North Central London
Integrated Care Board

NHS North Central London Integrated Care Board

Sponsorship and Joint Working with the Pharmaceutical Industry Policy

Version 1: July 2022

1.	**Summary**	This Policy sets out the procedures for Sponsorship and Joint Working with the pharmaceutical industry for NHS North Central London Integrated Care Board ('ICB').
2.	**Responsible officer**	Sarah McDonnell-Davies, Executive Director of Places
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4.	**Applies to**	All ICB members, employees, self-employed consultants, contractors, officers, office holders and committee members.
5.	**Groups/individuals who have overseen development of this policy**	Head of Governance and Risk; Heads of Medicines Management; Local Counter Fraud Specialist
6.	**Groups which were consulted and have given approval**	Medicines Management Committee of the CCG endorsed the policy for approval on 4th March 2021. The Audit Committee of the CCG approved the policy on 18th March 2021.
7.	**Equality Impact Analysis completed**	This Policy has been written in accordance with the provisions of the Equality Act 2010 ('EA 2010').
8.	**Ratifying committee and date of final approval**	ICB Board of Members approved this policy on 4 July 2022.
9.	**Version**	Version 1.0
10.	**Locations available**	ICB website; Staff intranet.
11.	**Related documents**	• The ICB's Constitution; • Conflicts of Interest Policy; • Counter Fraud, Bribery and Corruption Policy; • Disciplinary Policy; • Standards of Business Conduct Policy; • Speaking Up (Whistleblowing) Policy;

		• Procurement Policy • Any Qualified Provider Policy.
12.	**Disseminated to**	Board of Members including committee members, all staff, clinical leads and contractors.
13.	**Date of implementation**	4th July 2022.
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Document Version Control

Date	Version	Action	Amendments	Author
4 July 2022	1.0	Policy approved	This policy was amended from the previous NCL Clinical Commissioning Group's policy.	Paul Gouldstone, Head of Medicines Management-(Enfield); Pauline Taylor, Head of Medicines Management (Haringey); Jennifer Nabwogi, Governance and Risk Lead; Chipo Kazoka, Governance and Risk Lead; Craig McGuire, Governance and Risk Lead.

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1.0 Introduction

1.1 This document sets out the Sponsorship and Joint Working with the Pharmaceutical Industry Policy ('Policy') for NHS North Central London Integrated Care Board ('ICB').

1.2 The Department of Health and Social Care (DHSC) and The Association of the British Pharmaceutical Industry (ABPI) seek to encourage collaborative working between the NHS and the pharmaceutical industry for the benefit of the local healthcare economy and patients.

1.3 Pharmaceutical companies that are members of the ABPI are required to comply with the ABPI Code of Practice for the Pharmaceutical Industry 2015, which regulates the promotion of prescription medicines and certain other non-promotional activities. The ABPI guidance seeks to provide clarity and a framework for Joint Working and Sponsorship for pharmaceutical companies.

2.0 Equalities

2.1 This Policy meets the requirements of the Equality Act 2010 ('EA 2010').

3.0 Help and Support

3.1 For any support with this Policy, please contact a member of the Medicines Management Team using the contact details provided in Appendix 7 of this Policy.

4.0 Definitions: Joint Working, Sponsorship and Primary Care Rebate Schemes

4.1 Joint Working is defined in the Department of Health and Social Care Joint Working Guidance as: "situations where, for the benefit of the patient, 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."

4.2 The key requirements for the definition of Joint Working are that:

4.2.1 The Joint Working project must be focused on the benefits to patients, and;

4.2.2 There must be a 'pooling' of resources between the pharmaceutical company or companies and the NHS organisation(s). Each party must therefore make a significant contribution to the Joint Working project to avoid the arrangement being construed as merely a gift, benefit in kind or donation.

4.3 'Joint Working Agreement' means an agreement that formalises a Joint Working arrangement and approved under this Policy on the terms set out in paragraph 10 below.

4.4 Sponsorship is where one or more pharmaceutical companies provide funds for a specific event or work programme. This could also include the provision of medical

education, goods and services on an arm's length basis, for example, a specialist nurse working with General Practices on a fixed term basis.

4.5 For the purpose of this guidance, Sponsorship is defined as funding to the NHS from an external source for any item of expenditure. This may include but is not limited to the following:

4.5.1 Salary or costs of staff;

4.5.2 Costs of NHS research;

4.5.3 Training;

4.5.4 Non-pay items such as equipment;

4.5.5 Costs associated with meetings;

4.5.6 Gifts;

4.5.7 Hospitality including the provision of meals;

4.5.8 Provision of free services;

4.5.9 Provision of discounted items.

4.6 Primary Care Rebate Schemes are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer retrospective financial rebates to the ICB on GP practice prescribing expenditure for particular branded medicines. Further provisions on Primary Care Rebate Schemes are set out in paragraph 13 of this Policy.

5.0 Aims and Scope of This Policy

5.1 This Policy aims to:

5.1.1 Promote appropriate working relationships between the ICB and the pharmaceutical industry;

5.1.2 Provide a framework within which staff and all other persons to whom this Policy applies can work effectively with the pharmaceutical industry;

5.1.3 Ensure that the ICB complies with all relevant legislation and official guidance;

5.1.4 Ensure that outcomes of the ICB's engagement with the pharmaceutical industry are beneficial to patients, public health and to the ICB's financial management;

5.1.5 Ensure that all of the ICB's employees, office holders and contractors approached by the pharmaceutical industry respond in a consistent manner;

5.1.6 Ensure that the interests and integrity of the ICB are safeguarded, and that the public are reassured.

5.2 This Policy applies to all of the Board of Members, Clinical Leads, employees and other staff (including students, trainees, agency workers, seconded staff, and joint appointments). It also applies to self-employed consultants, contractors other officeholder members of the Board of Members, ICB committees and those partners engaged in commissioning, contracting and procurement on behalf of the ICB.

5.3 The ICB will ensure that its commissioning support services, Local Authorities and other key business partners are aware of the contents of this Policy.

5.4 The ICB will further ensure that any procurement led by a third party on behalf of the ICB is compliant with the terms of this Policy.

5.5 This Policy should be read in conjunction with the ICB's Conflicts of Interest Policy.

5.6 This Policy shall be reviewed annually.

6.0 Joint Working Arrangements

Preliminary Considerations for Joint Working Arrangements

6.1 Joint Working arrangements are primarily aimed at preserving patient care whilst delivering tripartite benefits to patients, the ICB and the pharmaceutical company or companies involved. Joint Working enables the ICB to improve on its use of NHS resources and benefits the pharmaceutical companies involved by enabling them to expand the potential patient population that they serve. Patients are, at all times, to be the principal beneficiaries of such arrangements.

