the primary care provider? - (e.g. is it likely that prescribing costs, pathology costs, referrals or admissions will change? Will patients have better health outcomes, be better informed about their condition or be inconvenienced in any way?)
- Ensure any recommendations that relate to medicines, medical appliances or health technology are in line with the local formulary approvals.
- What are the insurance arrangements for the industry personnel delivering the service?
- Ensure results of any work including ownership and next steps are agreed and signed up between the primary care provider and the industry.
- Are arrangements for access to patient records consistent with other activities within the primary care provider organisation and other information governance arrangements?

We would strongly advise that primary care providers seek the advice of ICB Medicines Optimisation Pharmacists before agreeing to participate in therapeutic review services offered by third parties. A compact is attached to the bottom of this document for use when entering joint working with a company.

The ABPI Code of Practice, SDMA Code of Practice and the ABHI Code of Ethical Business Practice gives the following guidance to companies offering such services:

1. The involvement of a company in such activities must be made clear to relevant health professionals and/or primary care provider staff.
2. The involvement of a pharmaceutical, medical appliance or health technology company in therapy review services should also be made clear to patients, if materials for patients are provided in connection with the service. (e.g. it must be obvious on any information for patients on healthcare or medicines that the material is sponsored by a pharmaceutical, medical appliance or health technology company). If there are no materials for patients this would be a matter for the relevant professional.
3. Companies should consider using staff other than medical/generic representatives when offering MEGS as these goods and services must not be linked to the promotion of products. This means that representatives must not promote the company's products AND offer a service at the same visit, although they could indicate that a service is available and provide materials e.g., an introductory letter.
4. If a change in medication, medical appliance or device to one of the company's products is agreed at a promotional visit the representative may not then offer a therapy review service to facilitate the change as this would be seen as a way for the company to ensure that the agreed change would in fact be made.
5. If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then medical representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse or pharmacist, may undertake activities relating to patient contact and/or patient identification.
6. Neither the company nor its medical/generic representatives may be given access to data/records that could identify or be linked to particular patients.
7. Sponsored health professionals should not be involved in the promotion of specific products.
8. The remuneration of those not employed as medical representatives but who are sponsored or employed as service providers must not be linked to sales in any particular area or to sales of a specific product may not include a bonus scheme linked to such sales.
9. Companies must ensure that patient confidentiality is maintained at all times and that data protection legislation is complied with.
10. Service providers must operate to detailed written instructions provided by the company. The written instructions should set out the role of the service provider and should cover patient confidentiality issues.

11. Service providers must take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.
12. A recipient of a service must be provided with a written protocol to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring company must be given. (e.g. a GP allowing a sponsored registered nurse access to patient records should be informed in writing of any data to be extracted and the use to which those data will be put).
13. Any printed material designed for use in relation to the provision of services must be non promotional and must identify the sponsoring company.
14. Companies are recommended to inform relevant parties such as primary care organisations of their activities where appropriate. This is particularly recommended where companies are proposing to provide services which would have budgetary implications for the organisations concerned.
15. Switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another, without clinical assessment, are prohibited under the ABPI Code of Practice. Companies may promote a straightforward switch but may not help to implement it in any way.
16. A therapeutic review (as distinct from a switch service) which aims to ensure that patients receive optimal treatment following a clinical assessment is a legitimate activity for a pharmaceutical, medical appliance or health technology company to support and/or assist. A genuine therapeutic review should include a comprehensive range of relevant treatment choices for the health professional and should not be limited to the medicines or products of the sponsoring company. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

Compact between the Provider Primary Care Providers and the Pharmaceutical, Medical Appliance or Health Technology companies listed

Primary Care to the Pharmaceutical, Medical Appliance or Health Technology Company:

- We recognise and acknowledge that as businesses, a key aim for you is the generation of revenue and a return on investment
- We acknowledge that the pharmaceutical, medical appliance and health technology sector is a key stakeholder in the health economy. We recognise and acknowledge the important contribution the pharmaceutical, medical appliance and health technology industry has made to the health of the nation over decades, with regards to the development of new treatments, devices, diagnostics, medications, and innovations in patient care
- We seek to work with you for the good of our patients, in an open, honest, and transparent manner, acknowledging that at times we may have to step back from a piece of work for ethical and business reasons

- We will endeavour to create time for good quality clinical discussions around diagnostics, medications, devices and treatments as well as patient pathways, and value-based proposals in conjunction with colleagues as appropriate.

Pharmaceutical, Medical Appliance and Health Technology Companies to Primary Care:

- We recognise and acknowledge that you are driven by a desire to provide the best outcomes for your patients, and that such outcomes are driven by clinical as well as value-based considerations
- We acknowledge and respect that any decisions made regarding, appliances diagnostics, medications, devices, treatments or patient pathways must be taken by clinicians and colleagues in light of national and local guidelines and principles, and that we will only promote, medical appliances diagnostics, medications, devices, treatments or patient pathways that are in line with such guidelines and principles. We acknowledge our work should be focused on ICB priorities
- We recognise and acknowledge the importance of primary care's role in the delivery of excellent quality care for patients, and we will endeavour to support this work by being mindful and respectful of the limited time clinicians and managers have
- We seek to work with you for the good of your patients, in an open, honest, and transparent manner.

