NHS
Wigan Borough
Clinical Commissioning Group

Working with the Pharmaceutical Industry Policy

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Contents

1. Introduction

1.1. The Department of Health (DH) and the Association for British Pharmaceutical Industry (ABPI) seek to encourage collaborative working for the benefit of the local healthcare economy and ultimately the patient.

1.2. Pharmaceutical companies that are members of the ABPI are required to comply with the ABPI Code of Practice for the Pharmaceutical Industry 2015, which regulates the promotion of prescription medicines and certain other non-promotional activities.

1.3. The ABPI guidance seeks to provide a framework and greater clarity for pharmaceutical companies about various aspects of Joint Working and Sponsorship.

2. Purpose

2.1. This policy applies to Wigan Borough Clinical Commissioning Group (WBCCG) staff, employees, members and associates when any arrangements are being considered or implemented to engage, collaborate, work jointly or be sponsored by any company outside of the NHS with particular reference to the pharmaceutical industry.

2.2. This policy aims to promote appropriate working relationships between the pharmaceutical industry and the NHS and should be used in conjunction with the DH/ABPI document "Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry"[1].

2.3. This Policy should be read in conjunction with WBCCG's Standing Orders (SOs) and Standing Financial Instructions (SFIs), which will take precedence over this or any other guidance. Failure to comply with SOs and SFIs may be regarded as a disciplinary matter.

3. Definitions

3.1. Joint Working is defined in the DH Joint Working Guidance and Joint Working Toolkit as:
Situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

3.2. The key requirements from this definition are:

- the Joint Working project must be focused on benefits to patients; **and**
- there must be a "pooling" of resources between the pharmaceutical company or companies and the NHS organisation(s) involved. Each party must, therefore, make a significant contribution to the Joint Working project to avoid the arrangement being construed as merely a gift, benefit in kind, donation or some other non-promotional/commercial practice. Resources may come in various forms, including people, expertise, equipment, communication channels, information technology and finance.

[1] Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI), Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840

3.3. Joint working differs from sponsorship. Sponsorship is where pharmaceutical companies simply provide funds for a specific event or work programme. For the purpose of this guidance, sponsorship is defined as funding to the NHS from an external source for any expenditure item including the following:

- The salary or costs of staff
- Costs of NHS research
- Training
- Non pay items such as equipment
- Costs associated with meetings
- Gifts
- Hospitality including the provision of meals
- Hotel and transport costs (including trips abroad)
- Provision of free services (speakers)
- Provision of free or discounted products of any description
- Provision of free stationery bearing commercial advertising.

4. Principles

4.1. The following principles will apply to Joint Working and/or Sponsorship:

- All Joint Working and Sponsorship must be for the benefit of patients
- All Joint Working and Sponsorship will support projects that address local and national priorities, and will maintain the freedom of Clinicians to prescribe the most clinically appropriate and effective treatment for individual patients
- Joint Working and Sponsorship will be conducted in an ethical, open and transparent manner
- Joint Working will take place at a corporate (organisational) level, and not with individual healthcare professionals or NHS administrative staff
- Joint Working contracts will be negotiated on fair and reasonable terms, in line with NHS values
- Confidentiality of information received in the course of the Joint Working arrangement will be respected and never used outside the scope of the project. All patient identifiers will be removed from data to preserve and respect patient confidentiality in line with the Data Protection Act 1998
- In the interests of transparency, the overall arrangements for Joint Working and Sponsorship must be made public
- Joint working and Sponsorship is based on mutual trust and respect. Pharmaceutical companies must comply with the ABPI Code at all times. All NHS employed staff should comply with NHS, WBCCG and relevant professional body codes of conduct at all times
- Clinical and prescribing policies or guidelines must be based upon principles of evidence-based medicine and cost effectiveness. They will be consistent with national recommendations including the National Institute for Health and Clinical Excellence (NICE), expert bodies such as the Royal College of General Practitioners (RCGP) and local guidance including all GMMMG guidance, pathways etc.
- The Nolan Principles embedded within the constitution of WBCCG must always be followed
- There should be good governance through the Clinical Governance and Audit Committees
- The Pharmaceutical Industry should not have undue influence
- Sponsorship must not provide any financial or personal benefit.