6.2 The anticipated benefits of Joint Working arrangements must be clearly set out in advance. Both the ICB and the pharmaceutical company or companies involved should give consideration to quantifying, as far as is possible, the anticipated benefits of Joint Working before committing to entering into such arrangements.

6.3 All Joint Working arrangements must be underpinned by a formal Joint Working Agreement. Further guidance on the key contents of a Joint Working Agreement is set out in paragraph 10 below.

6.4 In the interest of transparency and probity, where a Joint Working Agreement is entered into, the ICB should ensure that an executive summary of the Joint Working Agreement is published on the ICB's website before any work on the project formally begins.

6.5 The executive summary referred to in paragraph 6.4 above shall be approved by the Chief Executive prior to publication. The approved executive summary shall be presented to the Integrated Medicines Oversight Committee for noting.

7.0 Ethical Principles to be Applied to Joint Working Arrangements

7.1 The following principles are to be applied to Joint Working arrangements:

7.1.1 Joint Working arrangements should take place at an organisational level and not with individual health professionals.

7.1.2 Any Joint Working between the ICB and the pharmaceutical industry should be conducted in an open and transparent manner. Agreements must include an exit strategy, contingency arrangements, clear milestones and a commitment to measure, sustain and document outcomes to facilitate replication and scaling across the NHS.

7.1.3 Each party must make a significant and defined contribution to the project, and transfers of value made by companies must be publicly disclosed. Contribution of resources may come in various forms, including people, expertise, equipment, communication channels, information technology and finance.

7.1.4 Contract negotiations should be conducted in line with NHS values, including the Nolan Principles of Standards in Public Life

7.1.5 Where there is evidence of any unauthorised or disadvantageous arrangement which threatens to compromise the interests of patients, the ICB or the public interest, ICB staff should act swiftly to deal with the situation and bring it line with patient and clinical needs, the aims of the ICB, the public interest and the requirements of this Policy.

7.1.6 ICB staff should be aware of NHS guidance, the content of this Policy, the legal position and appropriate and relevant professional codes of conduct as described in existing NHS guidance;

7.1.7 All ICB staff or other persons to whom this Policy applies must respect all confidential and commercially sensitive information which they receive in the course of carrying out their duties with the ICB on any Joint Working arrangement. They must never use any such information for their own personal benefit outside the scope of the Joint Working arrangement out of which they gained the knowledge of such information. All such information shall be treated by the ICB staff as being held by them on trust for the ICB and to be used by them for the ultimate benefit of patients and in serving the public interest.

8.0 Decision Pathway for the Adoption of a Joint Working Initiative/Proposal

8.1 The decision pathway to be followed in order for an initiative to be adopted as a proposal for a Joint Working arrangement and for any such proposal to be subsequently progressed to the status of a Joint Working Agreement is set out in Appendix 1.

8.2 All key risk and governance issues should be considered at the initial planning stage of any proposed Joint Working initiative in order to safeguard the interests of patients, the ICB and the public.

9.0 The Approval Process for Joint Working Arrangements

9.1. All proposals for potential Joint Working arrangements with the pharmaceutical industry will be taken through the processes for consideration, approval, recording, monitoring and evaluation that are set out in this Policy. Their potential clinical and

financial outcomes will undergo a robust risk assessment at every stage of the approval process set out in this Policy.

The Line Manager Approval Stage

9.2 An initiative for Joint Working should be commenced by the project lead, with the prior permission of their line manager. The project lead should complete the Joint Working Assessment Form set out in Appendix 2 of this Policy.

9.3 On receiving the completed Joint Working Assessment Form, the line manager must assess the merits of the proposed initiative, its suitability for Joint Working against its conformance with flowchart set out in Appendix 1 and the extent to which responses to the questions set out in Appendix 2 are in the affirmative.

9.4 In order for the line manager to be satisfied that the Joint Working initiative does not threaten to compromise the interests of patients and those of the ICB, the line manager must ensure that all the responses to the questions set out in Appendix 2 are in the affirmative.

9.5 If there is a negative response to any one of the questions in Appendix 2, the line manager should not progress the initiative to the next stage and may require the project lead to revise the proposed initiative in order to ensure that any elements of the proposed initiative that fall short are brought in line so that an affirmative response to each question can be given.

9.6 If satisfied with the proposed initiative, whether in the first instance or upon reconsideration, the line manager shall refer the initiative to the Head of Medicines Management nominated by the ICB to be the point of contact through whom a further review of the proposed initiative can be referred.

The Heads of Medicines Management Approval Stage

9.7 The ICB's nominated Head of Medicines Management shall, in consultation with other Heads of Medicines Management within the ICB, review the proposed initiative in order to ensure its alignment with the aims of the ICB's approach to medicines management.

9.8 It is the responsibility of the ICB's Heads of Medicines Management to resolve any contentious issues and to have the final say on whether or not any proposed initiative for Joint Working with the pharmaceutical industry is suitable for progression to the next stage of the approval process.

9.9 In making their decision on whether or not any initiative is suitable for progression to the next stage of the approval process, the Heads of Medicines Management must assess the merits of the proposed initiative, its suitability for Joint Working against its conformance with flowchart set out in Appendix 1 and the extent to which responses to the questions set out in Appendix 2 are in the affirmative.

9.10 If the ICB's Heads of Medicines Management are not satisfied that the proposed initiative is suitable for Joint Working when assessed in accordance with paragraph 9.9 above, the ICB's Heads of Medicines Management should not progress the initiative to the next stage of the approval process. The ICB's Heads of Medicines shall

give written reasons for their decision which will be communicated through their nominated representative referred to in paragraph 9.6 and 9.7 above.

9.11 In the circumstances referred to in paragraph 9.10 above, the ICB's Heads of Medicines Management may require the project lead to revise the proposed initiative in order to ensure that any of its elements that fall short are brought in line.

9.12 If satisfied with the proposed initiative, whether in the first instance or upon a reconsideration, the ICB's Head of Medicines Management shall, through their nominated representative, refer the proposed initiative to the ICB's Executive Director responsible for Medicines Management (currently the Executive Director of Places) for further review. The referral to the Executive Director by the Heads of Medicines Management shall contain their recommendations for an appropriate decision to be made by the Executive Director.

The Executive Director Approval Stage

9.13 If, on receipt and consideration of the proposed Joint Working initiative, the Executive Director responsible for Medicines Management (the Executive Director of Places) is not satisfied with its merits and/or is of the view that it fails to meet the decision pathway criteria set out in paragraph 8 above and in Appendix 1 or any other requirement of this Policy, the Executive Director may refuse to progress the proposal to the next stage of the approval process giving written reasons for their refusal.

