North East and North Cumbria

Corporate	ICBP006 Commercial sponsorship and joint working with the pharmaceutical industry Policy

Version Number	Date Issued	Review Date
1	July 2022	January 2022

Prepared By:	Clinical Services Manager, NECS
Consultation Process:	Integrated Governance Workstream Medicines Optimisation Team
Formally Approved:	July 2022
Approved By:	Executive Committee

EQUALITY IMPACT ASSESSMENT

Date	Issues
June 2022	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

Approval

Role	Name	Date
Approver	ICB Board	July 2022

Contents

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 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.

While the ICB recognises that GP practices are providers in their own right the ICB would encourage practices to adopt this policy.

In the past, contacts between the pharmaceutical 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, the 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.

DH Guidance encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical industry, 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 is 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 primary care 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 industry. Many parts of the healthcare system already undertake collaborative work with drug 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 practices may lead to larger, longer term collaborations that meet the needs of all parties including pharmaceutical industry.

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 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 ABPI Code of Practice.

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 industry
- ensure that the ICB and its staff respond consistently to approaches from the pharmaceutical industry and that the interests of patients, the public and the ICB are maintained
- ensure staff comply with ICB commercial sponsorship 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*
- inform and advise staff of their main responsibilities when entering into joint working arrangements with the pharmaceutical industry. 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 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 ICB Boards, Committees/sub-committees and boards including North of England Commissioning Support staff.

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.

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, 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 are 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

Staff should refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgment or integrity, or to seek to exert influence to obtain preferential consideration. All such gifts should be returned and hospitality refused. Companies may supply inexpensive notebooks, pens and pencils at meetings.

Modest hospitality, provided it is reasonable and not excessive, like lunches in the course of working visits, may be accepted. This hospitality should be similar in scale to that which the ICB would be likely to offer.

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 industry frequently request meetings to discuss pharmaceutical products and services. If a topic is of interest, staff should ask for information to be sent to them. 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 see representatives on behalf of the ICB as necessary.

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

- Staff should have a clear agenda from a pharmaceutical 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 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.
- 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 medicines optimisation team.

- A record of the visit should be made.
- This policy supports the facilitation of joint meetings between the ICB, Primary Care and pharmaceutical 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 GP practices in conjunction with the priorities of the ICB.
- Any behaviour by pharmaceutical industry personnel felt to be inappropriate should be reported to the 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 to the Association of British Pharmaceutical Industries (ABPI).
- Should staff feel uncomfortable or compromised in any way they should end the meeting immediately and report,

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 company or other agency which may affect (or be considered to affect the ICB's policies or decisions. Examples may include:

- Holding shares in a pharmaceutical 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 a line manager, before taking on any outside work for the pharmaceutical 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 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 .

Any information shared with the industry must be compliant with ICB Information Governance policies.

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 appropriate research and ethics committee and follow ICB research and development guidelines.

3.2 Sponsorship

3.2.1 Conferences and Courses Attended By Staff

Staff must seek approval in advance from their line manager 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.

3.2.1 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 should be approached in order 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, all guidance complies with current evidence base and NHS and local guidance and the training could not be construed as an incentive to prescribe a particular pharmaceutical 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 operatingg 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.

3.2.2 Development of Guidelines

ABPI guidance states that it is legitimate for a pharmaceutical 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 guidelines development process.

Where representatives from the pharmaceutical 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.
- 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 pharmaceutical companies with interests in a given therapeutic area.
- All suggested comments and amendments by the pharmaceutical 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 industry 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 into 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 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 industry 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 into any joint working. The aims that the pharmaceutical 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 of one product may be viewed as a financial incentive to prescribe 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-pharmaceutical 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. This is available at:

https://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/joint%20working%20toolkit%20dh.abpi.pdf/vie w

The following sections are based on the toolkit. 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 2)

All projects should be managed by a named, nominated ICB representative and/ or steering group with clear terms of reference. 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 on the basis of 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 authorized by an appropriate ICB representative (preferably the accountable officer) for all joint working agreements agreement. 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 ICB.

