NHS
Sunderland
Clinical Commissioning Group

# Policy for working with the pharmaceutical industry

CO28

Better health for Sunderland

## Contents



## Version Control

| Version | Date Approved | Committee | Date of next review | CCG Lead |
|---|---|---|---|---|
| Final 2.1 | November 2014 | Quality, Safety and Risk Committee | November 2015 | Z Irannejad, Head of Medicines Optimisation |
| Final 3.5 | February 2016 | Executive Committee | February 2017 | Medicines Optimisation Team |
| Final 4.0 | September 2017 | Executive Committee | September 2018 | Medicines Optimisation Team |
| Final 5.0 | December 2018 | Executive Committee | December 2019 | Ewan Maule Head of Medicines Optimisation |
| Final 5.1 | June 2020 | In light of COVID19 extension granted. EIA has been updated | June 2021 | Ewan Maule Head of Medicines Optimisation |

## 1. Introduction

This document is intended as policy for NHS Sunderland Commissioning Group (hereafter refer to as the CCG) and its staff who are involved in working with the pharmaceutical industry. It is intended to complement the CCG Policy (CG019) on Standards of Business Conduct and Declarations of Interest.
*While the CCG recognises that GP practices are providers in their own right the CCG 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. Many companies have developed internal structures to encourage closer liaison with GP practices, GP Federations, Medicines Optimisation leads, CCG Boards and professionals working for the CCGs.

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 to be clearly stated and evidence presented to support such claims. The pharmaceutical industry are also able to be transparent about expected 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 GP practices already undertake collaborative work with drug companies to work on specific projects. Clinical commissioning groups 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 therefore that all projects are subject to the widest scrutiny to enable likely 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 product sales this must be in line with the CCG 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 CCG 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 CCG and its staff respond consistently to approaches from the Pharmaceutical Industry and that the interests of patients, the public and the CCG are maintained

- ensure staff comply with CCG 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 favourable light than is appropriate.

**This policy should be read in conjunction with CCG CO19: Standards of Business Conduct and Declarations of Interest Policy.**

For further information on the legislation and guidance:

- The Bribery Act 2010

- Standards of business conduct for NHS staff (HSG(93)5)

- Best practice guidance for joint working between the NHS and the pharmaceutical industry (DH 2008)

- The Code of Conduct: Code of Accountability in the NHS – Department of Health 2004

## 2. Definitions

For the purposes of this policy, the term ‘staff’ refers to all employees of Sunderland CCG, governing body and committee members and individuals acting on behalf of the CCG.

*The CCG recognises that GP practices are providers in their own right but would encourage practices to adopt the policy, in particular the advice to GP practices contained in Appendix 2, Guidance for practices considering joint working with the Pharmaceutical Industry.*

The pharmaceutical industry includes:

- Companies, partnerships or individuals involved in the manufacturing, sale, promotion or supply of medicinal products subject to the licensing provisions of the Medicines Act.

- Companies, partnerships or individuals involved in the manufacture, sale, promotion or supply of medical devices, appliances, dressings, and nutritional supplements which are used in the treatment of patients within the NHS.

- Trade associations representing companies involved with such products.

- Companies, partnerships or individuals who are directly concerned with research, development or marketing of a medicinal product that is being considered by, or would be influenced by, decisions taken by Sunderland Clinical Commissioning Group.

- Pharmaceutical industry related industries, including companies, partnerships or individuals directly concerned with enterprises that may be positively or adversely affected by decisions taken by Sunderland Clinical Commissioning Group.

- “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.

    - Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.

    - In joint working, goals are agreed jointly by the NHS organisation and company, in the interest of patients, and shared throughout the project. A joint working agreement is drawn up and management arrangements conducted with participation from both parties in an open and transparent manner.

- Given the significant governance and administrative requirements involved in setting up proper joint working arrangement, it is likely that joint working projects will be of a significant size and duration generally involving resources (man power, materials, fund etc.)

## 3. Collaborative working with the pharmaceutical industry – including joint working and industry sponsored projects and services

Collaborative 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.

