

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



Policy Review Checklist

	Yes/ No/NA	Supporting information
Has an Equality Impact Assessment Screening been completed?	Yes	EIA Screening has been completed which indicates that a full assessment is not required
Has the review taken account of latest Guidance/Legislation?	Yes	The policy is aligned to the Revised Guidance on Managing Conflicts of Interest in the NHS (February 2018)
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 addressed?	Yes	Mandatory training requirements are detailed in the policy. NHSE provides a mandatory training package which is completed annually.
Are there other HR related issues that need to be considered?	No	There are no HR related issues raised in this policy
Has the policy been reviewed by Staff Partnership Forum?	No	The policy does not raise HR issues and has not been reviewed by the staff partnership forum
Are there financial issues and have they been addressed?	No	There are no financial issues arising from the application of the policy
What engagement has there been with patients/members of the public in preparing this policy?	N/A	This policy describes a framework for ICB employees to work with the pharmaceutical industry and there has been no engagement with patients and members of the public.
Are there linked policies and procedures?	Yes	Associated policies and procedures are recorded in the policy
Has the lead Executive Director approved the policy?	Yes	Jo Medhurst
Which Committees have assured the policy?		Outcomes, Quality and Performance Committee
Has an implementation plan been provided?	Yes	

	Yes/ No/NA	Supporting information
How will the policy be shared with • Staff? • Patients? • Public?	Yes	The policy will be published on the ICB website and intranet and will be featured in the internal news communication. Regular prompts regarding declarations will be placed in internal communications.
Will an audit trail demonstrating receipt of policy by staff be required; how will this be done?	No	
Has a DPIA been considered in regard to this policy?	Yes	Yes this has been considered, but it is not required.
Have Data Protection implications have been considered?	Yes	

1	Introduction.....	5
1.1	BNSSG ICB Values.....	5
2	Purpose and scope	6
3	Duties – legal framework for this policy	6
3.1	UK Disclosure Database	7
4	Responsibilities and Accountabilities	8
5	Definitions/explanations of terms used.....	9
6	Commercial Sponsorship from the Pharmaceutical Industry	10
6.1	Principles	11
6.2	Authorisation	12
6.3	Gifts.....	12
6.4	Meetings and Hospitality	12
6.5	Training and Education	12
6.6	Clinical review services	12
6.7	Samples of Medicinal Products	13

6.8	Access to Staff and Premises by Representatives of the Pharmaceutical Industry	13
6.9	Research and Clinical Trials.....	14
7	Joint Working with the Pharmaceutical Industry.....	14
8	Examples of Potential Conflict	15
9	Primary Care Rebate Schemes offered by Pharmaceutical Companies	16
9.1	Core Principles.....	16
9.2	Types of Rebate Scheme.....	17
9.2.1	Price Discount.....	17
9.2.3	Risk Sharing Schemes	18
9.3	Governance and Management.....	18
9.3.1	Process for Approval of Rebate Schemes.....	19
9.3.2	Process for Monitoring the Implementation of rebate schemes ..	20
10	Free of charge (FOC) medicines schemes and commercial offers for High Cost Drugs	20
10.1	FOC medicines schemes	20
10.2	Commercial offers	21
11	Training requirements.....	21
12	Equality Impact Assessment	21
13	Implementation and Monitoring Compliance and Effectiveness.....	21
14	Countering Fraud	22
14.1	Fraud and Bribery Statement	22
14.2	Fraud.....	22
14.3	Bribery.....	22
15	References, acknowledgements and associated documents	22
16	Appendices	24
16.1	Appendix A. Pharmaceutical Company Representative Visit Request Form 24	
16.2	Appendix B. Screening questions when considering a rebate scheme	26

16.3 Appendix C. Checklist for management of High Cost Drug offers or schemes, post NICE	32
16.4 Appendix D. Equality Impact Assessment.....	37
16.5 Appendix E. Implementation Plan	38

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 several 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 ICB 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 ICB or their representatives engage with the pharmaceutical industry.

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

1.1 BNSSG ICB Values

This policy supports the ICB 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 ICB 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 ICB 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 ICB are upheld and maintained at all times.

It is recommended that staff liaise with the ICB 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 ICB support staff and includes advice for GP practices. Whilst the policy does not cover providers of services to the ICB, 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 [Standing Financial Instructions](#), the [Confidentiality and Security Information Policy](#), the [Information Governance Policy](#), the [Managing Conflicts of Interest policy](#) and the [Gifts and Hospitality policy](#).

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 be aware of the relevant NHS guidance, relevant legislation and appropriate professional codes of conduct.

In the interests of transparency, ICB 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 [Managing Conflicts of Interest](#) and [Gifts and Hospitality](#) policies.

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

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 complaints@pmcpa.org.uk. Where necessary staff will also report to the ICB 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 transfer of value i.e. payments and benefits in kind, made directly or indirectly 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. The ABPI offers the named Health Care Professionals (HCP) and Health Care Organisations (HCO) an opportunity to check the data submitted by companies before it is published on Disclosure UK. The HCP/HCOs don't need to approve it as the data will be published on Disclosure UK regardless, but are encouraged to check it is accurate. It is expected that all BNSSG ICB employees will agree and give consent for disclosure. This should also be declared on the ICB register.

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 can 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. Individuals have certain rights under the data protection laws and can raise objections about data published under their name on Disclosure UK at any time.

The ICB 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 employee's own time.

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

Any pharmaceutical industry sponsorship of events or projects should be reported to the ICB by completing a Declaration of Gifts, Hospitality and Sponsorship form which is available on The Hub and emailed to bnssg.corporate@nhs.net

The ICB 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 ICB'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.

Chief of Staff

- Maintains a database of all the sponsorship activity across the ICB
- 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 Chief of Staff & 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 ICB's behalf (e.g. Commissioning Support Unit) need to adopt and work under this policy. The ICB 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 ICB 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 Integrated Care Boards.

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 ICB staff should consult the [“Managing Conflicts of Interest”](#) and [“Gifts and Hospitality”](#) policies and ensure that they are aware of the statutory requirements from NHS England in the document [NHS England » Managing Conflicts of Interest in](#)

[the NHS: Guidance for staff and organisations](#) 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 [ABPI code of practice 2021](#). 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:

- are made for the purpose of supporting healthcare, scientific research or education
- do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines
- are prospective in nature
- 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 ICB should make it clear that sponsorship does not equate to endorsement of a company or its products.

Prior written agreement between authorised ICB 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 ICBs 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 ICBs 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 ICB guidelines or the Joint Formulary.

6.2 Authorisation

All offers of gifts, hospitality or sponsorship in any form to ICB and its staff will require authorisation. All offers should be authorised in line with the [Gifts and Hospitality Policy](#). 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

There are increasing numbers of companies offering clinical services across the ICS. This may be directly to ICBs or to individual GP practices, secondary care etc. This may be via facilitation and funding by the Pharmaceutical Industry. These companies offer services such as therapy reviews and other services to help providers achieve National targets. To carry out their function these companies may access patient level data with required permissions.

In order to ensure that these reviews fit with the strategic priorities of the ICB, and are in line with the BNSSG Joint Formulary, all BNSSG ICB 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.

Provider and ICB employees should be aware of the requirements for registered healthcare providers within the [Care Quality Commission's Key lines of enquiry, prompts and ratings characteristics for healthcare services](#) regarding the governance and management of arrangements with third party providers. Additionally, [NHS England's Primary Medical Care Policy and Guidance Manual \(PGM\) \(v4\)](#) contains details on Sub-contracting of Clinical Services and an Assurance Framework for commissioners.

Staff should also be aware that many of these companies would not themselves be required to register with a regulatory body.

6.7 Samples of Medicinal Products

The [ABPI code of practice 2021 Clause 21](#) 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 [ABPI code of practice 2021 Clause 17](#) 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 bnssg.medicines-optimisation@nhs.net.

If a representative of a pharmaceutical industry contacts a ICB Clinical lead directly to ask for a meeting, the clinical lead should initially decline and refer the representative to the Chief Pharmacist, Deputy Chief Pharmacist 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. ICB 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 ICB Research and Evidence Team are responsible for research management and governance within Bristol, North Somerset and South Gloucestershire ICB and can be contacted via their website <https://bnssg.icb.nhs.uk/about-us/research-and-evidence/>

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: <https://www.abpi.org.uk/publications/joint-working/>

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 ICB's [Standing Financial Instructions](#) for governance arrangements for authorisation of contracts that enable ICBs 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_4076078.pdf

The monitoring arrangements for gifts, hospitality or sponsorship in any form to ICBs and their staff are outlined in the [Gifts and Hospitality Policy](#) and the [Managing Conflicts of Interest Policy](#)

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 ICB 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 ICB 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. In exceptional circumstances rebate schemes may be considered for items not on the BNSSG Formulary if advised by the Medicines Optimisation team.
- 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 ICB organisational level, they should not be agreed at GP practice level.
- Schemes encouraging exclusive use of a particular drug should be avoided and BNSSG ICB 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 ICB 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 relevant Data Protection Legislation and patient confidentiality 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 ICB 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 ICB 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.

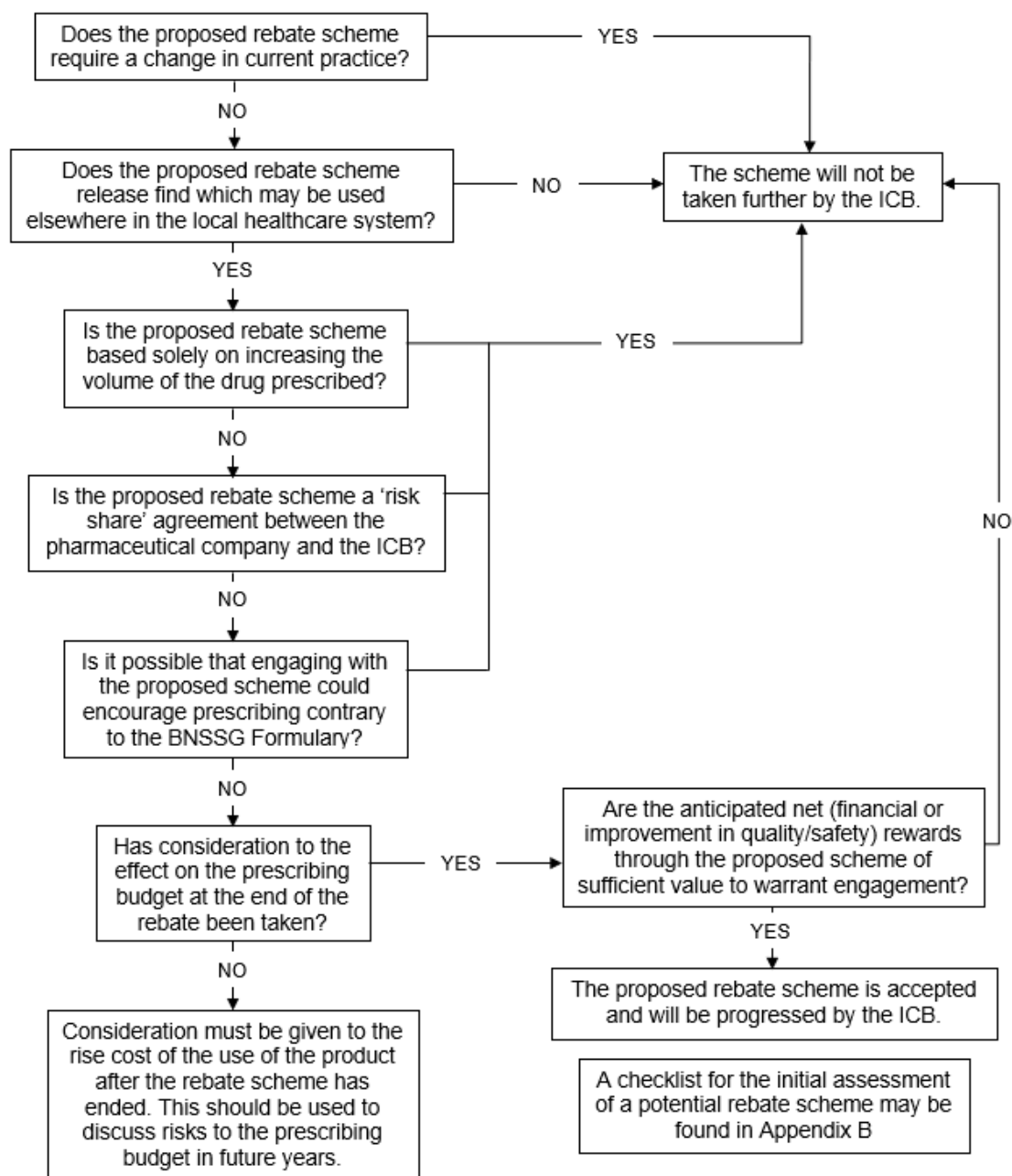
The agreement should set the scope and realise the mutual obligations between both the NHS and pharmaceutical companies depending on the occurrence of an agreed condition – the ‘risk’. The ‘risk’ varies by situation and can include pharmaceutical expenditure higher than agreed thresholds.

The ICB 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 ICB will ensure that the agreement entered into states that the pharmaceutical company that is offering the scheme will not use ICB 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 ICB.



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 ICB 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 or

- Rebate generating <£50,000 per year signed by Deputy CFO or Chief Pharmacist
- The Chief Pharmacist, Deputy Chief Pharmacist 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 ICB 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 ICB'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 ICB may be confidential and commercially sensitive and therefore such details are not publicly available documents.

The Medicine Optimisation Team will be responsible for maintaining a register of schemes the ICB has signed up to, 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 NHS [England Free of charge \(FOC\) medicines schemes – national policy recommendations for local systems](#) is followed.

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 their family member or

carer on their behalf as appropriate) or an identified cohort of patients. This definition also includes very discounted medicines offered at a price so low that they are almost free of charge for example, £1 per pack or schemes offering money back.

- Commissioners and providers must only undertake a free of charge scheme if the principles outlined in this policy are followed.

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 ICB 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 training packages are provided by NHS England and are available on ConsultOD. Training compliance rates are recorded as part of the ICB'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 ICB 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 <https://cfa.nhs.uk/reportfraud>, 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 ICB 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 ICB or when representing the ICB in any capacity and is contrary to the Bribery Act 2010.

15 References, acknowledgements and associated documents

- BNSSG ICB - Standing Financial Instructions
<https://bnssg.icb.nhs.uk/about-us/governance/governance-handbook/>

- BNSSG ICB - Confidentiality and Security of Information Policy
<https://bnssg.icb.nhs.uk/library/confidentiality-and-security-information-policy/>
- BNSSG ICB - Information Governance Policy
<https://bnssg.icb.nhs.uk/library/information-governance-policy1/>
- BNSSG ICB - Managing Conflicts of Interest Policy
https://bnssg.icb.nhs.uk/wp-content/uploads/2022/07/BNSSG_Managing-Conflicts-of-Interest-policy-ICB-v1.1_27_May_22-Agreed-1.7.22.docx
- BNSSG ICB - Gifts and Hospitality Policy https://bnssg.icb.nhs.uk/wp-content/uploads/2022/07/BNSSG_Standards_of_Business_Conduct_Policy-Gifts-and-Hospitality_ICB_27_May_22-Agreed-1.7.22.docx
- 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 in the NHS (Feb 2017): [NHS England » Managing Conflicts of Interest in the NHS: Guidance for staff and organisations](#)
- ABPI code of practice 2021 Clause 23
<https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf>
- Care Quality Commission Key lines of enquiry, prompts and ratings characteristics for healthcare services
https://www.cqc.org.uk/sites/default/files/20180628_Healthcare_services_KLOEs_prompts_and_characteristics_FINAL.pdf
- NHSE Primary Medical Care Policy and Guidance Manual
<https://www.england.nhs.uk/wp-content/uploads/2017/11/B1420-primary-medical-care-policy-and-guidance-manual-may-2022-v4.pdf>
- ABPI code of practice 2021 Clause 21
<https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf>
- ABPI code of practice 2021 Clause 17
<https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf>
- BNSSG ICB Research and Evidence
<https://bnssg.icb.nhs.uk/about-us/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.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4076078.pdf
- Free of charge (FOC) medicines schemes
<https://www.england.nhs.uk/long-read/free-of-charge-foc-medicines-schemes-national-policy-recommendations-for-local-systems/>
- BNSSG ICB Fraud and Bribery Policy
<https://bnssg.icb.nhs.uk/library/fraud-and-bribery-policy/>

16 Appendices

16.1 Appendix A. Pharmaceutical Company Representative Visit Request Form

This form is for pharmaceutical industry representatives requesting a meeting with ICB 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 Proprietary).....

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

--

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

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

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

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

ANY OTHER SUPPORTING INFORMATION:

--

16.2 Appendix B. Screening questions when considering a rebate scheme

Reproduced with permission from NHS London Procurement Partnership

Date:	
Name of Drug:	
Company Name:	
Company Contact:	
Version of contract assessed: (with track changes if 2nd version submitted)	
Date assessed	
Assessor name	
Date assessed by Medicines Optimisation Control 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 ICB. Before submission to the ICB, manufacturers are asked to make sure that their proposals provide ALL relevant information.

Issue		Good practice principles (*Mandatory)	Indicate 'met' or '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 established local decision-making processes. 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 rebate scheme is a secondary consideration.		
	1.3*	Any medicine considered under a Primary Care Rebate Scheme (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 a particular indication for use.	*Mandatory field	
	1.4*	Rebate schemes promoting unlicensed or off label uses must 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 drug in question.	*Mandatory 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. ICBs 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.		<i>For local determination</i>
	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		<i>For local determination</i>

		care and Director level approval.		
	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.	*Mandatory field	
	2.4*	Primary care rebate schemes should be agreed at a statutory organisational level, they should not be agreed at GP practice level.	*Mandatory field	
	2.5	Schemes encouraging exclusive use of a particular drug should be avoided.		
	2.6	Rebate schemes for medicines in Category M and some medicines 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.		
	2.7	Ideally the PCRS should not be directly linked to requirements to increase market share or volume of prescribing.		

	2.8	Schemes which link a rebate directly 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.		
	2.9*	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.	*Mandatory field	
	2.10*	PCRS 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.	*Mandatory field	
	2.11*	The need for 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.	*Mandatory field	
	2.12*	Is the value of the offer quantifiable and proportionate to the administrative burden? Is there an appropriate return on investment?	*Mandatory field	
	2.13	Schemes which link a rebate to 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 Transparen cy	3.1	Primary Care Organisations should make public (for example on their website) the existence of any PCRS they have agreed to.		<i>Will be done at local level</i>
	3.2*	Primary care organisations should not enter into any PCRS which precludes them from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. These PCRS should all be considered using the same criteria.	*Mandatory field	
	3.3*	There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data.	*Mandatory field	
	3.4*	PCRS agreements must meet the requirements of the relevant Data Protection Legislation and patient confidentiality must never be compromised.	*Mandatory field	
	3.5*	Commissioners should not enter schemes that require them to provide information to a manufacturer about competitor products market share.	*Mandatory 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>				
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. ICB 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

Comments:	
Conclusion:	

Checklist approved by STP MO HCD group 2019

16.4 Appendix D. Equality Impact Assessment

Equality Impact Assessment Screening		
Query	Response	
What is the aim of the document?	To set out the ICB 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 in the NHS (Feb 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 one group more or less favourably than another based on the 'protected characteristics' in the Equality Act 2010:	Age (younger and older people)	no
	Disability (includes physical and sensory impairments, learning disabilities, mental health)	no
	Gender (men or women)	no
	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
	Human Rights (particularly rights to privacy, dignity, liberty and non-degrading treatment)	no – the ICB has in place to ensure that rights to privacy are protected

16.5 Appendix E. Implementation Plan

Target Group	Implementation or Training objective	Method	Lead	Target start date	Target End date	Resources Required
Board	Ensure the board is aware of the ICBs responsibilities and provide assurance that appropriate process is established to ensure legal compliance	Cover paper and policy to be presented to the ICB Board	Medicines Optimisation Team	July 2024	December 2024	Staff time, ICB Board time
Executive Directors	Ensure awareness of responsibilities to ensure compliance	ICB Board paper and discussion with individual directors if required	Corporate team (medicines optimisation team for specialist advice)	July 2024	Ongoing	Staff time, Executive Director time
All staff	Ensure awareness of ICB processes and procedures Information about the policy and ICB processes to be put on the hub Information about the policy and ICB processes to be communicated through the internal newsletter & verbally brought to staff attention via weekly HWGNFY meeting including 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/	July 2024	Ongoing	Staff time Training module
GP Practices	Information about the policy recommending that practices follow this and ICB processes to be communicated through the Medicines Optimisation newsletter	Policy to be sent directly to practices.	Principle Medicines Optimisation Pharmacist	July 2024	Ongoing	Medicines Optimisation Staff time