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.

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 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.

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 pharmaceutical 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 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 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 to 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 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.

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 the ICB Medicines Optimisation Group which 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 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 must be referred to the relevant prescribing group 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

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

4.2 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

5.1 The sponsoring director 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.

5.2 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, 2015. *The Code of Practice for the Pharmaceutical Industry 2015.* http://www.abpi.org.uk/our-work/library/guidelines/Pages/060115.aspx

Association of the British Pharmaceutical Industry 2009, *ABPI Guidance Notes on Joint Working Between Pharmaceutical Companies and the NHS and Others for the Benefit of Patients.*
Department of Health, 1998. *The new NHS, modern and dependable: a national framework for assessing performance.*
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolic yAndGuidance/DH_4002713
Department of Health, 2000. *Commercial sponsorship: Ethical standards for the NHS.*
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicy AndGuidance/DH_4005135
Department of Health, 2008. *Best practice guidance for joint working between the NHS and the pharmaceutical industry.*
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicy AndGuidance/DH_082370
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.*
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicy AndGuidan ce/DH_082840

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

8.2.1 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.

8.2.2 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

8.2.3 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.

8.3 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 2021.

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	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 Group	Responsible for maintaining strategic oversight of all joint working arrangements with the pharmaceutical industry and responsible for ratification of any joint working proposals. The Executive Committee would recommend any pooling of budgets to either the Finance, Performance and Investment Committee or the ICB Board.
All Staff	All staff, including temporary and agency staff, are responsible for: • 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 Contractors regarding support provided by the Pharmaceutical Industry

GP practices in the ICB should consider adopting the following best practice guide when entering into discussions about joint working with Pharmaceutical Industry. The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry (July 2012) allows for medical and educational goods and services (MEGS) to be provided by pharmaceutical 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 Medicines Optimisation team are frequently asked to advise on the possible benefits and risks of accepting offers of therapeutic review services from the industry. The provision of such services is strictly regulated through the ABPI Code of 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, GP practices should also consider whether the service on offer will genuinely improve the care of patients of the practice:

- Will the service in question help to address a clinical priority for the practice or the ICB?
- What are the potential benefits and risks for patients and for the practice? - (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 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 practice and the pharmaceutical industry.
- Are arrangements for access to patient records consistent with other activities within the practice and other information governance arrangements?

We would strongly advise that practices 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 into joint working with a company.

The ABPI Code of Practice gives the following guidance to companies offering

such services:

1. The involvement of a pharmaceutical company in such activities must be made clear to relevant health professionals and/or practice staff.
2. The involvement of a pharmaceutical 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 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 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 confidentialityissues.
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 pharmaceutical 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 pharmaceutical

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 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 of the sponsoring pharmaceutical 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 Practices and the Pharmaceutical companies listed

Primary Care to the Pharmaceutical Companies:

- 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 sector is a key stakeholder in the health economy. We recognise and acknowledge the important contribution the pharmaceutical industry has made to the health of the nation over decades, with regards to the development of new treatments and 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 medications and treatments as well as patient pathways, and value based proposals in conjunction with colleagues as appropriate

Pharmaceutical 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 medications, 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 medications, treatments or patient pathway 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