9.14 In the circumstances referred to in paragraph 9.13 above, the Executive Director responsible for Medicines Management (the Executive Director of Places) may give directions to the ICB's Heads of Medicines Management, through their nominated representative, with respect to any amendments that may be required to be made to the proposed Joint Working initiative in order for it to be reconsidered by the Executive Director.

9.15 If satisfied with the proposed Joint Working initiative, whether in the first instance or upon reconsideration, the Executive Director responsible for Medicines Management (the Executive Director of Places) shall escalate it to the Executive Management Team for further consideration. The Executive Director's referral of the proposed Joint Working initiative to the Executive Management Team shall include the Executive Director's recommendations for an appropriate decision to be made by the Executive Management Team.

Executive Management Team Approval Stage

9.16 If, on its receipt of and consideration of the proposed Joint Working initiative, the Executive Management Team is not satisfied with its merits and/or if the Executive Management Team is of the view that the proposed initiative fails to meet the decision pathway criteria set out in paragraph 8 above and in Appendix 1 or falls short of meeting any other requirement of this Policy, the Executive Management Team may refuse to progress the proposed Joint Working initiative to the next stage of the approval process. The Executive Management Team shall give reasons for its refusal.

9.17 In the circumstances referred to 9.16 above, the Executive Management Team may, through the Executive Director responsible for Medicines Management (the Executive Director of Places), give directions to the ICB's Heads of Medicines Management with

respect to any amendments that may be required to be made to the proposed Joint Working initiative in order for it to be reconsidered by the Executive Management Team. The Executive Director shall communicate the Executive Management Team's decision through the nominated representative of the ICB's Heads of Medicines Management.

9.18 If satisfied with the proposed Joint Working initiative, whether in the first instance or upon a reconsideration, the Executive Management Team shall then formally adopt it as a proposal and escalate it, through the Executive Director responsible for Medicines Management (the Executive Director of Places), to the Integrated Medicines Oversight Committee for consideration and with recommendations for an appropriate decision to be made by the Integrated Medicines Oversight Committee.

9.19 The decision of the Executive Management Team shall, in any event, be recorded in the minutes of the meeting at which the proposal was received and considered by the Executive Management Team.

Integrated Medicines Oversight Committee Approval Stage

9.20 On receipt of the proposal for Joint Working from the Executive Management Team, the Integrated Medicines Oversight Committee shall consider the proposal taking into account:

9.20.1 The nature of the proposal and its merits;

9.20.2 The Executive Management Team's recommendations;

9.20.3 The proposal's conformance with the decision pathway for the adoption of a Joint Working arrangement as required by paragraph 8 of this Policy and illustrated in Appendix 1;

9.20.4 The proposal's suitability for adoption as a Joint Working arrangement as evidenced by the positive responses to all of the questions set out in Appendix 2;

9.20.5 The Integrated Medicines Oversight Committee's own assessment of the potential financial and clinical outcomes of the proposed Joint Working arrangement;

9.20.6 The Integrated Medicines Oversight Committee's assessment of the potential impact that the Joint Working arrangement could continue to have on the ICB after its conclusion.

9.20.7 Any other matters that the Integrated Medicines Oversight Committee may reasonably consider to be relevant to the interests of patients, the ICB and the public interest.

9.21 If, having taken into account the matters set out paragraph 9.20 above, the Integrated Medicines Oversight Committee is not satisfied that the proposal is suitable for adoption by the ICB as a Joint Working arrangement, the Integrated Medicines Oversight Committee shall refuse to adopt the proposal. The Medicines Management Committee shall give reasons for its decision.

9.22 In the circumstances set out in paragraph 9.21 above, the Integrated Medicines Oversight Committee may give directions to the Executive Management Team, through the Executive Director responsible for Medicines Management (the Executive Director of Places) or their nominee, with respect to any amendments that may be required to be made to the proposal for Joint Working in order for it to be reconsidered by the Integrated Medicines Oversight Committee.

9.23 If satisfied with the terms of the proposal for Joint Working, whether in the first instance or upon reconsideration, the Integrated Medicines Oversight Committee may approve the proposal.

9.24 The Integrated Medicines Oversight Committee may give such further directions on any other steps that may need to be taken on behalf of the ICB in order to enable the ICB to formally enter into a Joint Working Agreement between the ICB and the relevant counterparty to the Joint Working arrangement.

9.25 The decision of the Integrated Medicines Oversight Committee shall, in any event, be recorded in the minutes of the meeting at which the proposal was considered by the Integrated Medicines Oversight Committee.

10.0 The Joint Working Agreement

10.1 Following the Integrated Medicines Oversight Committee's approval of a Joint Working proposal under paragraph 9 above, the ICB's Executive Director responsible for Medicines Management (the Executive Director of Places) or their nominee shall, with the support and advice of the Heads of Medicines Management, negotiate and agree the terms of the Joint Working Agreement which shall include the matters set out in paragraph 10.3 below.

10.2 The Executive Director of Places shall be responsible for signing the Joint Working Agreement whose terms will have been agreed with the relevant counterparty following the negotiations referred to in paragraph 10.1.

10.3 The Executive Director of Places shall ensure that the Joint Working Agreement to be signed by the Executive Director of Places, on behalf of the ICB, contains provisions which cover the following key issues, as a minimum:

10.3.1 A clear outline of the perceived benefits of the Joint Working arrangement for all parties concerned;

10.3.2 Clear milestones on what is expected to be achieved for the benefit of patients and for the ICB through the ICB's participation in the Joint Working arrangement;

10.3.3 A commitment to measure, sustain and document outcomes in order to facilitate replication and scaling across the NHS, if necessary;

10.3.4 Any other potential implications for patients and the ICB that could reasonably be foreseen to result from the ICB's entering into and carrying on with the Joint Working Agreement;

10.3.5 The duration of the Joint Working Agreement;

10.3.6 An effective exit strategy capable of dealing with a situation where premature termination may become necessary;

10.3.7 Any other contingency arrangements, short of termination, that could reasonably be expected to safeguard the interests of patients, the ICB and the public under the Joint Working Agreement.

11.0 Monitoring and Review of Approved Joint Working Arrangements

11.1 All Joint Working arrangements approved by the Integrated Medicines Oversight Committee shall remain subject to monitoring and review by the Executive Director responsible for Medicines Management (the Executive Director of Places) who shall provide assurance on performance of the Joint Working Agreement to the Integrated Medicines Oversight Committee on such regular basis and to such level of detail as may be required by the Integrated Medicines Oversight Committee.

