

# **Pharmaceutical and Related Industries Joint Working Policy**

### Review and Amendment Log / Version Control Sheet

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<b>Date Approved:</b>	25 <sup>th</sup> November 2020
<b>Committee:</b>	Governing Body
<b>Version:</b>	4.0
<b>Review Date:</b>	November 2023

#### Version History

Version no.	Date	Author	Description	Circulation
1.0	February 2016	Sally Bower	Initial draft approved by Senior Management team, NHS Leeds West CCG	Senior Management Team Patient leaders
2.0	March 2018	Sally Bower	Amended NHS Leeds West CCG to Leeds CCG Partnership	Senior Management Team Patient leaders
3.0	April 2019	Kim Mooring	Annual update completed	Senior Management Team Patient leaders
4.0	October 2020	Sally Bower	Revision of previous versions following updated ABPI Code 2019,(particularly clause 20) and associated guidance	Clinical Directors Head of Corporate Governance and Risk Patient leaders

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## 1 Introduction

Department of Health Guidance encourages NHS organisations and their staff to consider opportunities for joint working with the pharmaceutical industry, where there are clear advantages to patient care and improvements to patients' health and well-being.

In the past, contact between the Pharmaceutical Industry and primary health care professionals has 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. Many companies have developed internal structures to encourage closer liaison with GP practices, CCGs and health care professionals working for CCGs.

The NHS does not always have the expertise or necessary tools to aid implementation of innovation or best practice at the pace or scale that it desires. Pharmaceutical and other health care companies may wish to partner with the CCG to support this adoption of innovation. The 'Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS' report sets out a strategy for collaboration between the NHS and industry to improve health outcomes for patients.

It is essential that all projects or dealings with the Industry are open and transparent and are subject to the widest scrutiny to enable likely pitfalls to be highlighted at an early stage.

## 2 Purpose

The aim of this policy is to:

- Provide all staff working for or on behalf of NHS Leeds CCG with a framework and guidance for appropriate joint working
- Ensure at all times that the interests of patients, public and NHS Leeds CCG are upheld and maintained
- Assist NHS Leeds CCG to achieve its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical and related industries
- Inform and advise staff of their responsibilities when entering into joint working arrangements with the pharmaceutical and related industries. Specifically, it aims to:
  - ◆ Assist NHS Leeds CCG and its 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.

Staff are always reminded that they have a responsibility to comply with their own professional codes of conduct and CCG's standards of business conduct policy. In the interests of transparency staff must comply with CCG's Hospitality, gifts and sponsorship policy and Declarations of interest's policy.

Representatives of the pharmaceutical industry must comply with the ABPI Code of Practice for the Pharmaceutical Industry as a condition of their membership. Pharmaceutical companies must publicly disclose all 'Transfers of Value' to health care professionals and health care organisations on an annual basis for the preceding year. Non-member pharmaceutical industries who promote prescription medicines are also encouraged by the ABPI and MHRA. If staff believe that a pharmaceutical industry representative has broken the Code, they can report their complaint to the Director of the Prescription Medicines Code of Practice Authority (PMCPA) at [complaints@pmcpa.org.uk](mailto:complaints@pmcpa.org.uk)

Further details on the ABPI Code including a guide for health professionals, is available at <https://www.pmcpa.org.uk/the-code>

### 3 Definition of Joint Working

For the purpose of this policy, joint working is defined as situations where, for the benefit of patients, the NHS and commercial organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.

### 4. Values

In line with the NHS Code of Conduct three public service values underpin the work of the NHS:

**Accountability** – everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgements of propriety and professional codes of conduct;

**Probity** – there should be an absolute standard of honesty in dealing with the assets of the NHS. Integrity should be the hallmark of all personal conduct in decisions affecting patients, staff and suppliers, and in the use of information acquired in the course of NHS duties. This includes ensuring that integrity is not only ensured in all decision making processes, but that it is also clearly perceivable from the point of view of a stakeholder or third party, and

**Openness** – there should be sufficient transparency about NHS activities to promote confidence between the organisation and its staff, patients and the public

## 5 Principles for Joint Working Arrangements

Joint working arrangements should be of mutual benefit, with 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 arrangement.