## 4. Duties and Responsibilities

| | |
|---|---|
| **Executive Committee** | Responsible for approval of the policy |
| **Chief Officer** | The Chief Officer has overall responsibility for the strategic direction and operational management, including ensuring that CCG process documents comply with all legal, statutory and good practice guidance requirements. |
| **Medical Director** | Ultimate responsibility for ensuring that requests from staff to engage with the pharmaceutical industry are properly assessed to ensure that the work is beneficial to the organisation and patients; and there are no conflict of interests. |
| **Medicines Optimisation (MO) Team** | The MO team are responsible for overseeing the development and updating of this policy and related procedures. |

| | |
|---|---|
| **All Staff** | All staff, including temporary and agency staff, are responsible for:<br>• Compliance with relevant process documents.<br>• Co-operating with the development and implementation of policies and procedures and as part of their normal duties and responsibilities.<br>• 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.<br>• Identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager.<br>• Attending training / awareness sessions when provided.<br>• Staff are encouraged to report any breach of the British Pharmaceutical Industry Code of Practice (http://www.abpi.org.uk) to the SCCG Medicines Optimisation team. |
| **Representatives of the pharmaceutical industry** | Must comply with the Association of British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry. |

## 5. Implementation

**5.1** This policy will be available to all Staff for use in relation to the specific function of the policy.

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

### 5.3 Principles of collaborative working

The following principles will also apply to collaborative working:

- All collaborative 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

- Collaborative working arrangements should take place at a corporate, rather than an individual, level

- Clinical and financial outcomes and risks or governance issues must be formally assessed at the planning stage by SCCG before the collaborative work commences.

- 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 company 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 CCG 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/view

Staff in the CCG, wishing to enter into joint working arrangements, are recommended to use the toolkit in conjunction with the recommendations below.

### 5.4 Mechanism for Monitoring Collaborative Working

All projects should be managed by a named, nominated CCG representative and/ or steering group. 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.

It is recommended that all meetings connected to the development or delivery of a collaborative project will be formally minuted and recorded.

Collaboration should be on the basis of explicit written agreements between the CCG and the company, which define the precise nature of the support provided. There should be a written business agreement signed off by an appropriate CCG representative (preferably the chief officer) for all collaborative working agreements. (See Appendix 4)

All proposals will specify sufficient reporting arrangements to enable progress to be monitored by the CCG.

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**.

#### 5.4.1 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.

#### 5.4.2 Financial Arrangements

All financial arrangements must comply with CCG standing financial instructions.

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

The CCG 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 CCG.

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 CCG. 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".

### 5.4.5 Confidentiality and Data Protection

Where a project involves access to, or processing of patient sensitive data all staff will comply with the CCG Information Governance Policy, advice may be sought from the Information Governance Lead.

It may be beneficial to for both parties to exchange 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.

### 5.4.6 Conflicts of Interest, Payments and Hospitality

All CCG staff must comply with NHS Sunderland Clinical Commissioning Group Standards of Business Conduct and Declarations of Interest Policy. Clinical staff must 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 proposal must declare any potential conflicts of interest they or their immediate family may have at the outset of the process.

### 5.5 Procedure for the approval of collaborative working projects between SCCG and the pharmaceutical industry

i. Identify potential collaborative work - any collaboration with the pharmaceutical industry must be transparent and defensible with agreed aims and objectives

   a. One particular concern is the impact of commercial sponsorship on prescribing. This will need to be assessed against certain criteria – please see appendix 2 - Sunderland CCG - Guidance for practices considering joint working with the pharmaceutical industry

ii. Complete collaborative working proposal (appendix 2, also available on the CCG intranet).The collaborative working proposal must be submitted to the locality commissioning manager or CCG executive lead.

iii. The medicines optimisation team will seek views from appropriate staff and stakeholders and assess appropriateness of application to ensure that the proposal project will not compromise SCCG strategies, that the work is beneficial to the organisation and that there is no conflict of interest. The checklist in appendix 2 will be used to support assessment.