5. Inducement to treatment

5.1. Any Joint Working/Sponsorship must ensure that all arrangements are neutral, free from preference regarding the use of the company's product over other more clinically appropriate or cost effective products or services. In addition, arrangements must be in keeping with local guidelines and formularies.

5.2. Wigan Borough CCG will act in a transparent, objective manner, never endorsing any individual company or product through such agreements.

6. Joint Working

6.1. Where Joint Working is being contemplated full consideration of the proposal must be given before any agreement is made. Advice should be sought from the Medicines Management Team and the Director linked to the project. Legal advice may also be necessary.

6.2. Where there is a Joint Working arrangement this should be a corporate arrangement. A Major Sponsorship/Partnership Working Agreement Form Appendix 2 must be completed by the lead WBCCG contact and signed by the supporting Director.

6.3. There must be a specific agreement for each Joint Working project which contains information on:

- The name of the Joint Working project, the parties to the agreement, the date and the term of the agreement
- The expected benefits for patients, the NHS and the pharmaceutical company. Patient benefits should always be stated first
- How the success of the project will be measured, when and by whom. A set of baseline measurements must be established at the outset of the project to track and measure the success of the project aims, particularly patient outcomes. For longer term projects (>1 year) patient outcomes should be analysed at least every six months as a minimum to ensure that anticipated patient benefits are being delivered
- An outline of the financial arrangements
- The roles and responsibilities of the NHS and the pharmaceutical company. All aspects of input from the company should be included such as training, support for service redesign, business planning, data analysis etc
- The agreement should specify criteria that result in high certainty that both parties can meet their commitments. For example, both parties should be able to demonstrate that they have the capability, resource or track record to deliver on the commitments they are making
- The planned publication of any data or outcomes
- Procedures for dealing with Freedom of Information Act requests
- If a pharmaceutical company enters into a Joint Working agreement on the basis that its product is already included in an appropriate place on the local formulary, a clear reference to this should be included in the Joint Working agreement so that all the parties are clear as to what has been agreed.
- The agreement should include contingency arrangements to cover possible unforeseen circumstances such as changes to summaries of product characteristics and updated clinical guidance. Agreements should include a dispute resolution clause and disengagement/exit criteria including an acknowledgement by the parties that the project might need to be amended or stopped if a breach of the ABPI Code is ruled

- Companies must make public an executive summary of their Joint Working agreements, for example on a clearly defined website or section of a website. WBCCG will publicly declare all Joint Working arrangements on the WBCCG website.

6.4. An equality impact assessment must be completed for any Joint Working agreement.

6.5. If any of the specific agreements are broken the joint venture will be terminated immediately. Each company that enters into a joint venture with WBCCG will be acknowledged for resources provided, but WBCCG will not endorse a particular product or company.

6.6. Approval must be obtained through governance arrangements (detailed below) before the project proceeds. This will allow a full evaluation of the Joint Working agreement including governance issues and the overall impact of the Joint Working to be assessed in relation to healthcare priorities.

6.7. The Senior Leadership Team will evaluate Joint Working projects using the paperwork contained in appendix 2 and approve or reject for submission to the appropriate committee of the Governing Body for consideration. Where the Senior Leadership Team considers that a particular Joint Working project may not fit in with national or locally agreed health priorities and guidelines (including prescribing), the group will seek advice from other groups such as the Medicines Management Team before making a final decision.

6.8. The Senior Leadership Team may attach specific conditions to the approval of Joint Working. It is the responsibility of the WBCCG lead contact involved in the Joint Working to ensure that these conditions are followed. The Senior Leadership Team will request from the WBCCG lead contact a progress report for all Joint Working projects.

6.9. WBCCG will retain control of projects and encourage the Pharmaceutical Industry to work through the WBCCG by transferring the relevant funds and management responsibilities.