11.2. Unless otherwise stated by the Integrated Medicines Oversight Committee, the assurance report of the Executive Director responsible for Medicines Management referred to in paragraph 11.1 above shall, in so far as is practicable, contain coverage on the matters referred to in paragraph 10.3 above.

12.0 Disclosures of Transfers of Value by Pharmaceutical Companies

12.1 From June 2016, the ABPI began publishing a public database declaring benefits that UK pharmaceutical companies give in cash or in kind to healthcare organisations, individual healthcare professionals and any relevant decision makers within a healthcare organisation. These benefits are termed ‘transfer of value’.

12.2 For individual healthcare professionals, transfers of value activities cover:

12.2.1 Events - registration fees;

12.2.2 Events - travel and accommodation;

12.2.3 Consultancy Services – fees;

12.2.4 Consultancy services - expenses.

12.3 For healthcare organisations, requirements cover:

12.3.1 NHS Joint Working projects;

12.3.2 Donations, grants and benefits in kind;

12.3.3 Provision of medical education goods and services.

12.4 All of the Board of Members, clinical leads, employees and other staff working for the ICB that undertake work with the pharmaceutical industry must declare it in accordance with the requirements of the ICB's Conflicts of Interest Policy.

12.5 The ICB maintains a Declarations of Interest Register and a Register of Gifts, Hospitality and Sponsorship. Declared interests will be included on these registers in accordance with the ICB's Conflicts of Interest Policy. Readers of this Policy are reminded that as part of the ICB's annual counter fraud review into conflicts of interest, the ABPI data for all of the Board of Members, clinical leads, employees and other staff working for the ICB will be reviewed.

12.6 The ICB considers it a mandatory requirement for ICB members, clinical leads, employees and other staff working for the ICB and undertaking work with the pharmaceutical industry and receiving any transfer of value or benefit in kind to give their consent for this to be declared on the ABPI Disclosure UK database. Failure to provide the necessary consent will be considered a breach of this Policy and of the ICB's Conflicts of Interest Policy and may result in disciplinary action which may lead to dismissal.

Bribery Legislation

12.8 Bribery Act 2010 imposes extensive obligations on all commercial organisations, including those in the healthcare sector, to ensure that they have adequate procedures in place to prevent bribery from occurring within their organisation. Compliance with this Policy supports the ICB's efforts in this area.

12.9 For further information, please refer to the Counter Fraud Bribery and Corruption Policy. To discuss any concerns relating to fraud or bribery, please contact the ICB's Local Counter Fraud Specialists (See Appendix 6 for contact information).

13.0 Primary Care Rebate Schemes

13.1 Primary Care Rebate Schemes ('PCRS') are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer retrospective financial rebates to the ICB on GP practice prescribing expenditure for particular branded medicines.

13.2 Such schemes are offered to ICB's by the pharmaceutical industry as a means to introduce new drugs into the NHS or more simply as a tool to increase/ establish market share of existing/new medicines.

13.3 The availability of such a scheme should not influence the inclusion or removal of specific medicines in care pathways or formularies.

13.4 It is preferable that pharmaceutical companies supply medicines to the NHS using transparent pricing mechanisms that do not create an additional administrative burden to the NHS, which rebate schemes have often done.

13.5 Any medicine should only be agreed for use within a rebate scheme if it is believed to be appropriate for a defined cohort of patients within a population. It is important that all patients continue to be treated as individuals, and acceptance of a scheme should not constrain existing local decision-making processes or formulary development. This is in line with the Department of Health Guidance on Strategies to Achieve Cost-Effective Prescribing (October 2010). This states that the following principles should underpin local strategies:

13.5.1 The decision to initiate treatment or change a patient's treatment regime should be based on up-to-date best clinical evidence or guidance, for example, from the National Institute for Health and Clinical Excellence ('NICE') or other approved authoritative sources;

13.5.2 Healthcare professionals should base their prescribing decisions on individual assessments of their patients' clinical circumstances, for example, patients whose clinical history suggests they need a particular treatment should continue to receive it;

13.5.3 The individual patient (or their guardian or carer, where appropriate) should be informed about the action being taken and suitable arrangements should be made to involve the patient, ensuring they have an opportunity to discuss a proposed switch of medicines, and to monitor the patient following any switch;

13.5.4 Prescribers should be able to make their choice of medicinal products on the basis of clinical suitability, risk assessment and value for money;

13.5.5 Schemes should be reviewed whenever relevant NICE or alternative guidance are updated;

13.5.6 Scheme terms, including details of relevant therapeutic evaluations underpinning the scheme, should be published on the ICB's website. The following details should be included in the publication, namely: the drug covered; the date the ICB joined scheme; therapeutic area, and; the name of company offering the scheme.

<u>The Scrutiny and Adoption Process for Primary Care Rebate Schemes</u>

13.6 PrescQIPP NHS Programme ('PrescQIPP'), reviews rebate schemes, identifies any issues and provides advice to primary care organisations. PrescQIPP has recommended that Primary Care Rebate Schemes may be implemented if they are not in breach of UK legislation and that they offer genuine benefits to the NHS and to patients.

13.7 PrescQIPP has developed a set of principles of good practice for primary care organisations to use to facilitate robust scrutiny and identification, adoption and implementation of Primary Care Rebate Schemes. The PrescQIPP principles of good practice are set out in Appendix 3 of this Policy.

13.8 Primary Care Rebate Schemes that have been reviewed through the PrescQIPP programme and are sought to be adopted by the ICB will be taken through a screening and approval process using the same staged approval process set out in this Policy in relation to Joint Working arrangements.

13.9 Primary Care Rebate Schemes which are not reviewed through the PresQIPP programme may, in exceptional circumstances, by reviewed by the ICB following the same approach as the PresQIPP programme. The approval process for such schemes will be the same as that for Joint Working arrangements set out in this Policy.

13.10 Any Primary Care Rebate Scheme sought to be adopted by the ICB will, at every stage of the approval process, be assessed against its compliance with the principles set out in Appendix 3 and using the checklist set out in Appendix 4 of this Policy.

14.0 Meetings with Pharmaceutical Company Representatives

14.1 The ICB does not approve of any 'cold calling' or unsolicited emails to staff or ICB members from pharmaceutical industry representatives. Any 'cold calling' or unsolicited emails must be promptly reported to the Head of Medicines Management and to the Governance and Risk Team.