iv. All staff must refer to the Sunderland medicines optimisation team if they feel unable to judge the suitability of proposals that involve or may involve medicines or other prescribed items. In order to ensure congruence with the strategic aims of the CCG prescribing agenda, each project will require approval by the head of medicines optimisation (or deputy). It is their responsibility to resolve any contentious issues and have the final say in determining the appropriateness of any collaboration with the industry. In the event of an appeal the joint working application will be reviewed by the Medical Director.

v. If the proposal is approved then the applicant must follow the CCG Gateway process by submitting a project brief and supplemental information (appendix 3) to the Programme Management Office in the first instance. If approved by PMO, a full business case will be submitted to PMO for Executive approval.

### 5.6 Primary care prescribing rebates

A primary care rebate scheme (PCRS) is an agreement between a Clinical Commissioning Group and a drug company that provides an economic benefit to the CCG.

When medicines are prescribed in primary care, the CCG pays the list price of the medicine/other prescribed item from the GP prescribing budget. Where a rebate scheme exists, the company will reimburse the CCG a proportion of the cost of the medicines and this is fed back into the prescribing budget.

Note that these are different to national patient access schemes, which are negotiated nationally by the Department of Health to enable patient access for very high cost drugs that have clear clinical benefits.

SCCG acknowledges that there is a potential conflict of interest with signing up to rebates in primary care with the GPs being both the prescribers and the commissioners and that PCRS could be seen to undermine national pricing agreements between the Department of Health and industry. However, measures have been taken to ensure that the CCG enters into rebate schemes that have been independently assessed as being appropriate, so that the NHS can benefit from the cost–efficiencies that the schemes offer.

### 5.7 Process for considering rebate scheme offers from the pharmaceutical industry.

The CCG will only enter into rebate schemes that have either been approved by the Regional Procurement Pharmacist (RPP), or individually and specifically approved by the Chief Finance Officer and Medical Director as appropriate.

#### 5.7.1 Process for considering rebate scheme offers using the Regional Procurement Pharmacist (RPP)

- Offers are directed to the Regional Procurement Pharmacist (RPP) who reviews proposals against standard criteria.

- The proposal and the outcome of the review are communicated to the SCCG medicines optimisation team.

- SCCG then considers the proposal and the outcome of the review before making a commitment to engage in the scheme or turn down the offer.

#### 5.7.2 Rebates approved by the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board (PISGRB)

- On occasion, SCCG may consider rebate schemes approved by the PrescQIPP PISGRB.

- SCCG will only enter into PrescQIPP PISGRB approved schemes which have been individually and specifically approved by the SCCG Chief Finance Officer and Medical Director.

### 5.8 Meeting with pharmaceutical representatives

#### 5.8.1 CCG staff

If CCG staff 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 CCG, GP practices 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 CCG and GP practices in conjunction with the priorities of the CCG.

- 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).

### 5.9 Samples

Samples of products including pharmaceuticals, dressings, devices or nutritional products should only be accepted in order to assess their physical properties. They should not be used to treat patients, as the CCG is liable for the quality of any items issued to patients and service users.

According to the ABPI Code of Practice, samples of a product can only be provided to a health professional in response to a written request, which has been signed and dated.

### 5.10 Provision of information to SCCG medicines optimisation team

A key role of the pharmaceutical industry is to provide useful information on new and existing medicinal products. However, it is not possible to meet with all pharmaceutical industry representatives to discuss all products. Therefore the following process for engagement has been devised:

i. The administration support for the medicines optimisation team will be the main point of contact for all pharmaceutical representatives wishing to discuss information about medicines.

ii. Initially representatives will be asked to send information for consideration via email to the administration support. Information should be as detailed as possible.

iii. Following this if a meeting is deemed necessary then representatives will be seen by appointment only when the product they wish to discuss has been identified as being a priority for the CCG.

iv. Information may be used for horizon scanning or to inform assessment of the product for inclusion on the joint formulary.

