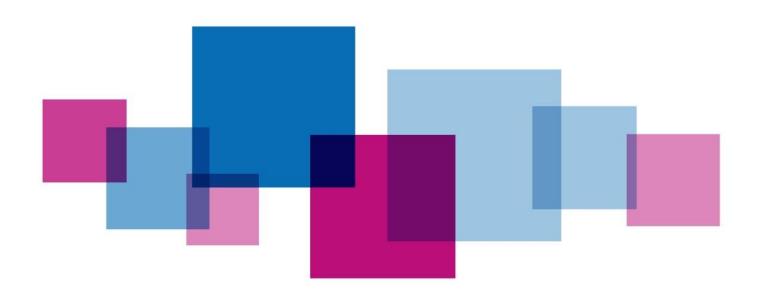


# Policy for the Sponsorship of Activities by and Joint Working with the Pharmaceutical Industry



#### Please complete the table below:

To be added by corporate team once policy approved and before placing on website

Policy ref no:	9
Responsible Executive Director:	Sarah Truelove, Deputy Chief Executive
	and Chief Finance Officer
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	Medicines Optimisation
	·
Date Approved:	March 2022
Approved by:	Governing Body
Date of next review:	March 2023

#### **Policy Review Checklist**

	Yes/ No/NA	Supporting information
Has an Equality Impact	Yes	EIA Screening has been
Assessment Screening been		completed which indicates
completed?		that a full assessment is not
		required
Has the review taken account of	Yes	The policy is aligned to the
latest Guidance/Legislation?		Revised Guidance on
		Managing Conflicts of
		Interest for CCGs (June
Lles legal advise been sevent?	No	2017)
Has legal advice been sought?	No	Advice has been provided by the Medicines Optimisation
		Team
Has HR been consulted?	No	The policy does not require
		specialist HR advice
Have training issues been	Yes	Mandatory training
addressed?		requirements are detailed in
		the policy. NHSE provides a

Are there other HR related issues that need to be considered?  Has the policy been reviewed by Staff Partnership Forum?  No There are no HR related issues raised in this policy  No The policy does not raise H issues and has not been reviewed by the staff partnership forum	that need to be considered? Has the policy been reviewed by Staff Partnership Forum?  Are there financial issues and have they been addressed?  What engagement has there been with patients/members of the public in preparing this	No No	mandatory training package which is completed annually. There are no HR related issues raised in this policy The policy does not raise HR issues and has not been reviewed by the staff partnership forum There are no financial issues arising from the application of the policy
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engagement with patients and members of the public.	~~··~, ·		1 .
and members of the public.			
	Are there linked policies and	Yes	
procedures? procedures are recorded in	•		· · · · · · · · · · · · · · · · · · ·
the policy	'		the policy
Has the lead Executive Director Yes Peter Brindle	Has the lead Executive Director	Yes	Peter Brindle
approved the policy?	approved the policy?		
	Which Committees have assured		Reviewed and agreed by the
the policy? Corporate Policy Review	the policy?		
Group which is not a			•
committee			committee
Has an implementation plan been Yes	Has an implementation plan been	Yes	
provided?	provided?		
	-	Yes	The policy will be published
with on the CCG website and	with		on the CCG website and
	• Staff?		intranet and will be featured
Patients?     in the internal news	<ul><li>Patients?</li></ul>		
Public?     communication. Regular	<ul><li>Public?</li></ul>		S .
prompts regarding			
internal communications.			declarations will be placed in
Will an audit trail demonstrating No	Will an audit trail demonstrating	No	internal communications.
receipt of policy by staff be	•	1.5	
required; how will this be done?			
·	. equ eq et i i i i i i be delle .	Yes	Yes this has been
		103	
required.	Has a DPIA been considered in regards to this policy?		



	Yes/ No/NA	Supporting information
Have Data Protection	Yes	
implications have been		
considered?		

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# Policy for the Sponsorship of Activities by and Joint Working with the Pharmaceutical Industry

#### 1 Introduction

NHS employees and contractors link with the pharmaceutical industry in a number of ways. Positive interaction with the pharmaceutical industry for the benefit of patients is encouraged, and the aim of this policy is to ensure that such interactions are subject to the appropriate probity and governance arrangements.

This policy provides a framework to assist CCG staff in determining when commercial sponsorship or a joint working agreement with the pharmaceutical industry is appropriate.

It sets out the principles and standards which should be applied when the employees of the CCG or their representatives engage with the pharmaceutical industry.

These principles and standards apply to all employees of the CCG, including any interim workers engaged by the CCG, all clinical leads, any elected office holders, and any Commissioning Support Unit employees acting on our behalf. It is strongly recommended that Member practices adopt this policy. It is essential that all projects or dealings with the Pharmaceutical Industry are open and transparent.

#### 1.1 BNSSG CCG Values

This policy supports the CCG values of the organisation by supporting staff to work collaboratively with the pharmaceutical industry, whilst maintaining appropriate ethical standards, to make improvements for the benefit of patients. This policy requires staff to act with integrity as it requires sufficient transparency about NHS activities to promote confidence between the organisation and its staff, patients and the public.

#### 2 Purpose and scope

It is recognised that CCG staff may wish to seek sponsorship from the pharmaceutical industry in order to progress a project or to enable training to go ahead.

The purpose of this policy is to provide a framework for the CCG in its interaction with pharmaceutical companies and other device and appliance manufacturers of prescribable products. It does apply to working with companies offering non-

prescribable products. The policy is to ensure that the interests of patients, public and NHS Bristol, North Somerset & South Gloucestershire CCG are upheld and maintained at all times.

It is recommended that staff liaise with the CCG Corporate Team in order to progress potential sponsorship requests in line with this policy. The Medicines Optimisation Team will provide support to the Corporate Team as required

The policy covers CCG support staff and includes advice for member practices. Whilst the policy does not cover providers of services to the CCG, providers would be expected to have their own policies for interaction with the pharmaceutical industry and have similar regard for good practice.

This policy must be read in conjunction with the <u>Standing Financial Instructions</u>, the <u>Information Governance Policy</u>, the <u>Managing Conflicts of Interest policy</u> and the <u>Gifts and Hospitality policy</u>.

#### 3 Duties – legal framework for this policy

NHS employers and employees need to maintain and demonstrate good standards and behaviours when dealing with other organisations.

Staff must be familiar with this policy and also be aware of the relevant NHS guidance, relevant legislation and appropriate professional codes of conduct.

In the interests of transparency, CCG employees are required to complete an annual Declaration of Interest form including any connection that they or a family member may have with other NHS Organisations or the pharmaceutical industry. This is outlined in further detail in the <u>Managing Conflicts of Interest</u> and <u>Gifts and Hospitality</u> policies.

NHS staff should be aware that pharmaceutical industry representatives must follow the ABPI (Association of the British Pharmaceutical Industry) <u>Code of Practice</u>. Representatives of the medical technology industry should follow the standards set out in the ABHI (Association of British Healthcare Industries) <u>Code of Business Practice</u>

These codes of practice are designed to ensure a professional, responsible and ethical approach to the promotion of prescription medicines and devices /medical technologies in the UK through self-regulation. A member of NHS staff who believes that an industry representative has broken the code of practice can report their complaint to the Director of the Prescription Medicines Code of Practice Authority (PMCPA) at <a href="mailto:complaints@pmcpa.org.uk">complaints@pmcpa.org.uk</a> Where necessary staff will also report to the CCG Local Counter Fraud Specialist for potential investigation, contact details can be found under section 14.1.



#### 3.1 UK Disclosure Database

In June 2016 the Association of British Pharmaceutical Industry (ABPI) launched Disclosure UK, a searchable online database showing payments and benefits in kind made to NHS staff and organisations by the pharmaceutical industry for key collaborations including speaking at and chairing meetings and symposia, training services, and participation in advisory board meetings.

Disclosure UK provides a valuable opportunity for healthcare professionals to further demonstrate their integrity in the eyes of patients and the public, which is why reference to it is included in the NHS England guidance on managing conflicts of interest.

Disclosure data is published annually in June, one year in arrears. Responsibility for submitting data to the website lies with the pharmaceutical companies, although healthcare professionals are required to give consent for disclosure of the payments made to them. It is expected that all BNSSG CCG employees will agree and give consent for disclosure. This should also be declared on the CCG register.

The information published on the Disclosure UK website includes:

- Healthcare professional's name
- Healthcare professional's principal practicing address
- The payment amount or equivalent benefit in kind in four categories:
  - o registration fees
  - travel and accommodation
  - o fees for service or consultancy
  - o related expenses for fees for service or consultancy
- Pharmaceutical company name

The ABPI only receives individual level data from companies where they have consent from healthcare professionals. This is the data which appears on the live database. Healthcare professionals are able to log on to a secure website to view the data that will be published before it goes live and raise any questions about the data before it is made public.

The CCG expects any staff member who does any work on behalf of pharmaceutical companies to allow disclosure of any payments on the UK Disclosure database, regardless of whether this is done in work time, or the employees own time.

In addition, any work with pharmaceutical companies should be recorded on the CCGs Conflict of Interest Register; this can be done through completing the Declaration of Interest form which are is available on BNSSG intranet known as The Hub.

Any pharmaceutical industry sponsorship of events or projects should be reported to the CCG by completing a Declaration of Gifts, Hospitality and Sponsorship form which is available on The Hub and emailed to <a href="mailto:bnssq.corporate@nhs.net">bnssq.corporate@nhs.net</a>



The CCG recommends all commissioned provider organisations ensure that their employees allow disclosure, in line with requirements in the NHS standard contract.

#### 4 Responsibilities and Accountabilities

#### **Chief Executive**

• Has overall accountability for the CCG's management of conflicts of interest and gifts, hospitality, and sponsorship

#### **Line Managers**

- Ensure members of their team are aware of and follow this policy.
- Provide basic advice on how working with the pharmaceutical industry should be managed, escalating queries to the Corporate Governance Team as necessary.
- Line managers should ensure that there is a process within their team to record any work with the pharmaceutical industry and that it is fed into the corporate team on a regular basis.

#### **Corporate Secretary**

- Maintains a database of all the sponsorship activity across the CCG
- Provides advice, support and guidance on how joint working with the pharmaceutical industry should be managed, when considering entering into working arrangements with support from Medicines Optimisation.
- Ensures that the appropriate administrative processes are in place to ensure compliance with legislation and statutory guidance.

#### **Medicines Optimisation Team**

- To hold an auditable trail of meeting requests from pharmaceutical representatives & register of all meetings.
- All medicines/medical device rebates must be approved through the
  assessment process in appendix B. The assessment must be carried out by
  one of the Principal Medicines Optimisation Pharmacist and a record of the
  completed assessment should be stored with the contract, so that there is an
  auditable trail. The assessment form must be completed before a rebate
  agreement is signed up to.
- Provide support to Corporate Secretary & other staff in relation to queries relating to joint working with the pharmaceutical industry where required.

#### **Individuals**

Every individual has the responsibility to ensure that they are aware of and maintain appropriate ethical standards in the conduct of NHS business when working with the pharmaceutical industry and other relevant commercial organisations.



Staff involved in working with the pharmaceutical industry will assess and understand the costs and benefits of any such agreement, to ensure that the decision-making process is transparent and defensible. Staff have a responsibility to declare any work with the pharmaceutical company through a declaration of interest form and maintain appropriate records including in relation to meeting requests.

Should there be any doubt about the appropriateness of accepting sponsorship; staff should seek advice from their line manager or the corporate team. Staff have a responsibility to report pharmaceutical sponsorship of events or projects by completing a declaration of gifts, hospitality and sponsorship form.

Staff must make it clear to sponsors that sponsorship does not equate to endorsement of a company or its products

Staff are obligated to report any activities which they believe do not comply with this policy in line with Counter Fraud requirements

#### Other

Anyone working on the CCG's behalf (e.g. Commissioning Support Unit) need to adopt and work under this policy. The CCG has the responsibility for ensuring that individuals are aware of this policy.

#### All Individuals – Disclosure UK Database

Disclosure UK provides a valuable opportunity for healthcare professionals to further demonstrate their integrity in the eyes of patients and the public. All CCG staff who undertake work with pharmaceutical companies must agree to the disclosure of payments and other benefits in kind on the UK Disclosure database. All work undertaken with pharmaceutical companies must also be recorded on a Declaration of Interest Form and given to the Corporate Governance Team.

#### 5 Definitions/explanations of terms used

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 appliances, dressings, nutritional supplements and medical devices 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 Clinical Commissioning Groups.

For the purposes of this policy, commercial sponsorship is defined as including:

- NHS funding from an external source, including funding of all or part of the costs of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs (including trips abroad), provision of free services (speakers), buildings or premises.
- Donations and grants are funds, benefits-in-kind or services freely given for the
  purpose of supporting healthcare, scientific research or education, with no
  consequent obligation on the recipient organisation, institution and the like to
  provide goods or services to the benefit of the pharmaceutical company in return.
  Donations and grants to individuals are prohibited. In general, donations are
  physical items, services or benefits in-kind which may be offered or requested.
  Grants are the provision of funds.

Joint working differs from sponsorship. Sponsorship can be described as pharmaceutical companies simply providing funds for a specific event or work programme.

The Department of Health defines joint working between the NHS and the pharmaceutical industry 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.

For further information on Joint Working, see **Section 7** 

#### **6** Commercial Sponsorship from the Pharmaceutical Industry

Sponsorship of NHS events by external parties is valued. Offers to meet some or part of the costs of running an event can secure the ability to take place, benefiting NHS staff and patients. Without sponsorship there may be fewer opportunities for learning, development and joint working. However, there is a potential for conflicts of interest to arise as a result there should be proper safeguards in place.

Members of CCG staff should consult the <u>"Managing Conflicts of Interest"</u> and <u>"Gifts and Hospitality"</u> policies and ensure that they are aware of the statutory requirements from NHS England in the document <u>Managing Conflicts of Interest: Revised Statutory Guidance for CCGs</u> if they are offered sponsorship, gifts, hospitality or expenses from the pharmaceutical industry.

If members of staff are in any doubt about accepting a gift, hospitality, sponsorship or expenses from the Pharmaceutical Industry they should consult their line manager in



the first instance. Alternatively they can consult the Corporate Services Team or the Medicines Optimisation Team.

As a general rule, any donation and grants should ideally be provided in the form of a written agreement in line with donations and grants arrangement as set out in clause 23 of the <u>ABPI code of practice 2021</u>. This facilitates donation and grants without any element of promotion of a product.

Donations and grants to healthcare organisations, patient organisations or other organisations are only allowed if they:

- o are made for the purpose of supporting healthcare, scientific research or education
- o do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines
- o are prospective in nature
- o do not bear the name of any medicine although they may bear the name of the company providing them.

#### 6.1 Principles

All offers of sponsorship, funding or gifts from the pharmaceutical industry must comply with the ABPI code of practice.

Clinical decisions must always be made in the best interest of patients. No sponsorship agreements are acceptable that compromise clinical judgement or are not in line with local policy or guidelines. The CCG should make it clear that sponsorship does not equate to endorsement of a company or its products.

Prior written agreement between authorised CCG officers and prospective sponsors must be obtained for all sponsorship arrangements and include details of any agreed payments.

All agreements must include a mutually agreed and effective exit strategy 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.

In any agreement with the pharmaceutical industry, patient and data confidentiality should comply with legal and ethical requirements for the protection and use of patient information and other NHS information. Use of patient identifiable information must be consistent with Caldicott principles and CCGs individual Information Governance policies. Under no circumstances should representatives of the pharmaceutical industry be accessing patient's records in order to make changes to their prescribed medicines, appliances or devices.

Sponsorship agreements which involve several sponsors are to be preferred to those which involve a single sponsor.



Sponsorship arrangements involving CCGs should be at a corporate rather than individual level.

Joint Working with the Pharmaceutical Industry will not influence formulary decisions under any circumstances and should not conflict with current CCG guidelines or the Joint Formulary.

#### 6.2 Authorisation

All offers of gifts, hospitality or sponsorship in any form to CCG and its staff will require authorisation. All offers should be authorised in line with the <u>Gifts and Hospitality Policy</u>. Sponsorship of events should only be approved if a reasonable person would conclude that the event would result in a clear benefit for the organisation and the NHS.

#### 6.3 Gifts

See Gifts and Hospitality Policy

#### 6.4 Meetings and Hospitality

See Gifts and Hospitality Policy

#### 6.5 Training and Education

Employees must seek authorisation from their line manager before attending events sponsored by the pharmaceutical industry and make it clear to the trainer that their attendance is without endorsement of the sponsor's products.

Managers should be careful to ensure that staff are not pressurised by the sponsors of training to alter their own practice to accord with the sponsors wishes where these are not backed up by appropriate evidence or are contradictory to current guidelines. Note that the receipt of training funded by the pharmaceutical industry might be considered a gift, or a potential perceived conflict of interest. Therefore, it is essential that the Gifts and Hospitality Policy and Managing Conflicts of Interest Policy are referred to before any 'gift' is accepted and this must be declared using the Declaration of Gifts, Hospitality and Sponsorship form which can be found on The Hub.

#### 6.6 Clinical review services offered by the Pharmaceutical Industry

Pharmaceutical companies sometimes offer clinical based review services to CCGs, or to individual GP practices.

In order to ensure that these reviews fit with the strategic priorities of the CCG, and are in line with the BNSSG Joint Formulary, all BNSSG CCG employees must direct companies offering such review services to the Medicines Optimisation Team; it is strongly encouraged that practices also direct companies to the Medicines Optimisation Team, so that the overall impact (including clinical and financial impact) can be assessed.

#### **6.7 Samples of Medicinal Products**

The <u>ABPI code of practice 2021 Clause 21</u> governs the acceptance of samples of medicinal products.



A sample is a small supply of a medicine provided to a health professional so that they may familiarise themselves with it and acquire experience of dealing with it.

Samples may only be provided to a professional qualified to prescribe that product. They must not be provided to other relevant decision makers. No more than four samples of a particular medicine may be provided to an individual during the course of a year.

Samples may only be supplied in response to written requests which have been signed and dated. A sample must be no larger than the smallest presentation of a medicine on the UK market, be labelled as a free medical sample, not for resale (or similar), and accompanied by a copy of the summary of product characteristics.

## 6.8 Access to Staff and Premises by Representatives of the Pharmaceutical Industry

The <u>ABPI code of practice 2021 Clause 17</u> details the standards expected of representatives of the Pharmaceutical Industry.

"Representatives must ensure that the frequency, timing and duration of calls on health professionals and other relevant decision makers in hospitals and NHS and other organisations, together with the manner in which they are made, do not cause inconvenience. The wishes of individuals on whom representatives wish to call and the arrangements in force at any particular establishment, must be observed. When briefing representatives, companies should distinguish between expected call rates and expected contact rates."

The Medicines Optimisation Team will be the default point of contact for all Pharmaceutical Industry representatives wishing to discuss information pertaining to medicinal products.

First contact by a pharmaceutical company representative should be directed to the team administrators supporting the Medicines Optimisation team via <a href="mailto:bnssg.medicines-optimisation@nhs.net">bnssg.medicines-optimisation@nhs.net</a>.

If a representative of a pharmaceutical industry contacts a CCG Clinical lead directly to ask for a meeting, the clinical lead should initially decline and refer the representative to the Deputy Director (Medicines Optimisation), Associate Director Medicines Optimisation or a Principal Medicines Optimisation Pharmacist for further discussion.

It is best practice that representatives are only seen by appointment, and they should be asked to complete the appropriate form (see Section 16 Appendix A)

A record will be kept of all meetings by the Medicines Optimisation Team and will be available to anyone requesting such information under the Freedom of information legislation.

The proposed subject of the appointment should be advised by e-mail, along with any supporting references. Information should be provided electronically, rather than as a



hard copy. CCG staff must request that the appropriate form is completed (Section 16 Appendix A)

The Medicines Optimisation Team will expect to be given the following information at these meetings:

- Drugs / developments about which the company representative is talking to local GPs, if he/she has access to GPs
- The evidence on which these drugs are being promoted
- What approaches are being made to local prescribers

Due to the priority that must be allocated to NHS work, from time to time it may be necessary to change appointments, in which case every effort will be made to offer an additional appointment. A mobile phone number should be left at the time of booking.

See Appendix A for a form which must be used to capture all information required from representatives at the time of booking an appointment

#### 6.9 Research and Clinical Trials

Research and clinical trials are not covered within this policy. The CCG Research and Evidence Team are responsible for research management and governance within Bristol, North Somerset and South Gloucestershire CCG and can be contacted via their website <a href="https://bnssqccg.nhs.uk/about-us/what-we-do/research-and-evidence/">https://bnssqccg.nhs.uk/about-us/what-we-do/research-and-evidence/</a>

#### 7 Joint Working with the Pharmaceutical Industry

Joint working between the pharmaceutical industry and the NHS must be for the benefit of the patients or the NHS and ensure the quality of patient care. Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner.

It is required that every joint working project will have a formal agreement document in place setting out what each party has agreed before the project begins. It should also clearly define the benefits to both parties, of the joint working agreement. Clearly defined, mutually agreed exit criteria must be written into joint working agreements at the outset.

The Association of the British Pharmaceutical Industry (ABPI) have published a Joint Working Toolkit – a Guide for NHS and Pharmaceutical Industry partners, that contains a guide to choosing the most appropriate model for cross-sector working in conjunction with a ten step process that should be followed when developing a joint working project: <a href="https://www.abpi.org.uk/publications/joint-working/">https://www.abpi.org.uk/publications/joint-working/</a>

The purpose of the toolkit is to provide information and give access to tools which will help with joint working. The toolkit should be utilised when considering joint working arrangements with the pharmaceutical industry or other commercial organisations. The document also contains example case studies of joint working between the NHS



and the pharmaceutical industry and may be referred to for examples of joint working agreements in other areas.

Staff should refer to the CCG's <u>Standing Financial Instructions</u> for governance arrangements for authorisation of contracts that enable CCGs to receive funding from a third party.

Any proposed joint working must have organisational approval at the Commissioning Executive Committee unless clear delegation has been given.

#### 8 Examples of Potential Conflict

The Department of Health published examples of potential conflict of interest in Commercial Sponsorship – Ethical Standards for the NHS November 2000 and can be accessed via the link below

http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/dr consum dh/groups/dh digitalassets/@dh/@en/documents/digitalasset/dh 407607 8.pdf

The monitoring arrangements for gifts, hospitality or sponsorship in any form to CCGs and their staff are outlined in the <u>Gifts and Hospitality Policy</u> and the <u>Managing Conflicts of Interest Policy</u>

# 9 Primary Care Rebate Schemes offered by Pharmaceutical Companies

Primary care prescribing rebate schemes are contractual agreements offered by pharmaceutical companies or other third party companies which offer a financial rebate on primary care prescribing for a particular named medicine or device. This section sets out the framework and principles on how BNSSG CCG will consider primary care prescribing rebate schemes. All primary care prescribing rebate scheme proposals will be considered on clinical, financial and contractual grounds.

#### 9.1 Core Principles

 Rebate schemes should only be considered if the medicine in question is appropriate for BNSSG CCG patients, and already accepted onto the BNSSG Formulary or BNSSG Prescribing Guidelines through the usual process based on consideration of clinical effectiveness, resource implications, patient factors and safety. Acceptance of a rebate scheme should not constrain the existing local decision-making processes or formulary development and should not influence treatment decisions for individual patients. In summary,



- any financial benefit accrued from these schemes should be viewed as incidental and not as a driver for local population or individual decision-making.
- Rebate schemes should only be entered into for UK licensed medicines and be based on use of the medicine in accordance with the medicines Summary of Product Characteristics (SPC). Where there is more than one licensed indication for a medicine, the scheme should cover all indications. Rebate schemes promoting unlicensed or off-label use will not be entered into.
- Primary care rebate schemes should be agreed at a CCG organisational level, they should not be agreed at GP practice level.
- Schemes encouraging exclusive use of a particular drug should be avoided and BNSSG CCG should not enter into any schemes that preclude them from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. The CCG should not enter into schemes that require them to provide information to a manufacturer about competitor products market share.
- Resilience of supply of relevant products is important. The availability of the
  product should match the likely uptake should the scheme be adopted widely
  within BNSSG. This is not a contractual element but reassurance will be
  sought that any significant increase or spike in demand can be managed by
  the company.
- The administrative burden to the NHS of setting up and running the scheme must be factored into the assessment of the likely financial benefit of the scheme, managing the scheme should be minimal once the scheme has been agreed.
- All rebate schemes should be considered on their own merits using the same criteria (see Appendix B)
- The proposed scheme should not be directly linked to requirements to increase market share or volume of prescribing. In practice only schemes that offer a simple discount based on ePACT prescribing data are likely to be approved. There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.
- Agreements must meet the requirements of the General Data Protection Regulations (GDPR) and patient confidentially must never be compromised.
- A formal written contract is required, signed by both parties to ensure that the
  terms of the scheme are clear and to maximise legal protection. Agreements
  should include a right to terminate on notice (i.e. without having to have any
  reason for doing so) with a sensible notice period e.g. three or six months.
- Information relating to rebate schemes is disclosable under Freedom of Information (FOI). This should be discussed with the manufacturer before any agreement is entered into. Ideally, redacted non-commercial contracts should be provided as commercially sensitive information is contained in the contract. A further source of advice is available from PrescQIPP.(PrescQIPP is an NHS



funded not-for-profit organisation that supports quality, optimised prescribing for patients and BNSSG CCG subscribe to this resource. It produces evidence-based resources and tools for primary care commissioners, and provide a platform to share innovation across the NHS, which includes a section on Rebate Schemes)

#### 9.2 Types of Rebate Scheme

#### 9.2.1 Price Discount

In these schemes, the pharmaceutical company would offer a simple discount on the price of the medicine or device (i.e. the NHS would receive a discount of a proportion of the list price). The agreement with the pharmaceutical company would usually set out the data that the CCG has to supply about the prescription of the drug in order to claim the discount.

#### 9.2.2 Volume Rebate on Price Schemes

These schemes work in a similar way to simple price discount schemes. The level of discount received is however based on the volume of the medicine or device that is prescribed. These schemes offer a greater financial reward if the market share of the relevant product increases.

#### 9.2.3 Risk Sharing Schemes

These are agreements between the NHS and pharmaceutical companies that aim to reduce the impact on the prescribing budget of new and/ or existing medicines brought about by either uncertainty of the value of the medicine and/ or the need to work within finite budgets.

The agreement should set the scope and realise the mutual obligations between both the NHS and pharmaceutical companies depending on the occurrence if an agreed condition – the 'risk'. The 'risk' varies by situation and can include pharmaceutical expenditure higher than agreed thresholds.

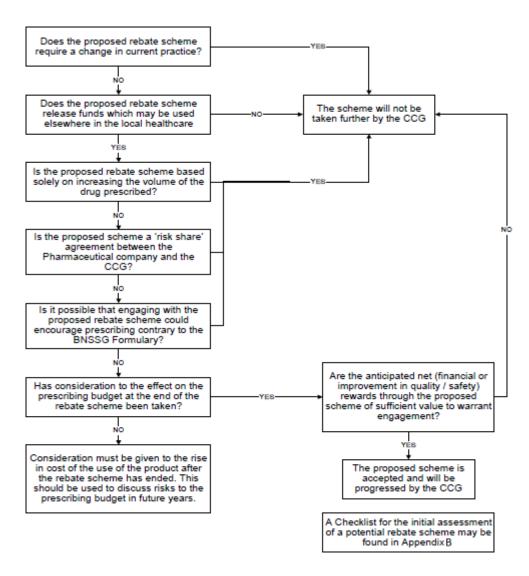
The CCG does not normally enter into these types of agreements.

#### 9.3 Governance and Management

- In entering into such schemes with a pharmaceutical industry there are a number of questions which must be asked to ensure that the proposal is in the best interests of both patients and the organisation and the local NHS.
   All proposals must be treated equally, and decisions made will need to stand up to scrutiny if questioned
- Initial screening will be carried out by a Principal Medicine Optimisation pharmacist who will screen the proposed rebate scheme in line with the schematic flow diagram (overleaf) and using the Screening Questions to

- consider a rebate checklist (Appendix B) to evaluate whether the scheme is appropriate to consider.
- In addition wherever possible schemes will have been evaluated through the PrescQIPP rebate scheme and when this is the case only schemes rated by the PrescQIPP process as amber or grey will be considered (Grey = No significant reservation, Amber = Not fully appropriate and RED = not suitable)
- In cases where a scheme is agreed, the CCG will ensure that the agreement entered in to states that the pharmaceutical company that is offering the scheme will not use CCG engagement in the scheme to promote their company's activities that are related to this agreement, or in any other promotional activity for their benefit.

The schematic (below) details how progression of a rebate scheme will be determined by the CCG.



#### 9.3.1 Process for Approval of Rebate Schemes

- All approaches from the pharmaceutical industry with proposals for rebate will be coordinated by the Medicines Optimisation Team who will initially screen each proposal and filter out any that do not adhere to the principles.
- Those that do adhere will be considered and where appropriate, signed off by the Medicines Optimisation Control Centre.
- In line with the agreed CCG sign off process, the contract with the Pharmaceutical Industry will be signed by;
  - Rebate generating >£50,000 per year signed by Chief Finance Officer (CFO) or Deputy CFO and Medical Director (Clinical effectiveness or Deputy Director (Medicines Optimisation)) or
  - Rebate generating <£50,000 per year signed by Deputy CFO or Deputy Director (Medicines Optimisation)
- The Deputy Director (Medicine Optimisation) or one of the Principal pharmacists will hold the formal agreements and notify the finance department of each scheme.

#### 9.3.2 Process for Monitoring the Implementation of rebate schemes

- A clear audit trail must exist detailing the evaluation of schemes, their approval, and the process by which contracts are drawn up and signed in line with this, and other relevant CCG policies.
- The Medicines Optimisation Team and Finance Lead will be responsible for the provision of a clear audit trail and for undertaking the administration tasks associated with schemes that have been approved (for example, the supply of prescribing volume data).

Each scheme should have a signed agreement which should include clearly defined, mutually agreed exit criteria. Any income from rebate schemes must be credited to the CCG's bank account and should be attributed to the same cost centre that primary care prescribing costs are attributed to.

Specific details of rebate schemes entered into by BNSSG CCG may be confidential and commercially sensitive and therefore such details are not publically available documents. However, the register of which schemes the CCG has signed up to will be a public document available on the BNSSG website.

The Medicine Optimisation Team will be responsible for the upkeep of the register, including financial details and will work with finance colleagues to ensure appropriate invoicing to the relevant pharmaceutical industries takes place on a quarterly basis (or as per contractual agreement)



# 10 Free of charge (FOC) medicines schemes and commercial offers for High Cost Drugs

#### 10.1 FOC medicines schemes

The advice and guidance of the Regional Medicines Optimisation Committee (RMOC) is followed. <a href="https://www.sps.nhs.uk/articles/free-of-charge-foc-medicines-schemes-rmoc-advice-for-adoption-as-local-policy/">https://www.sps.nhs.uk/articles/free-of-charge-foc-medicines-schemes-rmoc-advice-for-adoption-as-local-policy/</a>

#### In summary:

- A free of charge medicines scheme is defined as an arrangement where a UK licensed or unlicensed medicine is provided free of charge by the pharmaceutical company to an individual patient or an identified cohort of patients.
- Commissioners and providers must only undertake a free of charge scheme if the principles outlined in this policy are followed.
- Trusts or commissioners should not sign up to a free of charge (FOC) scheme which is solely offering a licensed medicine free of charge in advance of NICE approval.

#### 10.2 Commercial offers

In addition to free stock schemes, providers and commissioners may be approached with a variety of commercial offers post-NICE publication that may involve, for example, discounted stock/additional clinical support through patient support schemes etc. that may be over and above those negotiated by the NICE patient access schemes. Each offer will be shared and scrutinised by the BNSSG STP High Cost Drugs Group to ensure that a number of appropriate good practice principles are met to ensure that the offer is equitable, transparent and does not compromise patient care in any way.

#### 11 Training requirements

The information and responsibilities within this policy will be disseminated to staff by the publication of this policy on the BNSSG CCG website and intranet. Conflict of interest training which includes gifts and hospitality is mandatory for all staff and is to be completed annually. Conflicts of interest packages are provided by NHS England and are available on ConsultOD. Training compliance rates are recorded as part of the CCG's annual conflicts of interest audit.

#### 12 Equality Impact Assessment

All relevant persons are required to comply with this document and must demonstrate sensitivity and competence in relation to the nine protected characteristics as defined by the equality Act 2010. If you, or any other groups,



believe you are disadvantaged by anything contained in this document please contact the Document Lead (author) who will then actively respond to the enquiry.

#### 13 Implementation and Monitoring Compliance and Effectiveness

An implementation plan has been prepared is attached at appendix E. Compliance with this policy will be monitored by the Corporate Governance team. Reports on Conflicts of interest and Gifts, Hospitality and Sponsorship are presented to the Audit, Governance and Risk Committee. The Corporate Governance team review Disclosure UK on an annual basis and reconcile the online database to the Gifts, Hospitality and Sponsorship register. Any discrepancies are investigated by the Corporate Governance team and either added to the Gifts, Hospitality and Sponsorship register or reported to the Disclosure UK team.

#### 14 Countering Fraud

#### 14.1 Fraud and Bribery Statement

The CCG has a zero-tolerance approach to acts of Fraud and Bribery. Any suspicions or concerns of acts of fraud or bribery can be reported confidentially, either to the Local Counter Fraud Specialist, online via <a href="https://cfa.nhs.uk/reportfraud">https://cfa.nhs.uk/reportfraud</a>, or via the NHS Fraud and Corruption Reporting Line on 0800 028 40 60. All calls are dealt with by experienced trained staff and any caller who wishes to remain anonymous may do so.

#### **14.2 Fraud**

The Fraud Act 2006 created a criminal offence of Fraud and defines three main ways of committing it:

- Fraud by false representation (e.g. falsely representing a payment from a pharmaceutical company);
- Fraud by failing to disclose information (e.g. failing to disclose payments made by a pharmaceutical company); and
- Fraud by abuse of position (e.g. abusing one's position to gain from a pharmaceutical payment).

In these cases, an offender's conduct must be dishonest and their intention must be to make a gain or cause a loss (or the risk of a loss) to another.

#### 14.3 Bribery

The Bribery Act 2010 defines bribery as giving or receiving an advantage (financial or other) in return for performing a function improperly. This could include receiving money from a pharmaceutical company to induce improper performance when conducting CCG business. There are four different classifications of bribery:



- Bribing another person
- Being bribed
- Bribing a foreign public official,
- Failure to prevent bribery

Any offering, promising, giving, requesting, agreeing to, receiving or accepting of any bribe is strictly forbidden by any employee when conducting business on behalf of the CCG or when representing the CCG in any capacity and is contrary to the Bribery Act 2010.

The CCG has a zero-tolerance approach to acts of Fraud and Bribery committed by its staff. Any suspicions or concerns of acts of fraud or bribery can be reported confidentially, either to the Local Counter Fraud Specialist, online via <a href="https://cfa.nhs.uk/reportfraud">https://cfa.nhs.uk/reportfraud</a> or via the NHS Fraud and Corruption Reporting Line on 0800 028 40 60. All calls are dealt with by experienced trained staff and any caller who wishes to remain anonymous may do so.

#### 15 References, acknowledgements and associated documents

- BNSSG CCG Standing Financial Instructions https://bnssgccg.nhs.uk/library/detailed-financial-policies/
- BNSSG CCG Information Governance Policy <a href="https://bnssgccg.nhs.uk/library/information-governance-policy1/">https://bnssgccg.nhs.uk/library/information-governance-policy1/</a>
- BNSSG CCG Managing Conflicts of Interest Policy https://bnssgccg.nhs.uk/library/managing-conflicts-of-interest-policy/
- BNSSG CCG Gifts and Hospitality Policy <a href="https://bnssgccg.nhs.uk/library/gifts-and-hospitality-policy/">https://bnssgccg.nhs.uk/library/gifts-and-hospitality-policy/</a>
- Association of the British Pharmaceutical Industry Code of Practice http://www.pmcpa.org.uk/thecode/Pages/default.aspx
- Association of British HealthTech Industries Code of Ethical Business Practice https://www.abhi.org.uk/resource-hub/file/8860
- Managing conflicts of interest: revised statutory guidance for CCGs 2017 <a href="https://www.england.nhs.uk/publication/managing-conflicts-of-interest-revised-statutory-guidance-for-ccgs-2017/">https://www.england.nhs.uk/publication/managing-conflicts-of-interest-revised-statutory-guidance-for-ccgs-2017/</a>
- ABPI code of practice 2021 Clause 23 <a href="https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf">https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf</a>
- ABPI code of practice 2021 Clause 21 <a href="https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf">https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf</a>
- ABPI code of practice 2021 Clause 17 <a href="https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf">https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf</a>
- BNSSG CCG Research and Evidence https://bnssgccg.nhs.uk/about-us/what-we-do/research-and-evidence/
- The Association of the British Pharmaceutical Industry (ABPI) Joint Working Toolkit
  - https://www.abpi.org.uk/publications/joint-working/
- The Department of Health Ethical Standards for the NHS November 2000 http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov



<u>.uk/dr consum dh/groups/dh digitalassets/@dh/@en/documents/digitalasset/dh 4076078.pdf</u>

- Free of charge (FOC) medicines schemes
   https://www.sps.nhs.uk/articles/free-of-charge-foc-medicines-schemes-rmoc-advice-for-adoption-as-local-policy/
- BNSSG CCG Fraud and Bribery Policy <u>https://bnssgccg.nhs.uk/library/fraud-and-bribery-policy/</u>

#### 16 Appendices

### 16.1 Appendix A. Pharmaceutical Company Representative Visit Request Form

This form is for pharmaceutical industry representatives requesting a meeting with CCG staff in accordance with clause 17 of the ABPI Code of Practice for the Pharmaceutical Industry 2021

Pharmaceutical Company:	Date:
Representative's Name	
Contact Telephone number	
Email	

#### Procedure

1. Please provide brief reasons for wishing to discuss each product in the comments section underneath each product. Include a link to the SPC (where applicable) and the cost to the NHS.



- 2. Please cite the journal articles where relevant clinical trials have been published
- 3. Our staff will consider whether a meeting is mutually beneficial and if it is they will get in touch to arrange a suitable appointment time. Note that telephone appointments may be preferred.

Product 1 - Name (	(Generic Pro	prietary)	)	

Is it a new product? Yes / No	Is the product currently on the BNSSG Joint Formulary? Yes / No	Recent change to evidence base? Yes / No	Recent price change? Yes / No
0			
Comments:			

#### Product 2 – Name (Generic & Proprietary).....

Is it a new	Is the product currently on the BNSSG Joint Formulary? Yes / No	Recent change to	Recent price
product?		evidence base?	change?
Yes / No		Yes / No	Yes / No
Comments:			

Product 3 – Name (Generic & proprietary).....



Is it a new product? Yes / No	Is the product currently on the BNSSG Joint Formulary? Yes / No	Recent change to evidence base? Yes / No	Recent price change? Yes / No
Comments:			
ANV OTHER	R SUPPORTING INFORM	MATION:	
ANT OTHER	A SUFFORTING INFORM	IATION.	
6.2 Append	lix B. Screening questi	ions when considering a	a rebate
scheme	•		
Poproducod w	vith normission from NHS	London Procurement Partne	orchin
reproduced w	nui peimission nom Ni is	London Frocurement Faithe	zi Si ii p
Date:			
Name of Drug:			
Company Nam			
Company Cont	ract:		
Version of con	tract		
assessed:			
(with track cha	nges if		
2nd version submitted)			
Date assessed			
Assessor name			
Date assessed	by		



**Medicines** 

<b>Optimisation Control</b>	
Centre	

Demonstration of compliance with the criteria highlighted and marked with an asterisk below is mandatory before a rebate scheme will be assessed or re-assessed by Bristol, North Somerset, South Gloucestershire CCG. Before submission to the CCG, manufacturers are asked to make sure that their proposals provide ALL relevant information.

illiorillation.			ı	
Issue		Good practice principles (*Mandatory)	Indicate 'met' or 'not met'	Comments
1. Product-	1	Before any consideration of price,		
related		the clinical need for the medicine		
	1	and its place in care pathways		
		should have been agreed by		
		established local decision-making		
		processes. The clinical decision		
		should inform the		
		financial/procurement decision		
		and not vice versa.		
	1	Health professionals should		
		always base their prescribing		
	2	decisions primarily on		
		assessments of their individual		
		patients' clinical circumstances.		
		The impact of a rebate scheme is		
		a secondary consideration.		
	1	Any medicine considered under a		
		Primary Care Rebate Scheme		
	3	(PCRS) must be licensed in the		
	*	UK. Where there is more than one		
		licensed indication for a medicine,		
		a scheme should not be linked to	*Mandatory	
		a particular indication for use.	field	
	1	Rebate schemes promoting		
		unlicensed or off label uses must		
	4	not be entered into. All		
	*	recommendations for use of a		
		medicine within a PCRS must be		
		consistent with the Marketing		
		Authorisation of the medicine in		
		question i.e. the PCRS should		
		only advocate the use of the drug		
		in line with the data sheet for the	*Mandatory	
		drug in question.	field	

	1 5	Medicines not recommended by NICE might still be the subject of a PCRS, but specific and documented consideration must be given to how such a product can properly be recommended to prescribers notwithstanding NICE's position. CCGs will need to explain how the scheme helps it meet its duty to use its resources effectively, efficiently and		
		economically.		
2. Rebate scheme- related	2 1	Decision making processes should be clinically-led and involve all appropriate stakeholders, including patients where appropriate.		For local determination
	2 . 2	Rebate schemes should be approved through robust local governance processes that include Medicines Optimisation Committee/Area Prescribing Committee (or equivalent) approval, involving both primary and secondary care and Director level approval.		For local determination
	2 . 3 *	The administrative burden to the NHS of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme.  Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.  Primary care rebate schemes should be agreed at a statutory organisational level, they should	*Mandatory field *Mandatory	
	*	not be agreed at GP practice level.	field	
	2 5	Schemes encouraging exclusive use of a particular drug should be avoided.		

2	Rebate schemes for medicines in		
-	Category M and some medicines		
6	in Category C of the Drug Tariff,		
	should be especially carefully		
	considered because of the		
	potential wider impact on		
	community pharmacy		
	reimbursement. Short term local		
	savings are likely to be offset by		
	increased costs to the wider NHS		
	in the longer term. Schemes which		
	promote prescribing of branded		
	generics or original brands in		
	preference to generics pose the		
	added risk that they undermine the		
	concept of generic prescribing.		
2	Ideally the PCRS should not be		
_	directly linked to requirements to		
7	increase market share or volume		
<b>'</b>	of prescribing.		
0			
2	Schemes which link a rebate		
	directly to increase in volume of		
8	prescribing above a defined		
	threshold could be judged to be an		
	attempt to influence prescribing		
	inappropriately and should		
	generally be avoided. The		
	administrative burden of		
	monitoring such schemes should		
	be carefully considered.		
2	Commissioners should ensure that		
	a formal written contract is in		
9	place, signed by both parties to		
*	ensure (i) that the terms of the		
	scheme are clear and (ii) to		
	maximise the legal protection. All		
	negotiations around a scheme		
	should be expressed as being		
	"subject to contract" i.e. not		
	binding until the formal contract	*Mandatory	
	has been signed by both parties.	field	
2	PCRS agreements should include		
	a right to terminate on notice (i.e.,		
1	without having to have any reason		
0	for doing so) with a sensible notice	*Mandatory	
*	period e.g. three or six months.	field	
2	The need for exit criteria and an	IIGIU	
	exit strategy should be considered		
1	before a scheme is agreed. It is		
1	essential to allow flexibility to	***	
*	respond to emergence of	*Mandatory	
	significant new clinical evidence,	field	

			I	
		or significant changes in market		
		conditions. A shorter notice period		
		should be agreed in these		
		circumstances.		
	2	Is the value of the offer		
		quantifiable and proportionate to		
	1	the administrative burden? Is there		
	2	an appropriate return on	*Mandatory	
	*	investment?	field	
	2	Schemes which link a rebate to		
		prescribing of more than one drug		
	1	should be especially carefully		
	3	considered to avoid the risk that		
		savings made on one are		
		indirectly offset by costs incurred		
		on another.		
3.	3	Primary Care Organisations		Will be done at local level
Information		should make public (for example		
and	1	on their website) the existence of		
Transparen		any PCRS they have agreed to.		
су				
	3	Primary care organisations should		
		not enter into any PCRS which		
	2	precludes them from considering		
	*	any other schemes subsequently		
		offered by manufacturers of		
		competitor drugs, should they wish		
		to do so. These PCRS should all	<b>*N.4 1</b> - <b>1</b> - ·	
		be considered using the same	*Mandatory	
	3	criteria.  There should be no requirement to	field	
	3	collect or submit to the		
	3	manufacturer any data other than		
	*	volume of use as derived from	*Mandatory	
		ePACT data.	field	
	3	PCRS agreements must meet the		
		requirements of the General Data		
	4	Protection Regulations(GDPR)		
	*	and patient confidentiality must	*Mandatory	
		never be compromised.	field	
	3	Commissioners should not enter		
		schemes that require them to		
	5	provide information to a		
	*	manufacturer about competitor	*Mandatory	
		products market share.	field	

3 . 6 *	Freedom of Information – As a general principle information relating to rebate schemes is likely to be releasable, these issues should be discussed with the manufacturer before a commissioner enters into any agreement with them. Ideally, provisions about FOI requests and commercially sensitive information should be contained in the contract. As a general principle, information about rebate schemes may be released under FOI requests, but commercially sensitive information is usually withheld. See legal advice for more details.	*Mandatory field	
3 7 *	Discounts and details of any PCRS offered should be allowed to be shared within the NHS. This should be agreed as part of the PCRS contract.	*Mandatory field	
3 8 *	Is the invoicing process transparent as per NHS financial requirements?	*Mandatory field	

#### **Summary of Assessment:**

	Indicate yes or no
No reservations	
Minor reservations only – details below	
Major reservations – details below	

Comments:	

# 16.3 Appendix C. Checklist for management of High Cost Drug offers or schemes, post NICE

Date:	
Name of Drug:	
Company Name:	
Company Contact:	

Version of contract assessed: (with track changes if 2nd version submitted)	
Screened by and date	

<u>Demonstration of compliance with the criteria highlighted and marked with an asterisk below is mandatory before a scheme will be assessed or re-assessed by STP MO High Cost Drugs group.</u>

<u>чгоар</u> .			Obsess White Wife	
Issue		Good practice principles (*Mandatory)	Choose "Met" if criteria/principle met, or "Not met" if criteria/principle not met	Comments
1. Product-related	1.1	Before any consideration of price, the clinical need for the medicine and its place in care pathways should have been agreed by the Joint Formulary Group. The clinical decision should inform the financial/procurement decision and not vice versa.		
	1.2	Health professionals should always base their prescribing decisions primarily on assessments of their individual patients' clinical circumstances. The impact of a scheme is a secondary consideration.		
	1.3*	Is the medication licensed? Unlicensed go to 1.4. Where there is more than one licensed, is the scheme being offered to all indications?		
	1.4*	Schemes promoting unlicensed or off label uses must not be entered into as per RMOC free of charge policy. All recommendations for use of a medicine within a scheme must be consistent with the Marketing Authorisation of the medicine in question i.e. the scheme should only		

		advocate the use of the drug in line with the data sheet for the drug in question.	
	1.5	Medicines appraised and not recommended by NICE might still be the subject of a scheme, but specific and documented consideration must be given to how such a product can properly be recommended to prescribers notwithstanding NICE's position. CCG will need to explain how the scheme helps it meet its duty to use its resources effectively, efficiently and economically.	
2. Scheme-related	2.1	Decision making processes should be clinically led and involve all appropriate stakeholders, including patients where appropriate.	
	2.2*	The administrative burden to the NHS of setting up and running the scheme must be factored into assessment of likely financial benefit of the scheme. Consideration should be given to audit requirements, financial governance, data collection, any other hidden costs and practical issues such as the term of agreement.	
	2.3	Schemes encouraging exclusive use of a particular drug should be avoided.	
	2.4	Ideally the scheme should not be directly linked to requirements to increase market share or volume of prescribing.	

2.5	Schemes which directly link to increase in volume of prescribing above a defined threshold could be judged to be an attempt to influence prescribing inappropriately and should generally be avoided. The administrative burden of monitoring such schemes should be carefully considered.	
2.6*	Commissioners should ensure that a formal written contract is in place, signed by both parties to ensure (i) that the terms of the scheme are clear and (ii) to maximise the legal protection. All negotiations around a scheme should be expressed as being "subject to contract" i.e. not binding until the formal contract has been signed by both parties.	
2.7*	Scheme agreements should include a right to terminate on notice (i.e., without having to have any reason for doing so) with a sensible notice period e.g. three or six months.	
2.8*	The need for financial exit criteria and an exit strategy should be considered before a scheme is agreed. It is essential to allow flexibility to respond to emergence of significant new clinical evidence, or significant changes in market conditions. A shorter notice period should be agreed in these circumstances.	
2.9*	Is the value of the offer quantifiable and proportionate to the administrative burden? Is	

		there an appropriate return	
		on investment?	
	2.1	Schemes which link prescribing of more than one drug should be especially carefully considered to avoid the risk that savings made on one are indirectly offset by costs incurred on another.	
3. Information and Transparency	3.1*	Secondary care organisations should not enter into any schemes which precludes them from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. These schemes should all be considered using the same criteria.	
	3.2*	There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from define.	
	3.3*	Scheme agreements must meet the requirements of the Data Protection Act and patient confidentiality must never be compromised.	
	3.4*	Commissioners and providers should not enter schemes that require them to provide information to a manufacturer about competitor products market share.	

3.5*	Freedom of Information – As a general principle information relating to schemes is likely to be releasable, these issues	
	should be discussed with the manufacturer before a commissioner enters into any agreement with them. Ideally, provisions about	
	FOI requests and commercially sensitive information should be contained in the contract. As a general principle, information about rebate	
	schemes may be released under FOI requests, but commercially sensitive information is usually withheld. See legal advice for more details.	
3.6*	Discounts and details of any schemes offered should be allowed to be shared within the NHS. This should be agreed as part of the scheme contract.	
3.7*	Is the invoicing process transparent as per NHS financial requirements?	

#### **Summary of Assessment from STP MO High Cost Drugs Group**

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Comments:				
Conclusion:				

Checklist approved by STP MO HCD group 2019



#### **16.4 Appendix D. Equality Impact Assessment**

Equality Impact Assessment Screening					
Query					
What is the aim of the document?	To set out the CCG responsibilities in relation to managing Sponsorship of Activities and Joint Working with the Pharmaceutical Industry in line with Revised Statutory Guidance on Managing Conflicts of Interest for CCGs (June 2017) and processes to ensure compliance.				
Who is the target audience of the document (which staff groups)?	All staff				
Who is it likely to impact on and how?	Staff	yes, in that it describes the way in which staff are required to declare all interests as set out in the policy. It does not have an impact on staff in terms of Equalities and Human Rights (see below)			
	Patients	no			
	Visitors	no			
	Carers	no			
	Other – governors, volunteers etc	yes – all those defined as staff in the policy are required by statutory guidance to conform to the policy. It does not have an impact in terms of Equalities and Human Rights (see below)			
Does the document affect	Age (younger and older people)	no			
one group more or less favourably than another based on the	Disability (includes physical and sensory impairments, learning disabilities, mental health)	no			
'protected	Gender (men or women)	no			
characteristics' in the Equality Act 2010:	Pregnancy and maternity	no			
	Race (includes ethnicity as well as gypsy travellers)	no			
	Sexual Orientation (lesbian, gay and bisexual people)	no			
	Transgender people	no			
	Groups at risk of stigma or social exclusion (e.g. offenders, homeless people)	no			

rights to privacy, dignity,	no – the CCG has in place to ensure that rights to privacy are protected			
treatment)	protected			

#### 16.5 Appendix E. Implementation Plan

Target Group	Implementation or Training objective	Method	Lead	Target start date	Target End date	Resources Required
Governing Body	Ensure GB is aware of the CCGs responsibilities and provide assurance that appropriate process is established to ensure legal compliance	Cover paper and policy to be presented to the Governing Body	Medicines Optimisation Team	March 2022	March 2022	Staff time, Governing Body time
Executive Directors	Ensure awareness of responsibilities to ensure compliance	Governing Body paper and discussion with individual directors if required	Corporate team (medicines optimisation team for specialist advice)	March 2022	Ongoing	Staff time, Executive Director time
All staff	Ensure awareness of CCG processes and procedures Information about the policy and CCG processes to be put on the hub Information about the policy and CCG processes to be communicated through the internal newsletter & verbally brought to staff attention via weekly HWGNFY meeting including in regard to sharing information about meeting requests.  Completion of Annual Conflicts of Interests training module	Policy to be placed on the website/The Hub	Medicines Optimisation team / Corporate Team/ training manager	May 2022	Ongoing	Staff time Training module
GP Practices	Information about the policy recommending that practices follow this and CCG processes to be communicated through the Medicines Optimisation newsletter	Policy to be sent directly to practices.	Principle Medicines Optimisation Pharmacist	May 2022	Ongoing	Medicines Optimisation Staff time