14.2 All requests for meetings and contacts by pharmaceutical industry representatives to ICB staff or members should be done via the dedicated pro-forma set out in Appendix 5of this Policy. All contact should then be via email to the generic email address set out in Appendix 7until a decision has been made that a meeting or direct contact will take place.

14.3 In reviewing requests for meetings with representatives of the pharmaceutical industry, consideration should be given as to whether the meeting will represent best use of ICB staff or member's time and therefore not all requests can be granted.

14.4 All completed pro-formas will be lodged centrally with the Medicines Management Team and held for six years for reference.

14.5 GPs and any other clinician members of the ICB who may be contacted by pharmaceutical industry representatives in their capacity as providers rather than commissioners should follow good practice and ensure inclusion in a practice register of dealings with the pharmaceutical industry. The register should include details of the meeting, date, representative and company name, practice members present, drugs and services discussed and hospitality received. The register should be available for both ICB and public scrutiny.

15.0 Sponsorship of Meetings

15.1 Sponsorship of routine internal ICB meetings is not permitted. Sponsorship may be obtained for educational or special events. This must be agreed by both the

Governance and Risk Team and the designated Head of Medicines Management. The contact details of both Teams are provided in Appendix 7 of this Policy.

15.2 The ABPI Code states that meetings must be held in appropriate venues conducive to the main purpose of the event. Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting, that is, subsistence only. Hospitality should adhere to the ICB's Conflicts of Interest Policy.

15.3 If meetings are sponsored by pharmaceutical companies, the fact must be disclosed in all of the papers relating to the meetings and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure readers are aware of it at the outset.

16.0 Meetings of the ICB

16.1 The ICB holds meetings of its Board of Members in public as is required to do so both by statute and its' Constitution. The meetings may be attended by representatives of the pharmaceutical industry. Those representatives attend meetings in their capacity as members of the public and have no special privileges when they do so. They should receive no greater or lesser opportunity to participate in any meeting or engage with individual members of the ICB than would any other member of the public unless requested to do so by the ICB.

16.2 Members of the ICB may be approached by representatives who seek to engage with them with the purpose of promoting their particular products or canvassing support for products or projects. It is recommended that ICB members politely but firmly decline to engage with pharmaceutical industry representatives in these circumstances. All such contacts must be reported to the Head of Medicines Management or to the Governance and Risk Team.

17.0 Roles and Responsibilities

17.1 The ICB has a duty to ensure that staff feel protected when carrying out their official duties and are not placed in a vulnerable position. If staff have concerns about any procedures or processes that they are asked to be involved in, the ICB has a duty to ensure that those concerns are listened to and addressed. Any such concerns must be reported to the member of staff's line manager in the first instance. If this is not appropriate, then these should be reported to the Medicines Management Team or the Governance and Risk Team.

18.0 Chief Executive

18.1 The ICB's Chief Executive has responsibility for the ICB'S systems of internal control. The Chief Executive, therefore, has a duty to ensure that:

18.1.1 The ICB has in place an effective Sponsorship and Joint Working with the Pharmaceutical Industry Policy;

18.1.2 The policy is reviewed and updated as required.

19.0 Executive Director of Places

19.1 The Executive Director of Places, as the Executive Director with responsibility for Medicines Management, is responsible for providing advice, with the help of the Head of Medicines Management, as to whether any proposed Joint Working initiative meets best practice guidelines. The Executive Director of Places will review Joint Working proposals in line with this Policy in order to ensure that the proposed initiatives do not conflict with existing ICB's prescribing policies and guidelines.

19.2 The Executive Director of Places shall ensure that any Joint Working arrangement complies with UK procurement law.

20.0 Senior Information Risk Owner

20.1 The Senior Information Risk Owner ('SIRO') is responsible for ensuring that any proposed information sharing to be carried on as part of a Joint Working Agreement, is in line with the ICB's legal duties.

21.0 Chief Development and Population Health Officer

21.1 The Chief Development and Population Officer is responsible for advising if, for any Joint Working proposals, there are any implications for the ICB's strategic commissioning.

22.0 Commissioners of Services

22.1 Commissioners are to ensure that a copy of this Policy is accessible to all commissioned services partners and that service provider policies are aligned with this Policy where relevant.

22.2 The effect on prescribing of medicines and devices should always be considered when commissioning or redesigning services. Commissioners should contact the Medicines Management Team at the earliest opportunity to ensure any impacts on medicines supply or prescribing are taken into account in any new or changed service, particularly if pharmaceutical industry partnership or sponsorship is anticipated.

23.0 Heads of Medicines Management

23.1 The ICB's Heads of Medicines Management are responsible for:

23.1.1 Assisting the Executive Director of Places in respect of their role set out in paragraph 19;

23.1.2 Updating this Policy and ensuring that the latest approved version is published on the ICB's website;

23.1.3 Maintaining a register of existing Joint Working arrangements with pharmaceutical companies, accepted and declined Sponsorships (of events,

gifts and hospitality) offered by pharmaceutical companies; meetings requested by representatives of pharmaceutical companies and meetings held with them, the dates of such meetings, the pharmaceutical company representative(s) present and the company they represented, names of ICB staff or representative(s) present at such meetings, the drugs and services discussed and any hospitality received, if at all.

23.1.4 Presenting, on a quarterly basis, to the Integrated Medicines Oversight Committee, the register of existing Joint Working arrangements with pharmaceutical companies, accepted and declined Sponsorships (of events, gifts and hospitality) offered by pharmaceutical companies; meetings requested by representatives of pharmaceutical companies and meetings held with them, the dates of such meetings, the pharmaceutical company representative(s) present and the company they represented, names of ICB staff or representative(s) present at such meetings, the drugs and services discussed and any hospitality received, if at all.

23.1.5 Presenting an annual report of Sponsorships and Joint Working to the Integrated Medicines Oversight Committee.

24.0 Human Resources Team

24.1 The Human Resources Team is responsible for ensuring the appropriate use of the ICB's disciplinary procedures that may become applicable following a breach of this Policy.

25.0 Managers

25.1 It is the responsibility of line managers to ensure that employees who report to them are aware of this Policy and act in accordance with it.

26.0 Employees and Other ICB Staff

26.1 It is the responsibility of each member of the ICB, Clinical Lead, office holder, employee and/or other staff members to read this Policy and follow it when considering Sponsorship or Joint Working with the pharmaceutical industry.