## 5.11 Summary

5.11.1 SCCG and member practice staff will:

i. Engage with the pharmaceutical industry, in line with ABPI guidelines on joint working with the pharmaceutical industry and with this policy, where there is a clear benefit to the patient.

ii. Engage with staff from the pharmaceutical industry regarding new or existing medications where appropriate to ensure staff stay informed of key developments.

iii. Publish finalised guidelines or other documents on the SCCG website.

iv. Maintain positive relationships with members of the pharmaceutical industry.

v. Ensure that at all times clinical decisions take into account evidence and cost effectiveness and are not in any way influenced by the pharmaceutical industry.

5.11.2 SCCG and member practice staff will **not**:

i. Engage in activities which contravene the ABPI guidance on joint working with the pharmaceutical industry.

ii. Accept funds for the provision of staff directly employed by the CCG.

iii. Allow any employee from a pharmaceutical company to attend any internal CCG meetings or event unless specifically requested by SCCG staff.

## 6. Training Implications

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

## 7. Related Documents

### 7.1 Other related policy documents

- CCG019 – Standards of business conduct and declarations of interest policy.

### 7.2 Best practice recommendations

- Association of the British Pharmaceutical Industry (2016) Code of Practice for the Pharmaceutical Industry.

- Department of Health (2000) Commercial Sponsorship – Ethical Standards for the NHS

- Department of Health (2008), Best Practice Guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations.

## 8. Monitoring, Review and Archiving

### 8.1 Monitoring

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

The policy will be communicated to all CCG staff and GP practice prescribing leads via e-mail and will be available on the SCCG website.

### 8.2 Review

8.2.1 The Governing Body 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 The policy will be reviewed every two years or sooner if there are changes in legislation or guidance or specific circumstances.

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

8.2.4 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 director 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

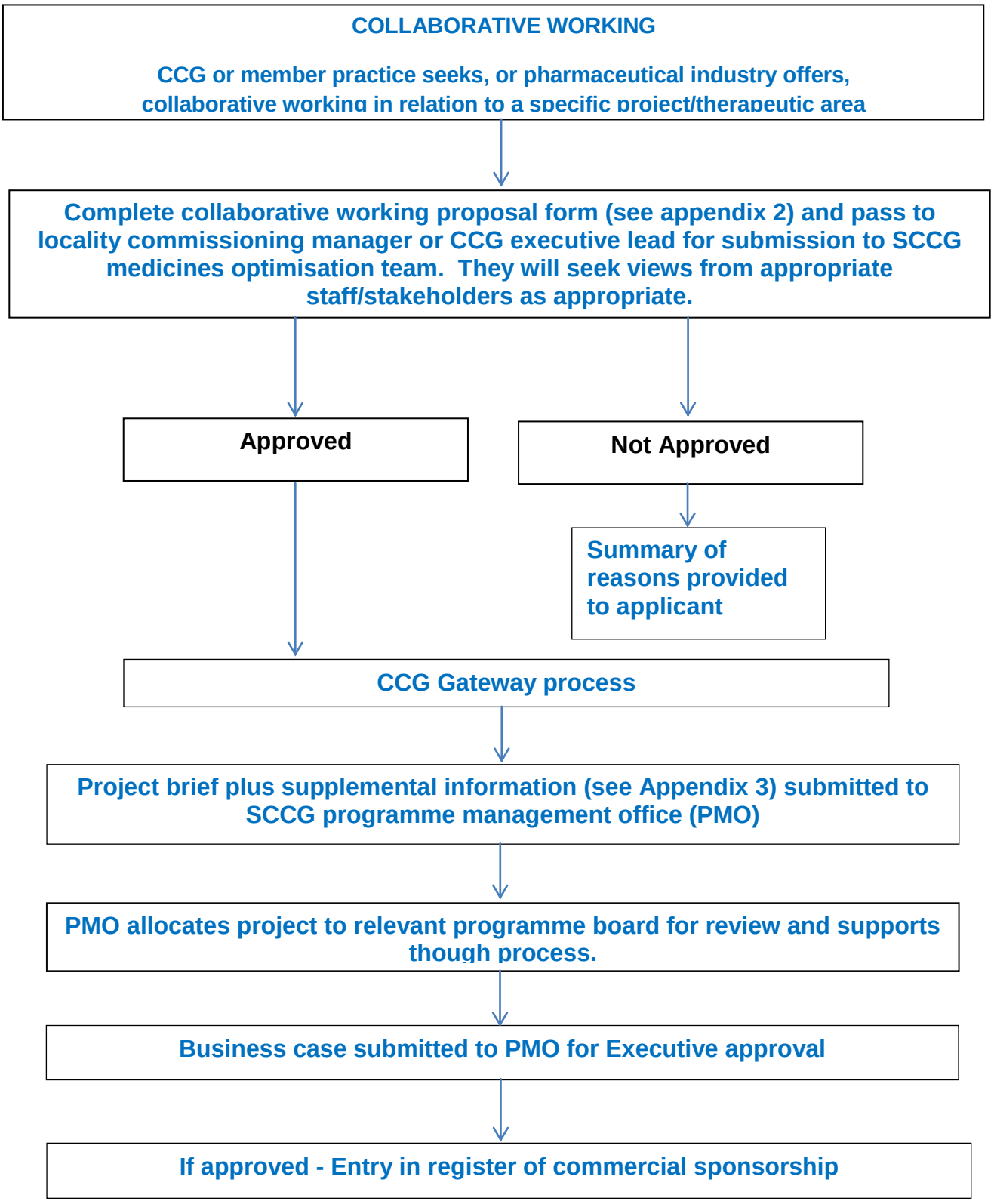
The Governing Body will ensure that archived copies of superseded policy documents are retained in accordance with Records Management: Code of Practice for Health and Social Care 2016.