The following principles also apply:

- Staff must be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct in relation to joint working initiatives.
- Contracts 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.
- Whilst joint working arrangements should take place at a corporate, rather than an individual level the role (or lack thereof) of sales representatives must be agreed during scoping and them and appropriate NHS staff made aware.
- Clinical and financial outcomes will be assessed through a process of risk assessment.
- Each company that enters into a joint venture with NHS Leeds CCG will be acknowledged for resources provided. NHS Leeds CCG will only endorse a particular medicine as a result of the joint venture in line with national or local guidance provided that all parties are agreed that the activity is ethical and in patients' best interest and the marketing authorisation of the medicine involved.
- NHS Leeds CCG or its staff will not agree to practice under any condition that compromises professional independence or judgement, or imposes such conditions on other health care professionals.
- 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 such collaborations are being considered then the proposal must be presented at a Governing Body meeting for approval before any formal agreement is made. Legal advice may also be necessary.
- NHS Leeds CCG will retain control of all projects whilst accommodating joint working partners' involvement and their regulatory obligations.

## **6 Minimum Data Set Required for Project Approval**

Each joint working arrangement will be supported by a project initiation document setting out the following:

- The vision, objectives and outcomes of the project
- The benefits to the patient of the proposed joint working initiative
- The benefits to NHS Leeds CCG
- The benefits for the pharmaceutical company
- Deliverables and key success factors
- The resources the pharmaceutical company will provide
  
- The resources that NHS Leeds CCG will provide
- Timelines and milestones
- Accountabilities, roles and responsibilities
- Governance and Project Management arrangements
- Any issues identified in relation to information governance and/or information sharing including the need for transparency, (executive summary published before implementation, disclosure of pharmaceutical company involvement in all documentation and communication, public disclosure of the pharmaceutical company resource as a Transfer of Value to NHS Leeds CCG.
- Any issues identified in relation to public sector procurement duties
- Arrangements for monitoring and evaluation
- An exit strategy

## **7 Confidential and Patient Identifiable Data**

The project should be assessed at an early stage to determine if access to sensitive data such as confidential or patient identifiable information is proposed as part of the project.

The Senior Information Risk Owner should be approached for advice where the project may require access to confidential or sensitive CCG information.

The CCG Caldicott Guardian should be approached for advice where the proposal may require access to patient identifiable information.

## **8 Freedom of Information**

NHS Leeds CCG supports the principles of transparency enshrined in the Freedom of Information Act. Arrangements made between the CCG and the Pharmaceutical and related industries will be made available in line with Freedom of Information legislation.

## **9 Duties / Accountabilities and Responsibilities**

Duties within organisation

The CCG's lead project manager will be responsible for developing the project proposal and getting advice from the CCG's Head of Medicines Optimisation, Commissioning team, Senior Information Risk Owner, Caldicott Guardian, Head of Contracting and Communication and Engagement team on the appropriateness of the proposed project.

The CCG's Head of Medicines Optimisation, Commissioning team will be responsible for providing advice on whether the joint working initiative meets best practice guidelines. A check of all joint working proposals will also be made to ensure that the proposed initiatives do not conflict with existing CCG prescribing policies and guidelines.

The Senior Information Risk Owner will be responsible for ensuring that any proposed information sharing as part of a joint working agreements is in line with the CCG's legal duties.

The CCG Caldicott Guardian is responsible for assessing if any proposed access to patient identifiable data meets the Caldicott principles.

The CCG's Head of Contracting is responsible for advising if there are any implications from the CCG's public sector procurement duties.

The CCG's Head of Communication and Engagement is responsible for including in the engagement plan outlining information in section 6 and ensuring that risks identified are managed.

## **10 Responsibilities for approval**

Proposals for joint working will be reviewed by the CCG Quality team to consider the quality aspects of the proposal and Finance team to consider financial, procurement and links to CCG priorities.

Recommendations from the Quality and Finance teams will be taken to a public Governing Body Meeting for formal approval of the joint working proposal.

The pharmaceutical company is required to review and formally approve the final version of the project initiation document and executive summary of the joint working agreement before implementation.

## **11 Public Sector Equality Duty**

NHS Leeds CCG aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others.

## **12 Scope of the Policy**

This policy applies to NHS Leeds CCG including all employees, co-opted members and members of the Governing Body and its committees, who must comply with the arrangements outlined in this policy.

## **13 Monitoring Compliance with the Document**

The NHS Leeds CCG Audit Committee will monitor compliance with the policy.

## **14 Arrangements for Review**

This policy will be reviewed three years after the date of authorisation. The policy may be reviewed sooner if there is a change in legislation or new national guidance.