27.0 Integrated Medicines Oversight Committee

27.1 The Integrated Medicines Oversight Committee is responsible for the following:

27.1.1 Overseeing the arrangements for Sponsorship and/or Joint Working with the pharmaceutical industry and may make recommendations to the Audit Committee on changes to this Policy;

27.1.2 Reviewing and making decisions on Sponsorship and/or Joint Working with the pharmaceutical industry as per this Policy;

27.1.3 Overseeing and monitoring the arrangements agreed under this Policy;

27.1.4 Ensuring that the ICB and/or its relevant committee(s) have considered the wider business case which the Sponsorship and/or Joint Working with the pharmaceutical industry forms part of as appropriate.

28.0 Audit Committee

28.1 The Audit Committee approves this Policy. The Integrated Medicines Oversight Committee may make recommendations to the Audit committee on any matter relevant to the Policy and/or any changes.

29.0 Breach of This Policy

29.1 Any breaches of this Policy will be managed in accordance with the relevant sections of the ICB's Conflicts of Interest Policy.

29.2 Any allegations of fraud or bribery connected with the activity governed under this policy should be immediately reported to the ICB's Local Counter Fraud Specialists. Contact details are available in Appendix 6.

30.0 Training

30.1 The ICB will, at least once a year, provide training on working with the pharmaceutical industry to members of the Integrated Medicines Oversight Committee, contractors and to all ICB staff in the Medicines Management Team with specific responsibilities for medicines.

31.0 Monitoring Effectiveness

31.1 The ICB's Governance and Risk Team and Medicines Management Team will ensure effectiveness of the arrangements in this Policy through an annual review of the Policy and whenever there are changes to the prescribing guidelines, NHS Guidance and to the Conflicts of Interest Policy.

31.2 The Head(s) of Medicines Management will present, annually, a report of Joint Working with the pharmaceutical industry to the Integrated Medicines Oversight Committee. The report will consist of the following:

31.2.1 Summary of accepted and declined Sponsorships and Joint Working arrangements with the pharmaceutical industry;

31.2.2 Summary of developments in the official guidance around Sponsorship and Joint Working with the pharmaceutical industry, highlighting what those developments mean for the ICB;

31.2.3 Primary care rebate schemes that the ICB is involved in;

31.2.4 Staff training, awareness and engagement events in relation to this Policy;

31.2.5 Work done to promote awareness of this Policy to the ICB's commissioning support services, Local authority, Local GPs and the ICB's Procurement Team.

32.0 Related Policies

- Conflicts of Interest Policy;
- Speaking Up (Whistleblowing) Policy;
- Counter Fraud, Bribery and Corruption Policy;
- Disciplinary Policy;
- Procurement Policy;
- Any Qualified Provider Policy;
- Equality & Diversity Policy; and
- Standards of Business Conduct Policy.

33.0 References and Bibliography

33.1 ABPI. Code of Practice for the Pharmaceutical Industry. 2015. https://www.abpi.org.uk/publications/code-of-practice-for-the-pharmaceutical-industry-2019/

33.2 Equality Act 2010
http://www.legislation.gov.uk/ukpga/2010/15/pdfs/ukpga_20100015_en.pdf

33.3 Department of Health Best Practice Guidance for Joint Working between the NHS and the Pharmaceutical Industry.
https://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/dh_082569.pdf

33.4 NHS Values
https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england#nhs-values

33.5 The Nolan Principles (The Seven Principles of Standards in Public Life)
https://www.gov.uk/government/publications/the-7-principles-of-public-life

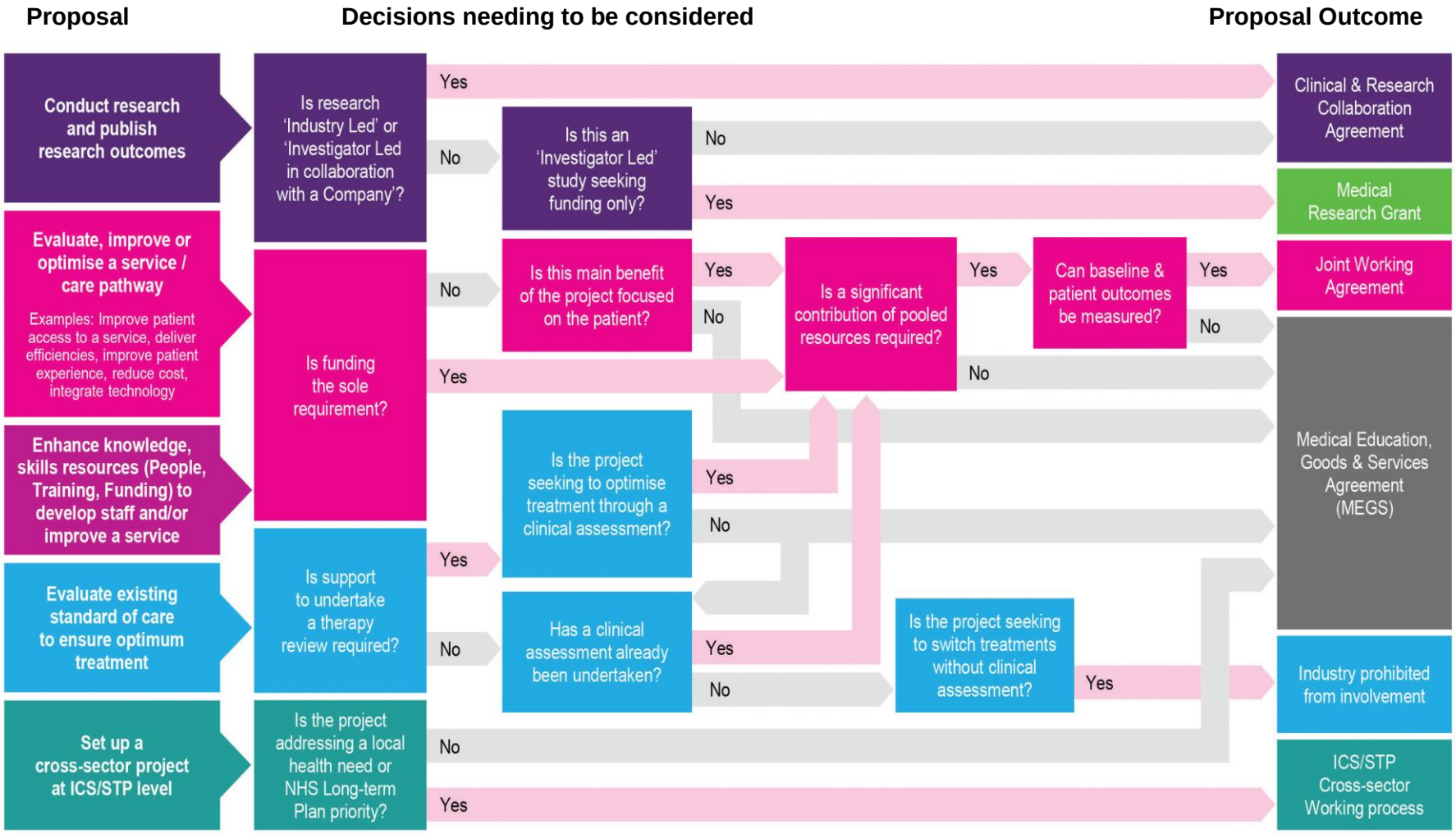
33.6 PrescQIPP NHS Programme https://www.prescqipp.info/our-resources/webkits/primary-care-rebates/