## 9. Equality Analysis

A full Equality Impact Assessment has been completed (appendix 5).

**Appendix 1**

**Process for approval of collaborative working with the pharmaceutical industry for SCCG and member practices**



**Appendix 2**

## Collaborative working proposal form

Name of applicant…….

Position…….

Practice/Organisation……

Name of pharmaceutical industry company ……

Sponsor contact name…… Date…….

**Please summarise the proposal- including the following information:**

- the potential implications for patients and the NHS – see flowchart over page for areas to be considered
- length of the arrangement
- whether legacy arrangements i.e. what will happen when the service or project ends and exit strategy have been included in in the proposal.

**What is the proposed contribution by the pharmaceutical industry?**

Once complete please pass this form to your locality commissioning manager or CCG executive and the medicines optimisation team and await outcome of the initial assessment of the project before proceeding further.

If the proposal is accepted, complete the collaborative working framework and agreement and send to the Sustainability and Development Group to seek agreement for the project. If the project involves “joint working”, a full business case is also required

**Appendix 2 (continued)**
**Flow chart to assess potential implications for SCCG and its member practices, and the wider NHS**

Consider:

- Will this impact on prescribing? **If YES – see below for further points.**
- Will this support the initiatives in the SCCG Plan on a Page for Better Health for Sunderland?
- What control will you have over the activities of any the staff provided by the company?
- If the project will involve initiation of a drug, or changes to existing treatment – how much control will you/the practice or SCCG have over choice of medicine?
- Are responsibilities around decision- making for individual patients clearly defined in the protocol?
- How many patients will the service need to see or review and how will this impact practices/SCCG?
- Will the protocol and medicines fit into current clinical pathways?

**If the proposal will impact on prescribing of medicines or other prescription product. Is it:**

- **Licensed** – for the indication and at the doses being discussed?
- **On the formulary?**
  - *has it been rejected (why?) or has it not been proposed for inclusion?*
- **Included in current local/national guidelines?**
- *Does the proposal follow these guidelines*
- **Suitable for initiation by GPs** – or is specialist initiation recommended?