6.10. WBCCG will contract or employ any staff required for work on the project. These staff will be required to sign confidentiality agreements.

6.11. Any staff, employees, members and associates involved, will not agree to practice under any condition that compromises their professional independence or judgment, or imposes such conditions on other professionals.

6.12. Pilot projects will be used, where feasible, to further assess the suitability of the projects for Joint Working before any longer term arrangements are made.

6.13. Where a Joint Working arrangement leads to the development of guidelines or advice, this will be carried out by the appropriate WBCCG working group independent of the Pharmaceutical Industry. While it is recognised that consultation with the industry may be necessary when developing a guideline, the overall decision on what is included should lie with WBCCG. Deals whereby funding is linked to the purchase of particular products to supply from particular sources are not allowed.

6.14. Pharmaceutical Companies should not use the WBCCG's name in any promotional material and WBCCG will not provide references for pharmaceutical companies that provide services within Wigan Borough.

6.15. Joint Working offers of any kind from pharmaceutical companies must be declared and registered whether refused or accepted and be available for public scrutiny on request.

6.16. WBCCG will encourage competitor companies to collaborate on any such ventures. If several companies are able to provide the same arrangements they should all – or at least a selection – be approached to ascertain their willingness to undertake Joint Working. If willing to do so, they could then share a Joint Working arrangement.

6.17. Joint Working and/or commercial relationships linked to the supply of goods or services will be reported to the Audit Committee and publicly declared in the WBCCG's Annual Report.

6.18. Any offers of Joint Working that could possibly breach this policy should be reported to the Audit Committee.

7. Sponsorship

7.1. **Clinical trials -** arrangements for this are not covered in this guidance.

7.2. **Package deals** - deals linked to the purchase of particular medicines, or to supply from particular sources are not allowed.

7.3. **Meetings and hospitality** - where these are associated with WBCCG business or are undertaken by an employee, associate, or contractor of the WBCCG undertaking WBCCG business, then these should be declared in line with the WBCCG's Gifts and Hospitality Policy.

7.4. Refer to WBCCG Gifts and Hospitality Policy for further information.

7.5. **Gifts, benefits in kind or pecuniary advantages** - where these are associated with WBCCG business or are undertaken by an employee, associate, or contractor of the WBCCG undertaking WBCCG business then these should be declared in line with the WBCCG's Gifts and Hospitality Policy.

7.6. Refer to WBCCG Gifts and Hospitality Policy for further information.

7.7. **Commercial payments** to healthcare professionals employed as consultants and advisers. These must be declared in line with the WBCCG's declaration of interests policy.

7.8. **The pro-active offer or provision of medical and/or educational goods and/or services (MEGS)** which enhance patient care, or benefit the NHS and maintain patient care, where these are associated with WBCCG business or are undertaken by an employee, associate, or contactor of the WBCCG undertaking WBCCG

business then these should be declared in line with the WBCCG's declaration of interests policy.

7.9. The Senior Leadership Team will evaluate any Sponsorship projects over the value of £25 and approve or reject for submission to the appropriate committee of the Governing Body for consideration. The paperwork included in appendix 1 must be completed and submitted to SLT and an equality impact assessment must be completed. Where the Senior Leadership Team considers that a particular Sponsorship project may not fit in with national or locally agreed health priorities and guidelines (including prescribing), the group will seek advice from other groups such as the Medicines Management Team before making a final decision.

7.10. The Senior Leadership Team may attach specific conditions to the approval of Sponsorship. It is the responsibility of the WBCCG lead contact involved in the Sponsorship to ensure that these conditions are followed. The Senior Leadership Team will request from the WBCCG lead contact a progress report for all Sponsorship projects.

7.11. Approval must be obtained through governance arrangements before the Sponsorship proceeds. This will allow a full evaluation of the Sponsorship agreement including governance issues and the overall impact of the Sponsorship to be assessed in relation to healthcare priorities.

7.12. Sponsorships will be included in the register, and reported to the Audit Committee.

7.13. Sponsorship offers of any kind from an external source, or cases where staff have actively canvassed for Sponsorship, must be declared and registered whether refused or accepted, and be available for public scrutiny on request.