## **15 Dissemination**

This policy will be shared with all members of the Executive Management Team, Clinical Directors and Governing Body. It will be published on both the CCG intranet and internet sites.

## 16 References

The following policies were used as the basis of this policy

1. Department of Health, February 2008. Best practice guidance for joint working between the NHS and the pharmaceutical industry.
2. Standards of business conduct for NHS Staff HSG (93).
3. ABPI, 2006. Best practice guidance for joint working between the NHS and the pharmaceutical industry. Department of Health, 2004. Code of Practice for the Pharmaceutical Industry. ABPI, 2019. Code of Conduct: Code of Accountability in the NHS. 2019 ABPI, 2009. Guidance Notes on Joint Working between pharmaceutical companies and the NHS and others for the benefit of patients.
4. Leeds CCG Standards of business conduct policy, Hospitality, gifts and sponsorship policy and Declaration of interest's policy.
5. Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS. Department of Health. 2011.

## 17. Appendices

1. **Equality Impact Assessment Tool**
2. **Criteria for joint working**

## Appendix 1

### Equality Impact Assessment Tool

#### Pharmaceutical and Related Industries Joint Working Policy

1.	<b>Does the policy/guidance affect one group less or more favorably than another on the basis of:</b>	Yes/No	Comments
	Race	No	
	Ethnic origins (including gypsies and travellers)	No	
	Nationality	No	
	Gender	No	
	Culture	No	
	Religion or belief	No	
	Sexual orientation including lesbian, gay and bisexual people	No	
	Age	No	
	Disability  Learning disabilities, physical disability, sensory impairment	No	
2.	<b>Is there any evidence that some groups are affected differently?</b>	No	
3.	<b>If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?</b>	No	
4.	<b>Is the impact of the policy/guidance likely to be negative?</b>	No	No impact has been identified from the proposed policy. An Equality Impact Assessment will need to be carried out on proposed schemes to be considered under this policy.
5.	<b>If so, can the impact be avoided?</b>		
6.	<b>What alternatives are there to achieving the policy/guidance without the impact?</b>		

7.	<b>Can we reduce the impact by taking different action?</b>		
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If you have identified a potential discriminatory impact of this procedural document, please refer it to, together with any suggestions as to the action required to avoid/ reduce this impact.

## Appendix 2

### Joint Working Criteria

(adapted from the Association of British Pharmaceutical Industry Joint Working Guide)

All potential parties should review this checklist and satisfy themselves that each criterion would be met under the project.

If the answer to any of the questions below is **no**, the project is not a true joint working arrangement and should not be viewed as such. Appropriate steps to address the outstanding areas should be taken before proceeding further.

	YES	NO
1 The main benefit of the project is focused on the patient	<input type="checkbox"/>	<input type="checkbox"/>
2 All parties acknowledge the arrangements may also benefit the NHS and pharmaceutical partners involved	<input type="checkbox"/>	<input type="checkbox"/>
3 Any subsequent benefits are at an organisational level and not specific to any individual	<input type="checkbox"/>	<input type="checkbox"/>
4 There is a significant contribution of pooled resources (taking into account people, finance, equipment, & time) from each of the parties involved	<input type="checkbox"/>	<input type="checkbox"/>
5 There is a shared commitment to joint development, implementation, and successful delivery of a patient centred project by all parties involved	<input type="checkbox"/>	<input type="checkbox"/>
1. Patient outcomes of the project will be measured and documented	<input type="checkbox"/>	<input type="checkbox"/>
7 All partners are committed to publishing an executive summary of the Joint Working Agreement	<input type="checkbox"/>	<input type="checkbox"/>
8 All proposed treatments involved are in line national guidance where it exists and based on evidence based clinical practice	<input type="checkbox"/>	<input type="checkbox"/>
9 All activities are to be conducted in an open and transparent manner	<input type="checkbox"/>	<input type="checkbox"/>
10 Exit strategy and any contingency arrangements have been agreed	<input type="checkbox"/>	<input type="checkbox"/>
11 Are you satisfied with your knowledge of the collaborating organisation i.e. is there evidence of audited accounts, is the organisation and ownership known?	<input type="checkbox"/>	<input type="checkbox"/>

12 Is the proposal on offer consistent with NHS Leeds CCG partnership priorities?	<input type="checkbox"/>	<input type="checkbox"/>
13. All parties have followed Caldecott and Data Protection principles.	<input type="checkbox"/>	<input type="checkbox"/>