33.7 Department of Health/ABPI. Moving Beyond Sponsorship: Interactive Toolkit for Joint Working Between the NHS and the Pharmaceutical Industry. 2010. https://webarchive.nationalarchives.gov.uk/20130123193137/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840

33.8 Department of Health Guidance on Strategies to Achieve cost Effective Prescribing October 2010.

https://www.gov.uk/government/publications/strategies-to-achieve-cost-effective-prescribing-guidance-for-primary-care-trusts-and-clinical-commissioning-groups

APPENDIX 1: Decision Pathway for the Adoption of a Joint Working Proposal



APPENDIX 2: Joint Working Assessment Form

Name of Applicant……

Position/Directorate……..

Name of the Proposed Joint Working Partner Organisation……..

Contact details of the nominated representative of the Joint Working partner organisation:

Name:……..……..

Contact Details:……

Date……

1. Please summarise the Joint Working proposal:

2. What is the proposed contribution by the proposed partner organisation?

3. List any potential risks, which may result from the proposed Joint Working arrangement?

4. Please answer the following questions:

Essential Criteria	**Yes**	**No**
1. Is there a shared commitment to joint development, implementation and successful delivery of a patient-centred project by all parties involved?		
2. Does the proposed project have clear aims and objectives?		
3. Is the main benefit of the proposed project focused on the patient?		
4. Are any subsequent benefits at an organisational level and not specific to any individual?		
5. Do all parties acknowledge that the arrangement may benefit the NHS and company partner(s) involved?		
6. Will anonymised, aggregated, patient outcome data be measured and documented?		
7. Have you reached an agreement with all members of your team involved that the service at the centre of the proposed arrangement is appropriate for carrying on as a Joint Working arrangement?		
8. Is there a significant contribution of pooled resources from all parties, which may include people, finance and equipment wholly or partly dedicated to the proposed project?		
9. If patients are involved, have arrangements been made to ensure that they are made aware of the service/products integral to the Joint Working arrangement, where appropriate?		
10. Are all proposed treatments involved in line with national guidance where it exists?		
11. Are you satisfied that all materials and information supplied are valid, evidence-based, balanced and non-promotional?		
12. Are you satisfied that the offer for Joint Working is independent of purchasing or prescribing decisions?		

13. Has an assessment been carried out anticipated the costs and benefits of the proposed Joint Working arrangement?		
14. Is the Joint Working proposal consistent with the guidance given in the ICB's Policy for Joint Working with the pharmaceutical industry?		
15. Can it be confirmed that a review of conflicts of interest has been carried out and that none exist or that where necessary, mitigations have been put in place?		
16. Has an exit strategy and any contingency arrangements been agreed?		
17. Will all activities be conducted in an open and transparent manner?		
18. Are all partners are committed to publishing an executive summary of the Joint Working Agreement prior to commencement on any work to implement the proposed arrangement?		
19. Is the involvement of the proposed partner organisation of an appropriate level for the purpose i.e. has the agreement been approved at a senior level within the partner organisation sufficient to commit the proposed partner organisation to the proposed arrangement?		
20. Is the ICB satisfied with its knowledge of the proposed Joint Working partner organisation, e.g. is it known to the ICB? Is there evidence of audited accounts? Is it capable of being independently audited?		

In order for the proposed initiative/proposal to be considered for approval, all answers to the above questions must be **YES**. If any answers are **No**, the project does not meet the ICB's Policy on Joint Working with the pharmaceutical industry and should not be approved.

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

Once complete please pass this to your line manager who, after reviewing it will then pass it on to the Heads of Medicines Management for approval.

Nominated Representative of the ICB's Head of Medicines Management:

Name: ……...

Signature: …….

Date: …….

Executive Director of Places:

Name: …………………………………………………………………………………………..

Signature: ………………………………………………………………………………………

Date: ………………………………………………………………………………………

APPENDIX 3: PrescQIPP Primary Care Rebate Schemes (PCRS) -Good Practice Principles

The detailed content of PCRS offered to primary care organisations will differ between schemes. Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources. Although these good practice principles can help ICB's assess PCRS, the ICB will need to be assured that the schemes offered do not breach any other UK legislation, in particular, reimbursement for pharmaceutical services according to the Drug Tariff, duty to comply with the Department of Health and Social and Care's (DHSC) controls on pricing made under the National Health Service Act 2006 , the Medicines Act, the Human Medicines Regulations 2012, the Bribery Act 2010, EU law and the public law principles of reasonableness and fairness.

a. Product Related

i. It is preferable that PCRS are considered for medicines that have been assessed by a regional / national primary care rebate governance board and has a positive outcome. In the absence of such an assessment, it is important that the details of any PCRS are assessed against the criteria listed in Appendix 4.

ii. Healthcare professionals should always base their prescribing decisions primarily on assessments of the individual patient's clinical circumstances. The impact of a PCRS is a secondary consideration.

iii. The ICB will not consider or promote unlicensed or 'off-label' uses of medicines as part of a PCRS.

iv. Furthermore, a PCRS for a drug or product must be linked to total use of that drug and not limited to particular indications for which that drug can be used, and in line with the Specific Product Characteristics (SPC) for the drug in question.

v. All recommendations for use of a medicine within a PCRS must be consistent with the UK Marketing Authorisation of the medicine in question.

vi. Medicines not recommended by NICE will not be considered under a PCRS.

vii. Schemes for medicines in Category M (generic drugs regularly available) and some in Category C (drugs not readily available where the price is based on a particular branded product) of the Drug Tariff are not normally appropriate because of the wider impact to Community Pharmacy reimbursement.

b. Rebate Scheme Related

i. Any and all decision making processes will be clinically-led and involve all appropriate stakeholders, including patients where appropriate.

ii. PCRS should not be linked directly to requirements to increase market share or volume of prescribing.

iii. All PCRS should be approved through robust local governance processes that include the Chair of the Medicines Management Committee and Executive Director level approvals as set out in this Policy.

iv. 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. There will be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT2 data.

c. Information and Transparency

The ICB shall endeavour to make public (for example on the website) the existence of any PCRS the ICB has agreed to.

The ICB will not enter into any PCRS which precludes it from considering any other schemes subsequently offered by manufacturers of competitor drugs, should the ICB wish to do so. These PCRS shall all be considered using the same criteria.

There should be no requirement to collect or submit, to the manufacturer, any data other than volume of use, as derived from ePACT2 data. PCRS agreements must meet the requirements of the Data Protection Act and patient confidentiality must never be compromised.

Commissioners should not enter schemes that require them to provide information to a manufacturer about competitor products market share.

Freedom of Information –As a general principle, information relating to PCRS 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 Freedom of Information Act (FOIA) requests and commercially sensitive information should be contained in the contract.

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.

The rebate schemes will not be shared or promoted to prescribers.

APPENDIX 4: Checklist for Assessment of Primary Care Rebate Schemes

(Adapted from LPP / NHS London Principles Document and PrescQIPP)

Drug/Device Name: …… Indication:

Company: ……....

Contract Length: ……....

Review Date: ……

Financial benefit of rebate per year ……..

Total potential savings/benefit for ICB for one year =

Issue	Principles	Scheme compliance and notes
1. Product Related	• The medicine has been assessed by a regional/ national primary care rebate governance board and has a positive outcome. • The ICB does not consider or promote unlicensed or 'off-label' uses of medicines as part of a PCRS. • A PCRS for a drug or product must be linked to total use of that drug and not limited to particular indications for which that drug can be used, and in line with the Specific Product Characteristics (SPC) for the drug in question. • All recommendations for use of a medicine within a PCRS must be consistent with the UK Marketing Authorisation of the medicine in question. • Medicines not recommended by NICE are not to be considered under a PCRS. • Schemes for medicines in Category M (Generic Drugs regularly available) and some in Category C (drugs not readily available where the price is based on a particular branded product) of the Drug Tariff are not normally appropriate because of the wider impact to Community Pharmacy reimbursement.	
2. Rebate Scheme Related	• Rebate schemes will be agreed following a recommendation by the Integrated Medicines	

	Oversight Committee to an ICB decision making committee. • Schemes encouraging exclusive use of a medicines are to be avoided. • Schemes for medicines in Category M (Generic Drugs regularly available) and some in Category C (drugs not readily available where the price is based on a particular proprietary product) of the Drug Tariff are not normally appropriate because of the wider impact to Community Pharmacy reimbursement. • Rebates schemes are linked to requirements to increase market share are not favoured • Formal written contracts should be in place, signed by both parties to ensure the terms of the scheme are clear • It should always be possible to terminate a PCRC on notice with a sensible period e.g. 3 to 6 months • Rebates schemes should have an exit criteria to allow flexibility to respond to significant new clinical evidence or significant changes in market conditions, with a shorter notice period • All PCRS should be approved through robust local governance processes that include the Chair of the Integrated Medicines Oversight Committee and Executive Director level approvals. • 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. Schemes generating less than £10,000 per annum should not be recommended.	

	• There will be no requirement to collect or submit, to the manufacturer, any data other than volume of use as derived from ePACT2 data.	
3. Information and Transparency	• Primary care organisations should make public (for example on their website) the existence of any PCRS they have agreed to. • Primary care organisations should not enter into any PCRS, which preclude them from considering any other schemes subsequently offered by manufacturers of competitor drugs, should they wish to do so. • There should be no requirement to collect or submit to the manufacturer any data other than volume of use as derived from ePACT data. • PCRS agreements must meet the requirements of the Data Protection Act and General Data Protection Regulation (GDPR). Patient confidentiality must never be compromised. • Commissioners should not enter schemes that require them to provide information to a manufacturer about competitor products market share. • Freedom of Information Act (FOIA) – 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 FOIA requests and commercially sensitive information should be contained in the contract. As a general principle, information about rebate schemes may be released under FOIA requests, but commercially sensitive information is usually withheld. See legal advice for more details. • 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. • Is the invoicing process transparent as per NHS financial requirements?	

APPENDIX 5:Pro-Forma For Request for Meetings with The Pharmaceutical Industry

Meeting Request Pro-Forma for Pharmaceutical Industry Representatives • All sections must be completed prior to consideration of a meeting • Completing this pro-forma does not guarantee a meeting.	
Request Date	
Name of Representative	
Name of Company	
Contact Telephone No. & Email	
1. Outline what you wish to discuss and attach relevant pre-reading material	
2. Have you seen a member of the ICB about this before?	
3. Have you met or visited any of the local GPs regarding this issue? If yes, please provide details.	
4. Does your product or service have a budget /cost implication for ICB's in NCL? If yes, how much?	
5. If your meeting is about a product/service, outline its clinical benefit to patients in North Central London	
6. Any Additional Comments? (Maximum of 50 Words)	

Office Use Only	
Accept the meeting **Yes/No**	
Details of appointment	
Reason, if the meeting request is rejected	
Completed form to be sent to the following email address:	

APPENDIX 6: Where to Report Concerns of Fraud, Bribery or Wrongdoing

Any suspicions of fraud against NCL ICB should be reported to:

Local Counter Fraud Specialists:

Matt Wilson

Tel: +44 (0)7484 040 691

or by emailing matt.wilson2@nhs.net

Kirsty Clarke

Tel: +44 (0)20 3201 8054

or by emailing: kirsty.clarke8@nhs.net

Alternatively, you can telephone the NHS Fraud Reporting Line in confidence on

0800 028 40 60

Or online

https://cfa.nhs.uk/reportfraud

NCL ICB has a Speaking Up Whistleblowing Policy here:
ICB-Speaking-Up-Whistleblowing-Policy.pdf (nclhealthandcare.org.uk)

NHS England's Guidance Freedom to Speak Up in Primary Care: Guidance to Primary Care Providers on Supporting Whistleblowing in the NHS, November 2017
https://www.england.nhs.uk/wp-content/uploads/2016/11/whistleblowing-guidance.pdf

APPENDIX 7: Help and Support with This Policy

For help and support with this Policy please contact:

Medicines Management Team:

Barnet MMT email: nclccg.barnetmmt@nhs.net	**Camden MMT email:** mmt.camdenccg@nhs.net	**Enfield MMT email:** enfccg.medicinesmanagement@nhs.net
Haringey MMT email: harccg.medicines@nhs.net	**Islington MMT email:** mmt.islington@nhs.net	

Governance and Risk Team:
E-mail: Ncl.governance@nhs.net