7.14. Sponsorship and/or commercial relationships linked to the supply of goods or services will be publicly declared in the WBCCG's Annual Report.

7.15. Any offers of Sponsorship that could possibly breach this policy should be reported to the Audit Committee.

8. Governance

8.1. All relationships must be open and transparent with a robust governance framework.

8.2. Before entering into any arrangements with a pharmaceutical company for Joint Working, all staff, employees, members and associates must seek approval through the SLT and Corporate Governance as detailed above.

8.3. For Joint Working projects the following must be submitted:

- the agreement documentation as described in section 6.3 above
- evidence that the proposed arrangement is the best and or most appropriate option
- a Project Initiation document (PID)
- assurance that all the guidance has been followed.

8.4. Consideration will be given to the implications of any proposed partnership, its costs and benefits, and an awareness of bias generated through financial contributions from industry, where this might impinge on professional judgement and impartiality.

8.5. The approval checklist contained in appendix 2 must be completed for all Joint working projects.

8.6. Oversight of all arrangements with the Pharmaceutical Industry and all offers, receipts, approvals etc. will be maintained through the Audit Committee.

8.7. Before entering into any arrangements with a pharmaceutical company for Sponsorship, all staff, employees, members and associates must seek approval through the SLT and Corporate Governance as detailed above.

8.8. For Sponsorship projects the following must be submitted:

- Details of the project ensuring that sponsorship is at a corporate rather than individual level
- Implications for subsequent prescribing in primary care where the project offers significant discounts on drugs
- If making purchasing decisions on products which originate from NHS intellectual property, how ethical standards will be ensured and how the standard is based on best clinical practice and not on whether royalties will accrue to an NHS body;
- Where the major incentive is income generated that how this will be governed and managed by income generation principles and a memorandum trading account kept;
- If there will be disclosure of confidential patient information procedures etc. that will be followed to ensure that legal and ethical restrictions are complied with. Additionally, disclosure for research purposes should not take place without the approval of the appropriate research ethics committee;
- Details of how outcomes will be monitored, i.e. clinical, financial, organisational;
- Details of the break clause built in to enable the agreement to be terminated if it becomes clear that it is not providing expected value for money/clinical outcomes (a break clause is essential for all sponsorship projects);

8.9. Consideration will be given to potential irregularities that may affect a company's ability to meet the conditions of the agreement; the reasons behind why the organisation wishes to provide the sponsorship and the benefits they will receive; the costs and benefits in relation to alternative options ensuring decision-making processes are transparent and defensible.

8.10. GP Practices are advised to consult with the Medicines Management Group prior to accepting sponsorship (including the loan of temporary clinical or non-clinical staff), from the pharmaceutical industry. The activities of the industry may conflict with best clinical practice and patient pathways that have been agreed within WBCCG. Such activities have also been known to result in significant financial pressures for the Practices and the CCG.

8.11. WBCCG, its staff, employees, members and associates will not:

- Enter into any arrangement which is not consistent with the GMMMG Formulary;

- Enter into any arrangement which appears to give preferential treatment to a particular company or its products or effectively excludes competitors from the market;
- Disclose information unless under the framework allowed for under Freedom of Information and Data Protection legislation;
- Participate in any arrangement which may impair clinical responsibility or inappropriately influence a clinician's choice of drugs or treatment regimens;
- Enter into any arrangement which impacts on the Pharmaceuticals Price Regulation Scheme (PPRS);
- Enter into any arrangement which contravenes the CCG Constitution, Standing Financial Instructions and /or Standing Orders.

9. Roles & Responsibilities

9.1. The CCG's lead contact will be responsible for developing the project proposal and getting advice from the Medicines Management Team, Senior Information Risk Owner, Caldicott Guardian and Head of Contracting to get advice on the appropriateness of the proposed project.

9.2. The CCG's Associate Director for Clinical Services 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.

9.3. 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.