Appendix 3

Framework for joint working between the NHS and pharmaceutical industry

I.	JOINT WORKING PROJECT SUMMARY	
1.	TITLE OF PROJECT	
2.	SUMMARY OF INTENDED AIMS & OBJECTIVES	*Describe the overall aim of the project.* *List the key objectives in a SMART format*
3.	SUMMARY OF EXPECTED OUTCOMES AND SUCCESS CRITERIA	*Describe the expected and desired outcome for each objective, and the measures to be used to assess by which success will be measured. Include how you will measure whether the project has been a success overall and the success of joint working.*
4	CONTEXT, BACKGROUND AND SUPPORTING EVIDENCE	*Include national policy context (e.g. NICE guidance, NSFs, national targets/standards, White Paper(s), national reports) description of local situation using local data, for example ICB performance indicators for the relevant clinical area such as admission rates, death rates. Refer to relevant local policies.* *Insert any clinical trial, pharmacoeconomic data or other supporting evidence.*
5	STAKEHOLDER OPINION AND SUPPORT	*Include current knowledge of stakeholder opinion and support (e.g. local expert opinion, NHS independent reviews) and plans to generate further support.* *Include opinions from relevant local patient groups, and any assessments of patient views in this area*.
6..	NAMES OF THE PARTNER ORGANISATIONS INVOLVED IN THE JOINT WORKING ARRANGEMENT	
7.	NAMES OF LEAD REPRESENTATIVES FOR EACH ORGANISATION	*Names of lead contacts for each organisation involved*
8.	DECLARATIONS OF INTEREST FOR LEAD REPRESENTETIVES	
9.	EXACT NATURE OF THE JOINT WORKING PROPOSAL	*Brief description of the project, the project outline and plan, what each party will contribute to the project and how resources will be used.*

10. INITIAL RISK ASSESSMENT	*Provide an assessment of the risks and benefits of the project. Include:* *Organisational benefits and risks* *Clinical benefits and risks* *Financial benefits and risks*
11. START DATE	
12. FINISH DATE	
13. EXIT STRATEGY	*Describe the steps that will be taken upon completion of the joint working arrangement. Also the steps to be taken should any party wish to terminate the arrangement before the planned finish date.*
II. RESOURCES AND COSTS	
1. OVERALL COST OF THE JOINT WORKING PROJECT	*Include financial costs for all parties*
2. DIRECT AND INDIRECT RESOURCES / COST COMMITMENTS BY EACH PARTNER	*Indicate resources required by each party to undertake the project and where these will come from and where these will come from. Outline which NHS/company budget(s) might be appropriate source of funding and how funding will be managed Resources include* *Staffing (including project management)* *Equipment* *Expertise* *Finance* *IT*
3 SERVICE IMPACT	*Describe the impact the project will have on other services Include :* *Staff workload* *Equipment and resources* *Prescribing budget* *Primary care* *Secondary care*
4. METHOD FOR MONITORING AND RECORDING RESOURCE AND COSTS	*Describe how the funding will be managed. Who will have authority to make decisions regarding funding.* *How will funding be accessed?*

5. INFORMATION ON COST EFFECTIVENESS (Has value for money been shown?)	*Describe how will value for money / cost effectiveness be measured and demonstrated*
6. ARRANGEMENTS FOR LONGER TERM FUNDING IMPLICATIONS OF PROJECT (To be clear and unambiguous)	
III. GOVERNANCE ARRANGEMENTS	
1. PARTIES CONSULTED PRIOR TO INITIATING JOINT WORKING PROJECT AND HOW CONSULTATION W AS CONDUCTED	
2. METHOD FOR INFORMING PATIENTS OF THE JOINT WORKING PROJECT	
3. DECISION MAKING PROCESSES W ITHIN THE JOINT WORKING PROJECT (To be open and transparent)	*Describe how decisions will be made* *Who will have authority to make decisions regarding allocation of resources.* *How will they be reported within the organisations*
4. OPERATIONAL AND MANAGEMENT ACCOUNTABILITIES (Include identified conflicts of interest)	*Describe how the project will be managed* *Give details of potential steering group members* *Outline their roles, responsibility and accountability* *Outline any potential conflicts of interest for any parties or individuals involved with the project and how these will be managed*
5. MANAGEMENT OF RISKS	*Describe how the risks identified in section I will be managed / addressed to minimise their impact*
6. PILOTING ARRANGEMENTS (State if this project is a pilot)	
7. RELATIONSHIP TO EXISTING SYSTEMS OF CARE IN PRIMARY AND SECONDARY CARE SECTORS	
8. FOR CLINICAL SERVICES, PROFESSIONAL INDEMNITY AND LIABILITY ARRANGEMENTS	
9. WRITTEN AGREEMENT STATING OBLIGATIONS OF CONFIDENTIALITY, SECURITY STANDARDS AND LIMITS OF USE OF INFORMATION TO THE PURPOSES SPECIFIED	

IV. MONITORING AND EVALUATION	
1. MANAGEMENT ARRANGEMENTS	*Describe the arrangement for monitoring and evaluating the project against the outcome criteria outlined in section I.*
2. LIST DESIGNATED RESPONSIBILITY AT EACH STAGE OF THE PROPOSAL	*List the roles and responsibilities for delivery of the project at each of the following stages* *Development* *Approval* *Implementation* *Monitoring & Evaluation*
3. METHOD OF EVALUATING PATIENT BENEFITS ON COMPLETION	*Describe how the project impact on patients will be measured*
4. LEARNING OPPORTUNITIES FROM THIS PROJECT	
5. EVALUATION AND AUDIT ARRANGEMENTS	*Describe evaluation and audit methods: what quantitative data will be used, (e.g. ePACT data, hospital prescribing data, admission rates, death rates); what qualitative measures will be used (if any)*.
6. METHOD FOR HIGHLIGHTING SIGNIFICANT PROBLEMS	*Describe how any significant problems during the course of the project will be addressed.*
V. DATA AND PATIENT PROTECTION	
1. LIST INTERESTS OF PARTNERS IN RELATION TO THE JOINT W ORKING PROPOSAL, AND WHERE THESE COINCIDE	
2. IDENTIFY "OWNERSHIP" OF THE DATA GENERATED BY THE PROJECT	
3. DESCRIBE ACCESS ARRANGEMENTS FOR THE DATA, AND FORMAT (Bearing in mind the requirements of the Data Protection Act and patient confidentiality of healthcare records)	
4. WHAT WILL THE DATA BE USED FOR?	

Appendix 4

Notification of Receipt of Hospitality, Gifts or Sponsorship

Template: Gifts, Hospitality and Sponsorship Form

Recipient Name	Position	Date of Offer	Date of Receipt (if applicable)	Details of Gift / Hospitality	Estimated Value	Supplier / Offer Name and Nature of Business	Details of Previous Offers or Acceptance by this Offeror/ Supplier	Details of the officer reviewing and approving the declaration made and date	Declined or Accepted?	Reason for Accepting or Declining	Other Comment

The information submitted will be held by the ICB for personnel or other reasons specified on this form and to comply with the organisation's policies. This information may be held in both manual and electronic form in accordance with the Data Protection Act 1998. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and published in registers that the ICB holds.

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

I **do / do not (delete as applicable)** give my consent for this information to published on registers that the ICB holds. If consent is NOT given, please give reasons:

Signed: **Date:**

Signed: **Position:** **Date: (Line Manager or a Senior ICB Manager)**

Please return to **<insert name/contact details for team or individual in CCG nominated to provide advice, support, and guidance on how conflicts of interest should be managed, and administer associated administrative processes>**

Equality Impact Assessment
Initial Screening Assessment (STEP 1)

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: Interim ICS Lead Pharmacist
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 the pharmaceutical 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?	☐	☒
Has there been or likely to be any staff/patient/public concerns?	☐	☒
Could this piece of work affect how our services, commissioning or procurement activities are organised, provided, located and by whom?	☐	☒
Could this piece of work affect the workforce or employment practices?	☐	☒
Does the piece of work involve or have a negative impact on: • 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	☐	☒

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 the pharmaceutical 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	☒	☐
Please provide the following caveat at the start of any written documentation: **"If you require this document in an alternative format such as easy read, large text, braille or an alternative language please contact (ENTER CONTACT DETAILS HERE)"**		
If any of the above have not been implemented, please state the reason:		

Click here to enter text.

Governance, ownership and approval

Please state here who has approved the actions and outcomes of the screening		
Name	**Job title**	**Date**
Click here to enter text.	Click here to enter text.	Click here to enter text.

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.

If you are not completing 'STEP 2 - Equality Impact Assessment' this screening document will need to be approved and published alongside your documentation.

Please send a copy of this screening documentation to:
NECSU.Equality@nhs.net for audit purposes.