**Yes?** → **Evaluate costs and benefits**

**No?** → **Seek further advice /do not continue**

**Potential Costs**

- **What is the drug tariff price and pricing structure?**
- **How does the cost compare to other treatment options?**
- *Are there other lower cost drugs that could be used? Are other drugs about to come off patent and reduce in price?*
- **What impact will increased use of this product have on your prescribing budget?**
- *Will the drug replace a similarly priced drug, or a cheaper drug?*
- *Or – will this drug be added to the existing treatments?*
- **Will patients need additional monitoring e.g. follow-up appointments or other - what impact on practice capacity and costs?**

**Potential Benefits**

**Patient**

- **Are there improved patient outcomes?** e.g. reduced mortality, morbidity, hospital admissions
- If the benefits surrogate measures - e.g. improvements in BP, HbA1c – how will these translate into patient benefits?
- Fewer side effects? *Remember – the full S/E profile of newer drugs is unknown.*
- Improved compliance? *If patient already has difficulties will switching drug make a difference?*

**Benefits to the practice/CCG**

- Are potential benefits aligned to the CCG priorities and Plan on a Page?
- Reduction in prescribing expenditure?

**Appendix 2 (continued)**

**Assessment checklist for use by SCCG – led by medicines optimisation team**

1. Is the joint working proposal consistent with the guidance given in the SCCG policy for engagement with the pharmaceutical industry? **Y / N**

2. Is the proposed involvement of the sponsoring organisation of an appropriate level for the purpose? **Y / N**

3. Is SCCG satisfied with its knowledge of the sponsoring organisation, e.g. is it known to the CCG? Could it be independently audited? **Y / N**

4. Is SCCG satisfied that the offer is independent of purchasing or prescribing decisions? **Y / N**

5. Can it be confirmed that there is no current conflict of interest for any parties in relation to the service offered? **Y / N**

6. Are you satisfied that all materials and information supplies are valid, evidence- based, balanced and non-promotional? **Y / N**

7. Have you reached an agreement with all members of your team involved that the service is appropriate? **Y / N**

8. If patients are involved have arrangements been made to ensure the patients are aware of the service where appropriate? **Y / N / Not applicable**

   N.B. If the answer is no to any of the above questions the proposed sponsorship is likely to be unsuitable and should be reviewed before submission.

9. Is SCCG satisfied that the scheme will be of benefit to patients, practices and/ or SCCG? **Y/N**

| **Proposal Reviewed by** | **Name and Designation** | **Date** | **Approved/Rejected** |
|---|---|---|---|
| **SCCG Medicines Optimisation Team** | | | |
| **Others** | | | |
| | | | |
| | | | |

## Appendix 3

### Framework for collaborative working

| | |
|---|---|
| **I. OVERVIEW OF PROJECT** | |
| 1. TITLE OF PROJECT | |
| 2. SUMMARY OF INTENDED AIMS & OBJECTIVES | |
| 3. SUMMARY OF EXPECTED OUTCOMES | |
| 4. NAMES OF THE PARTNER ORGANISATIONS INVOLVED IN THE PROJECT | |
| 5. NAMES OF LEAD REPRESENTATIVES FOR EACH ORGANISATION | |
| 6. EXACT NATURE OF THE PROPOSAL | |
| 7. START DATE | |
| 8. FINISH DATE | |
| 9. EXIT STRATEGY | |
| **II. RESOURCES AND COSTS** | |
| 1. OVERALL COST OF THE PROJECT | |
| 2. DIRECT AND INDIRECT RESOURCES/COST COMMITMENTS BY EACH PARTNER | |
| 3. METHOD FOR MONITORING AND RECORDING RESOURCE AND COSTS | |
| 4. INFORMATION ON COST EFFECTIVENESS AND VALUE FOR MONEY IMPLICATIONS | |
| 5. ARRANGEMENTS FOR LONGER TERM FUNDING | |
| **III. GOVERNANCE ARRANGMENTS** | |
| 1. PARTIES CONSULTED PRIOR TO INITIATING PROJECT AND HOW | |

| | |
|---|---|
| CONSULTATION WAS CONDUCTED | |
| 2. METHOD FOR INFORMING PATIENTS OF THE PROJECT | |
| 3. DECISION MAKING PROCESSES WITHIN THE PROJECT | |
| 4. OPERATIONAL AND MANAGEMENT ACCOUNTABILITIES (include identified conflicts of interest) | |
| 5. PILOTING ARRANGEMENTS (state if this project is a pilot) | |
| 6. RELATIONSHIP TO EXISTING SYSTEMS OF CARE IN PRIMARY AND SECONDARY CARE SECTORS | |
| 7. FOR CLINICAL SERVICES, PROFESSIONAL INDEMNITY AND LIABLITY ARRANGEMENTS | |
| 8. 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 | |
| 2. LIST DESIGNATED RESPONSIBIILTY AT EACH STAGE OF THE PROPOSAL | |
| 3. METHOD OF EVALUATING PATIENT BENEFITS ON COMPLETION | |
| 4. LEARNING OPPORTUNITIES FROM THIS PROJECT | |
| 5. AUDIT ARRANGEMENTS | |
| 6. METHOD FOR HIGHLIGHTING SIGNIFICANT PROBLEMS | |
| **V. DATA AND PATIENT PROTECTION** | |
| 1. LIST INTERESTS OF SCCG/MEMBER PRACTICE STAFF IN RELATION TO THE PROPOSAL AND WHERE THESE COINCIDE | |
| 2. LIST POTENTIAL CONFLICTS OF INTEREST | |

| | |
|---|---|
| 3. IDENTIFY "OWNERSHIP" OF THE DATA GENERATED BY THE PROJECT | |
| 4. DESCRIBE ACCESS ARRANGEMENTS FOR THE DATA AND FORMAT (bearing in mind the requirements of the Data Protection Act and patient confidentiality of healthcare records) | |
| 5. HOW WILL DATA BE USED | |

**VI.DECLARATION OF INTERESTS** YES ☐ NO ☐

**If yes, qualify by inserting a tick in one box in column A and one in column B**

| **A** | | **B** | |
|---|---|---|---|
| Personal | ☐ | Specific | ☐ |
| Non-personal | ☐ | Non specific | ☐ |

Signature _____ Date _____

**Personal** implies that you (or your spouse / partner) receive direct payment for services or hold shares in the relevant company concerned or a competitor.
**Non-Personal** implies that your unit benefits by receiving funding from the company.
**Specific** implies that you have undertaken work or given advice on other products made by the relevant manufacturer.
This system is based on that used by the Commission on Human Medicines and other national drug regulatory bodies.

**Appendix 4**

# Collaborative Working Agreement Template

AN AGREEMENT FOR COLLABORATIVE WORKING

BETWEEN

**NHS Sunderland Clinical Commissioning Group**

AND

*Insert second party (and any others as necessary)*

FOR

*Insert title of joint working initiative*

This agreement is to set out the principles and values that should underpin the joint working arrangement, as well as the objectives and modus operandi for the insert title of joint working initiative.

## 1. Name and Members of the Joint Working Arrangement

The insert title of joint working initiative will be a joint working arrangement between:

- Insert first party
- Insert second party (list further parties if more than two)

## 2. Aims and Objectives

Insert a paragraph giving a summary of the aims and objectives of the joint working project.

## 3. Values

The following values should underpin joint working:

- Transparency and trust
- Appropriateness of projects
- Patient focused
- Value for money
- Reasonable contact
- Responsibility
- Impartiality and honesty
- Truthfulness and fairness.

## 4. Principles of Joint Working

The following principles will apply to joint working:

- All joint working must be for the benefit of patients;
- Joint working will be conducted in an open and transparent manner;
- Joint working will take place at a corporate, rather than an individual, level;
- Arrangements will be of mutual benefit, the principal beneficiary being the patient;
- Contract negotiations will be negotiated in line with NHS values;
- Confidentiality of information received in the course of the 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;
- Reports and information pertaining to the agreement / projects will not be used or published without explicit permission given by all parties;
- Joint working must not be used or seen as endorsement or promotion of any specific medicine or product;
- Pharmaceutical companies must comply with the ABPI Code of Practice for the Pharmaceutical Industry at all times;
- All NHS employed staff must comply with NHS, and relevant professional body, Codes of Conduct at all times, and be aware of DH Guidance relating to joint working with the pharmaceutical industry (Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry, February 2008).

**5. Finances**

- The finance provided by each party will be limited to that agreed. Additional finance may be provided from other sources if agreed by the Parties;

**6. Outputs, Monitoring and Evaluation**

The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, together with a mutually agreed exit strategy, will be clearly outlined before commencement of joint working.

The parties will agree arrangements for recording, monitoring and evaluating the joint working arrangement.

**7. Data Ownership**

- All data generated by the project will be owned insert ownership arrangements by the parties;
- No data will be disclosed to any third party except on the explicit agreement of all parties;
- Patient confidentiality will be maintained at all times.

8. **Dissolution**

- The joint working arrangement shall be dissolved at any time if any party wishes to withdraw; a notice period will be given of insert notice arrangements
- Any outstanding matters must be wound up by all parties by agreement.

9**. Change of the Joint Working Agreement**

Changes may be made to the Joint Working Agreement by consensus of all parties at a meeting convened for the purpose.

**10. Declaration of Interests**

All declarations of interest must be declared by any working member. Declarations of interest will be recorded insert recording arrangements.

I have read the above Joint Working Agreement and commit to the Terms.

Signed: on behalf of:
Print Name: Date:

Signed: on behalf of:
Print Name: Date:

**Appendix 5**

# Equality Impact Assessment; Screening (Step 1)

As a public body organisation we need to ensure that all our strategies, policies, services and functions, both current and proposed have given proper consideration to equality and diversity, 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, Carers and Health Inequalities).

A screening process can help judge relevance and provides a record of both the process and decisions made.

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
Role: Head of medicines optimisation

**Title of the service/project or policy:**

Policy for working with the pharmaceutical industry

Is this a:

| | | | | | |
|---|---|---|---|---|---|
| X | Strategy / Policy | | Service Review | | Project |

If other, please specify:

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

•To assist the CCG in achieving its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry

•To ensure that the CCG and its staff respond consistently to approaches from the Pharmaceutical Industry and that the interests of patients, the public and the CCG are maintained
•Ensure staff comply with CCG 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.
•To assist NHS employers and staff in managing appropriate ethical standards in the conduct of NHS business
To highlight that NHS staff are accountable for achieving the best possible healthcare within the resources available
To highlight that NHS staff may be vulnerable to marketing techniques that may attempt to show some pharmaceutical companies in a more favourable light than is appropriate.

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

Consider the actual and potential impacts:

- [x] Staff
- [ ] service users/patients
- [ ] other public sector organisations
- [ ] voluntary / community groups / trade unions
- [ ] others, please specify:

| Questions | Yes | No |
|---|---|---|
| Could there be an existing or potential impact on any of the protected characteristic groups? | | x |
| Has there been or likely to be any staff/patient/public concerns? | | x |
| Could this piece of work affect how our services, commissioning or procurement activities are organised, provided, located and by whom? | | x |
| Could this piece of work affect the workforce or employment practices? | | x |
| Does the piece of work involve or have an impact on:<br>• Eliminating unlawful discrimination, victimisation and harassment<br>• Advancing equality of opportunity<br>• Fostering good relations | | x |

**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:**

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

# Governance, ownership and approval

| Please state here who has approved the actions and outcomes of the screening | | |
|---|---|---|
| **Name** | **Job title** | **Date** |
| Ewan Maule | Head of mediines optimisation | 01.07.2020 |

**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.**

A copy of all screening documentation should be sent to: **NECSU.Equality@nhs.net** for audit purposes.