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

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

10. Equality, Diversity & Human Rights Impact Assessment

10.1. The CCG is committed to mainstreaming inclusion and diversity throughout all we do; promoting equality and ensuring full inclusion for the population we serve.

10.2. This policy has been Equality Impact Assessed EqIA number 74/16.

11. Consultation & Approval Process

Consultation

11.1. This policy has been to CCG Senior Leadership Team for consultation.

Approval

11.2. This policy has been approved by the CCG Senior Leadership Team who have considered the content of the document in terms of best practice, delivery of the overall CCG strategy, corporate objectives and quality ambitions.

11.3. This policy has been approved by the Corporate Governance Committee who have considered the content of the document in terms of current best practice, guidelines, legislation, mandatory and statutory requirements.

12. Dissemination & Implementation

12.1. It is essential that all staff, employees, members and associates should be aware of this policy and adhere to it. The guidance therefore must be shared throughout the organisation.

12.2. This policy is available for all staff and the public to access via the CCG website. This document will be included in the Publication Scheme for Wigan Borough CCG in compliance with the Freedom of Information Act 2000.

13. Monitoring Compliance

13.1. The Assistant Director of Governance is responsible for monitoring compliance with this Policy.

13.2. Any non-compliance should be reported to the Corporate Governance Committee.

13.3. This policy will be monitored for effectiveness by self-assessment against any external accreditation that is applicable and may be subject to review by internal audit.

14. Standards & Key Performance Indicators

14.1. This policy must be reviewed at least every three years or when there are significant changes in the policy.

15. References & Bibliography

15.1. ABPI. Code of Practice for the Pharmaceutical Industry. 2015. http://www.pmcpa.org.uk/media/Documents/PMCPA%20Code%20of%20Practice%202015.pdf

15.2. ABPI. Guidance Notes on Joint Working between Pharmaceutical Companies and the NHS and Others for the Benefit of Patients. 2009. http://www.abpi.org.uk/our-work/library/guidelines/Documents/ABPI_Code_Guidance_Notes.pdf

15.3. Department of Health/ABPI. Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry. 2010. http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840

16. Associated CCG Documents & Useful Contacts

16.1. Conflicts of Interest Policy
http://wbccg-sharepoint.gp-alwpct.nhs.uk/sites/wbccg/Policies/Forms/AllItems.aspx

16.2. WBCCG Standards of Business Conduct Section 8 of WBCCG Constitution
http://www.wiganboroughccg.nhs.uk/your-ccg/our-strategies-policies-reports/our-constitution

16.3. WBCCG's Standing Orders (SOs) and Standing Financial Instructions (SFIs) Section 10 of WBCCG Constitution
http://www.wiganboroughccg.nhs.uk/your-ccg/our-strategies-policies-reports/our-constitution

16.4. Gifts and Hospitality Policy and Declaration form
http://wbccg-sharepoint.gp-alwpct.nhs.uk/sites/wbccg/Policies/Forms/AllItems.aspx

16.5. WBCCG Employee Code of Conduct Policy
http://www.wiganboroughccg.nhs.uk/your-ccg/our-strategies-policies-reports/our-policies

16.6. Anti-Fraud Bribery and Corruption Policy
http://wbccg-sharepoint.gp-alwpct.nhs.uk/sites/wbccg/Policies/Forms/AllItems.aspx

17. Appendix 1 Sponsorship Checklist and Approval Form

Sponsorship Checklist and Approval Form (>£25)

This form should be completed for sponsorship over the value of £25 which has been offered to the WBCCG or its employees/officers.

1. Project Summary	
Recipient (include WBCCG contact details)	
Sponsor(s) (including contact details)	
Details of Project	
Aims and Objectives of Project	
Benefits to Patient	

Benefits to WBCCG/NHS	
Benefits to Sponsor	
Start Date	
Finish Date	
Details of Funding	
Termination Arrangements (The agreement should be capable of early termination by the WBCCG)	
2. Resources and Costs	
Overall cost of Sponsorship Project	
The direct/indirect resource/cost commitments by sponsor(s)	

The direct/indirect resource/cost commitments by WBCCG	
Description of how resources/costs will be monitored and recorded	
Description of how payments will be made	
Will sponsorship lead to higher costs elsewhere in the NHS?	
List valid and relevant information on cost effectiveness/value for money.	
3. Governance and Management Arrangements	
Who has been consulted in relation to project and how was this done?	
How will patients be informed of project?	
What is the decision making process of the project?	