Primary Care providers in the ICB should consider adopting the following best practice guide when entering into discussions about joint working with pharmaceutical industry, medical appliance industry or health technology industry

Appendix 3

Framework for joint working between the NHS and pharmaceutical, medical appliance or health technology industry

Project title		
Name of industrial organisation(s) involved		
Project objectives	<i>Describe the questions or challenges the project seeks to address</i>	
Summary of evidence justifying project	<i>Summarise the evidence on the subject, which justifies the approach being proposed within this project</i>	
Industry contribution value and type	<i>Detail the contribution to this project from the industrial partner and the nature of this contribution. This should describe all costs including staffing, marketing, materials, consumables etc</i>	
ICB contribution value and type	<i>Detail the ICB resource that is required, including the type. This should also indicate whether a business case for any resource has been submitted/approved</i>	
Other contribution and type	<i>Detail the contribution from other sources, including NHS or private providers, voluntary sector etc</i>	
AHSN support	<i>Indicate whether this project has been supported by the AHSN, including name and contact details of the AHSN link if applicable</i>	
Start and end dates	<i>When is the project intended to start and end. Highlight any key milestones</i>	
Exit strategy	<i>What is the plan at the end of this project. What risks are involved in closing down the project – will there be legacy costs or will the project have raised patient expectation? What will be done to mitigate this?</i>	
Key personnel	<i>Who are the key personnel involved in this project. Please indicate what previous experience those individuals have of working with industry in general, and this industrial organisation in particular</i>	
Declaration	<i>Both signatories below are accepting that all key personnel have been made aware of their duty to conform to the policy on standards of business conduct and have declared any interests appropriately</i>	
Name and email address of ICB lead applicant	Role	Date
Name and email address of ICB sponsoring director	Role	Date

Appendix 4

Equality Impact Assessment

As a public body organisation we need to ensure that all our current and proposed strategies, policies, services and functions, have given proper consideration to equality, diversity and inclusion, do not aid barriers to access or generate discrimination against any protected groups under the Equality Act 2010 (Age, Disability, Gender Reassignment, Pregnancy and Maternity, Race, Religion/Belief, Sex, Sexual Orientation, Marriage and Civil Partnership).

This screening determines relevance for all new and revised strategies, policies, projects, service reviews and functions.

Completed at the earliest opportunity it will help to determine:

- The relevance of proposals and decisions to equality, diversity, cohesion and integration.
- Whether or not equality and diversity is being/has already been considered for due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED).
- Whether or not it is necessary to carry out a full Equality Impact Assessment.

Name(s) and role(s) of person completing this assessment:

Name: Ewan Maule

Job Title: Director of Medicine and Pharmacy

Organisation: NENC ICB

Title of the service/project or policy: Commercial sponsorship and joint working with the pharmaceutical industry Policy

Is this a;

Strategy / Policy

Service Review

Project

Other [Click here to enter text.](#)

What are the aim(s) and objectives of the service, project or policy:

This policy is intended for the Integrated Care Board (hereafter refer to as the ICB) and its staff who are involved in working with industry. It is intended to complement the ICB Policy on Standards of Business Conduct and Conflicts of Interest. It should also act as a guide for commissioning support staff who are responsible for working alongside the ICB in delivering effective partnering and conduct with the pharmaceutical industry.

Who will the project/service /policy / decision impact?

(Consider the actual and potential impact)

- **Staff**

- **Service User / Patients**
- **Other Public Sector Organisations**
- **Voluntary / Community groups / Trade Unions**
- **Others, please specify** Pharmaceutical industry

Questions	Yes	No
Could there be an existing or potential negative impact on any of the protected characteristic groups?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Has there been or likely to be any staff/patient/public concerns?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Could this piece of work affect how our services, commissioning or procurement activities are organised, provided, located and by whom?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Could this piece of work affect the workforce or employment practices?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does the piece of work involve or have a negative impact on: <ul style="list-style-type: none"> • Eliminating unlawful discrimination, victimisation and harassment • Advancing quality of opportunity • Fostering good relations between protected and non-protected groups in either the workforce or community 	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If you have answered no to the above and conclude that there will not be a detrimental impact on any equality group caused by the proposed policy/project/service change, please state how you have reached that conclusion below:

This policy sets out standards for how the ICB and its staff work with industry. The principles apply across the breadth of work the ICB does and is designed to eliminate or reduce the risks of a conflict of interest. This is a long standing and established policy and as well as their being no apparent equality risk, none have been identified with predecessor policies.

If you have answered yes to any of the above, please now complete the ‘STEP 2 Equality Impact Assessment’ document

Accessible Information Standard	Yes	No
Please acknowledge you have considered the requirements of the Accessible Information Standard when communicating with staff and patients. https://www.england.nhs.uk/wp-content/uploads/2017/10/accessible-info-standard-overview-2017-18.pdf	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Governance, ownership and approval

Please state here who has approved the actions and outcomes of the screening		
Name	Job title	Date
Executive Committee	Approval	April 2023

Publishing

This screening document will act as evidence that due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED) has been given.