What are the operational and management arrangements?	
How does the project relate to, and mesh with existing systems of care in primary and secondary care?	
Has the project been piloted or are there plans to do this? How would this be done?	
Has the project been compared with other proposals on offer?	
Has an equality impact assessment been carried out?	
Has the sponsor read the WBCCG Standards of Business Conduct and agree to abide by the rules detailed in this document?	
Does the project include the use of protocols and guidelines? Who is responsible for producing these? Please include full details of guidelines.	
What outcomes will be measured?	

4. Data and Patient Protection	
Does the project involve the sharing of clinical data at patient and/ or WBCCG level? Has the Caldicott Guardian been consulted?	
Are there potential conflicts of interest in relation to access to this data? Please give details.	
What arrangements have been put in place to ensure patient confidentiality and patient consent are considered?	
Where the project includes collection of data for research purposes, has this been approved by the Medical Ethics Committee?	
Who will have access to data and in what form?	
How will the data be used?	
For clinical services, what professional indemnity and liability arrangements will be in place?	

POSITION	NAME	SIGNATURE	DATE
WBCC Lead Contact			
WBCCG Director			
Sponsor Lead Contact			

Approval Checklist

Criteria	Yes	No
Does the sponsorship offer comply with the rules specified in the WBCCG Standards of Business Conduct and Commercial Sponsorship?		
As part of sponsorship, are all medicines or products, which are promoted or otherwise mentioned in line with locally agreed prescribing advice?		
Where sponsorship is offered to facilitate the development of Guidelines and protocols etc. will this be carried out by the appropriate WBCCG working group independent of the sponsors?		
Is this sponsorship in line with nationally and locally agreed healthcare priorities?		
Does the Sponsorship comply with the ABPI code of practice?		

For Senior Leadership Team use only	*For Committee use only*
Reference Number:	Reference Number:
Outcome: **Approved/Not Approved**	Outcome: **Approved/Not Approved**
Comments	Comments:

18. Appendix 2 Joint Working Approval Checklist

Joint Working Approval Checklist		
Essential Criteria	**Yes**	**No**
The main benefit of the project is focused on the patient		
All parties acknowledge the arrangements may also benefit the NHS and pharmaceutical partners involved		
Any subsequent benefits are at an organisational level and not specific to any individual		
There is a significant contribution of pooled resources (taking into account people, finance, equipment and time) from each of the parties involved		
There is a shared commitment to joint development, implementation and successful delivery of a patient centred project by all parties involved		
Patient outcomes of the project will be measured and documented		
All partners are committed to publishing an executive summary of the Joint Working Agreement		
All proposed treatments involved are in line with national guidance where such exists		
All activities are to be conducted in an open and transparent manner		
Exit strategy and any contingency arrangements have been agreed		

For Joint Working all answers must be **YES**. If any answers are No the project is not a true Joint Working arrangement and should not be viewed as such.

Additional Criteria	**Yes**	**No**
Will the project be managed by a joint project team with pharmaceutical industry, NHS and any appropriate third party representation.		
Do all parties and their respective organisations have appropriate skills and capabilities in place to manage the project thus enabling delivery of patient outcomes.		
Have all partner organisations got clear procedures in place for reviewing and approving Joint Working projects.		
Are all parties aware of and committed to using the Joint Working Agreement Template (or equivalent) developed by the DH and ABPI.		
Are all partners clear on who within their organisations is the signatory to ensure Joint Working agreements can be certified.		

All answers should be **YES –** any no answers indicate potential problem

For Senior Leadership Team use only	*For Committee use only*
Reference Number:	Reference Number:
Outcome: **Approved/Not Approved**	Outcome: **Approved/Not Approved**
Comments	Comments: