NHS
Bath and North East Somerset
Clinical Commissioning Group

CCG Board
Paper Summary Sheet

DETAILS	Part 1 *(Open)*	**X**	Part 2 *(Closed)*		**Agenda Item**	**3.2**
Title of Paper	**Pharmaceutical Rebate Schemes**					
Meeting	CCG Board					
Date	5st November 2015					
Executive Lead	Dawn Clarke, Director of Nursing and Quality					
Author	Joel Hirst, Senior Commissioning Manager for Medicines					
Appendices	Appendix 1: DH view on Rebate schemes November 2012 Appendix 2: Screening Questions when Considering Rebate Schemes Appendix 3: Documentation for Primary Care Rebate Schemes (separate attachment) Appendix 4: BaNES CCG Principles on Pharmaceutical Rebate Schemes					

PURPOSE	**Approval**	**X**	Discussion		Information		Assurance	

EXECUTIVE SUMMARY						
Summary of Key Points	This paper provides an overview of rebate schemes including DH concerns and then response from CCGs in London and the East of England. The paper proposes a governance process based on best practice from BNSSG and others which is proposed would be used by BaNES CCG to facilitate decision making for BaNES CCG on rebate schemes.					
Background	In recent years commissioners within primary care have seen the introduction, and significant increase in numbers, of rebates offered within primary care for medicines prescribed. At present there are tens of schemes offered by companies ranging from the smallest to the largest, with schemes varying in composition and size. The paper provides more detail on rebate schemes and governance frameworks that some CCGs utilise to decide which rebate schemes are worth engaging with.					
Risk	**High**		**Medium**	**X**	**Low**	

Issue	**Risk**	**Comment & Mitigation**
Impact to CCG Reputation	Medium	Having a "Formulary First" principle and clear and robust governance processes should mitigate this risk.
Administrative Burden	Low	The decision making process will ensure the administrative burden is proportionate to the CCG before agreeing to rebate schemes
Freedom of Information requests	Low	Plans to publish on the CCG website information on existing rebate schemes should mitigate this
Unintended impact on supply chain	Medium	Hard to predict, the market will adjust. Will mitigate through not

			promoting agreed rebate schemes to prescribers
	Formulary Decision Governance	Medium	CCG will need to declare an interest when new formulary decisions are in areas where CCG has existing rebate schemes. CCG officers will withdraw from decision making when appropriate in these occasions

Impact on Quality	Pharmaceutical Rebate should have no impact on Quality as they are retrospective rebates after robust formulary decisions have been made through the Bath Clinical Area Partnership (BCAP) Group. Formulary decisions are already based on effectiveness, safety, patient factors and cost effectiveness.
Impact on Finance	It has been estimated by PrescQIPP that up to £180kpa income could be generated for BaNES CCG. This is an estimate and will vary depending on the level of rebate schemes on offer, currently there appears to be a growth in rebate schemes being made available.
Recommendation	**The committee are recommended to:** • Accept the proposed governance framework for considering and signing up to Pharmaceutical Rebate Schemes • Agree a position statement on rebate schemes (Appendix 4)

OTHER INFORMATION	

Who has been involved/contributed	• Other CCG have been contacted regarding their current involvement in rebate schemes
	• All available external governance documents have included in the paper
	• Julie-Anne Wales, Head of Corporate Governance and Planning
	• Andrew Baldwin, Finance Manager
	• Joint Commissioning Committee (JCC) discussed the paper in September and requested the paper to go to Audit and Assurance for advice. JCC had some concerns :
	  o Ethics – is it right for the CCG to support Pharmaceutical Companies to operate a system where there is a UK published list prices and then operate a local rebate scheme?
	  o Reputational – Regardless of robust governance frameworks, does being in receipt of income from a Pharmaceutical Rebate Scheme have a detrimental impact
	• Audit & Assurance Committee (AAC) considered the issues highlighted by the JCC in October. The AAC supported the framework proposed and while having reservations about the "macro" issues felt that the CCG should engage with Rebate Schemes following the proposed framework.
	• Bath Research and Development, Research Design Service, University of Bath. BRD normally only comment on research ethics only, they did not identify and concerns about this paper
	
	NB No legal advice has been sought directly by the CCG

Cross Reference to Strategic Objectives	The recommended options address the following strategic objectives: • Creating a sustainable health system within a wider health and social care partnership
National Policy / Legislation	The following national policy and legislative requirements have been considered in preparing this paper: • DH Guidance – Appendix 1 • London Procurement Programme : Legal Advice from DAC Beachcroft September 2012
Review	Joint Commissioning Committee is recommended to receive an update every twelve months

Equality & Diversity	Applicable		Not Applicable	X
	As this process is only considering retrospective rebates there will be no impact on Equality and Diversity			

1. Background

In recent years commissioners within primary care have seen the introduction, and significant increase in numbers, of rebates offered within primary care for medicines prescribed. At present there are tens of schemes offered by companies ranging from the smallest to the largest, with schemes varying in composition and size.

a. What are rebate schemes?

The rebate schemes offer primary care organisations, entry into a retrospective discount agreement on GP prescribing expenditure for particular branded medicines(s) with a pharmaceutical manufacturer in order to reduce costs via a contractual arrangement. A recent survey commissioned by the *Health Service Journal* (February 2013) suggests that just under a third of primary care organisations had rebate schemes in place, but this may be a conservative estimate.

b. Why does the industry want to engage?

For the industry, providing discounts can be beneficial to cash flow, and rebate schemes provide a low-risk means of encouraging market growth. With rebate schemes the national list price is unaffected, which is important for many companies because the list price is the reference price for other countries, and if it varies there would be an impact on global pricing and revenue.

c. Types of rebate scheme

(i) *Price discount*: a simple discount on the price of the medicine or device (i.e. rather than paying the NHS list price, the NHS would pay a lower percentage of the list price). The agreement with the pharmaceutical company would usually set out the data that the CCG has to supply about the prescription of the drug in order to claim the discount.

(ii) *Volume rebate on price schemes*: These schemes work in a similar way to simple price discount schemes. However the level of discount received is based on the volume of the medicine or device that is prescribed. These schemes are aimed at increasing the market share of the product.

(iii) *Risk sharing schemes:* These are agreements between the NHS and pharmaceutical company that aim to reduce the impact on the prescribing budget of new and/ or existing medicines brought about by either uncertainty of the value of the medicine and/ or the need to work within finite budgets. The agreement should set the scope and realise the mutual obligations between both the NHS and pharmaceutical companies depending on the occurrence if an agreed condition – the 'risk'. The 'risk' varies by situation, and can include pharmaceutical expenditure higher than agreed thresholds.

d. What is the DH view on rebate schemes?

Appendix 1 was a statement circulated by the DH by email in November 2012. The key points are:

- Rebate scheme may undermine the NHS Pharmaceutical Price Regulation Scheme (PPRS) which is the national process of setting prices for Branded Medicines in the UK.
- Schemes may create an administrative burden to Primary Care Organisations (PCOs)
- The may be unintended consequences from to NHS Drug prices or the community pharmacy contract arrangements which are linked to some generic prices
- It is for individual NHS organisations to determine whether they should participate in such arrangements

The DH asked PCOs to have regard to the following six factors when considering rebate schemes:

1. Administration burdens
2. Longevity of arrangements
3. Resilience of supply of products
4. Accessibility of supply for community pharmacies and whether there are extra costs to community pharmacy
5. The need to obtain adequate independent legal advice to ensure there are no specific difficulties for example the Bribery Act, competition law and/or rules around procurement.
6. Access to robust data about product use and costs and patient confidentiality requirements.

e. The approach taken by CCGs in London

London Primary Care Medicines Use & Procurement QIPP sub-group in October 2012 sets out an assessment of all the key issues. http://www.lpp.nhs.uk/media/43744/Primary-Care-Rebate-Schemes-Principles-NHS-London-Procurement-Partnership.pdf

This work included legal advice from DAC Beachcroft LLP September 2012. It is clear that the legal advice allows CCGs to engage with rebate schemes and considered all the issues highlighted by the DH. The document sets some principles of good practice regarding rebate schemes around three themes: product selection, nature of scheme and information and transparency.

These principles include:

- The clinical need for the medicine should always be established and evaluated before the cost is considered i.e. Formulary Decision making happens first and is not influenced by any information about potential rebate schemes
- Rebate schemes procedures should be robust and transparent
- Rebate schemes should apply to licensed medicines only
- NHS organisations should not solicit rebate schemes
- Rebate schemes should be agreed with statutory NHS bodies, not individuals or GP practices
- Rebate schemes should not be based on volume targets or thresholds
- Rebate schemes should not be based on exclusive supply or bundled deals based on sales of several products

f. PrescQIPP

The PrescQIPP NHS Programme was established as a programme in 2010 by the East of England Strategic Health Authority (SHA) to help deliver prescribing efficiencies. In response to the NHS restructure and loss of central funding, CCGs continued to fund PrescQIPP's work through a subscription model which has expanded to many CCGs including BaNES CCG in the Summer of 2014.

In 2012, the PrescQIPP established the Pharmaceutical Industry Scheme Governance Review Board as one of their work streams in response to requests by CCGs to provide guidance as to the acceptability of Primary Care Rebate Schemes being offered to the NHS by the pharmaceutical industry. This has now grown to be the largest governance provider on behalf of the majority of CCGs in England, Health and Social Care Board Northern Ireland and the Health Boards of Wales. The PrescQIPP Operating Model is set out at:
https://www.prescqipp.info/primary-care-rebates/finish/76-primary-care-rebate-governance/467-primary-care-rebate-board-operating-model

The PrescQIPP assessment process is designed to identify potential issues that CCGs may wish to consider when deciding whether to use rebate schemes. The assessment is split into three sections:
1. Clinical.
2. Contractual. The board scrutinise the scheme for complexity, ease of administration, length vs. market uncertainties etc. Any problems are identified and commented upon.
3. Financial. The realisability, and size of any payback are considered.

The primary output of the board is an assessment summarising the recommendations for the scheme submitted. The schemes are classified as follows:

- Grey –scheme considered; No significant reservations
- Amber – Scheme considered; Not fully appropriate
- Red – Scheme considered; Inappropriate

All assessments are placed on the PrescQIPP website and are available to members. Currently there are 26 schemes that have been reviewed on their website. Based on the PrescQIPP Dashboard they estimate a potential rebate base for BaNES CCG on April to June 15 data of £45,661 i.e. potentially £180k pa.

g. Locally what our neighbouring CCGs doing

Somerset	Engages with a number of schemes since January 2013
Gloucestershire	Engages with a number of schemes
Bristol, North Somerset and South Gloucester	Have similar policies to each other on rebate schemes and analogous governance mechanisms based on the London Procurement Programme
Wiltshire	Have signed up to three schemes and have indicated plans to sign up to more
Swindon	Do not engage with any schemes

Bristol CCG has taken the work from London and North Somerset and developed a governance framework. The proposals in this paper are based on the Bristol Framework.

2. Proposal for a CCG Governance Process for Rebate Schemes

a. Pharmaceutical Rebate Process

It is proposed that the BaNES CCG decision making process has the following steps:

1. Each proposal is reviewed by Senior Commissioner – Medicines using the Flow Chart (Appendix 2) and Documented using (Appendix 3)
2. Consider schemes which have gone through the PrescQIPP governance board with a grey rating and are already on the BCAP formulary
3. Apply the BNSSG Flow chart (appendix 2) to support decision making, which includes key screening questions
4. Document fully the assessment of schemes using BNSSG Checklist tool (appendix 3)
5. Views are sort from Director Quality and Nursing, GP Board Member – Medicines Lead and Finance Lead.
6. CCG Executive signs off rebate schemes if all steps are completed

b. Decision Process

In entering in to schemes with a pharmaceutical industry partner 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. (Appendix 2 and 3)
All proposals must be treated equally and decisions made will need to stand up to scrutiny if questioned.

In addition to the checklist the potential value of the rebate scheme and indirect costs associated with administering the scheme should be considered.

In the cases where a scheme is agreed the CCG will ensure that the agreement entered in to states that the pharmaceutical company that is offering the scheme will not use our 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.

c. Schemes accepted following positive decision from the CCG Executive

The Medicines Team will be responsible for undertaking the administration tasks associated with schemes that have been approved, i.e. the, supply of prescribing volume ePACT data.

Each scheme should have a signed agreement which should include clearly defined, mutually agreed exit criteria.

A monitoring report, detailing rebates that have been received by the organisation will be presented at the Joint Commissioning Committee every twelve months and an appropriate summary published on the CCG website alongside the CCG position statement on rebate schemes.

The funds generated by a rebate scheme will be held in the budget where the saving has been made (i.e. prescribing budget) unless otherwise agreed by the CCG.

3. Recommendation

- Board are recommended to accept the proposed governance framework for considering and signing up to Pharmaceutical Rebate Schemes
- Agree a position statement on rebate schemes (Appendix 4)

Appendix 1: DH view on Rebate schemes: an extract from an email sent to colleagues on the UK Pharmaceutical Advisors Group November 2012

The Pharmaceutical Price Regulation Scheme (PPRS) *is the UK-wide voluntary scheme agreed between Government and the Association of British Pharmaceutical Industry to control the prices of branded medicines supplied to the NHS. Under the terms of the 2009 PPRS agreement (see paragraph 3.4 of the agreement), it states that the Department of Health does not support additional or alternative initiatives by health authorities in respect of the pricing of branded medicines in primary care.*

The concern about local schemes is that they may fundamentally undermine the integrity and intent of the PPRS, whose objectives are to deliver value for money, encourage innovation, promote access and uptake for new medicines and provide stability, sustainability and predictability. Alongside increasing administration burdens for local NHS organisations, local pricing arrangements for all medicines would be unlikely to deliver the full objectives of the PPRS.

The pricing arrangements under the 2009 PPRS aim to secure value for money for the NHS whilst providing companies with the right incentives to invest in new and effective medicines for the future. The Department's concern is that local rebate schemes potentially undermine the PPRS pricing arrangements but also, it is possible that companies will seek to make good lost revenues from rebate schemes elsewhere, for example by increasing the wholesale price on other medicines or not offering as much discount to community pharmacies. Both of these scenarios could have implications for the community pharmacy contractual framework funding arrangements or lead to higher growth in the NHS drugs bill.

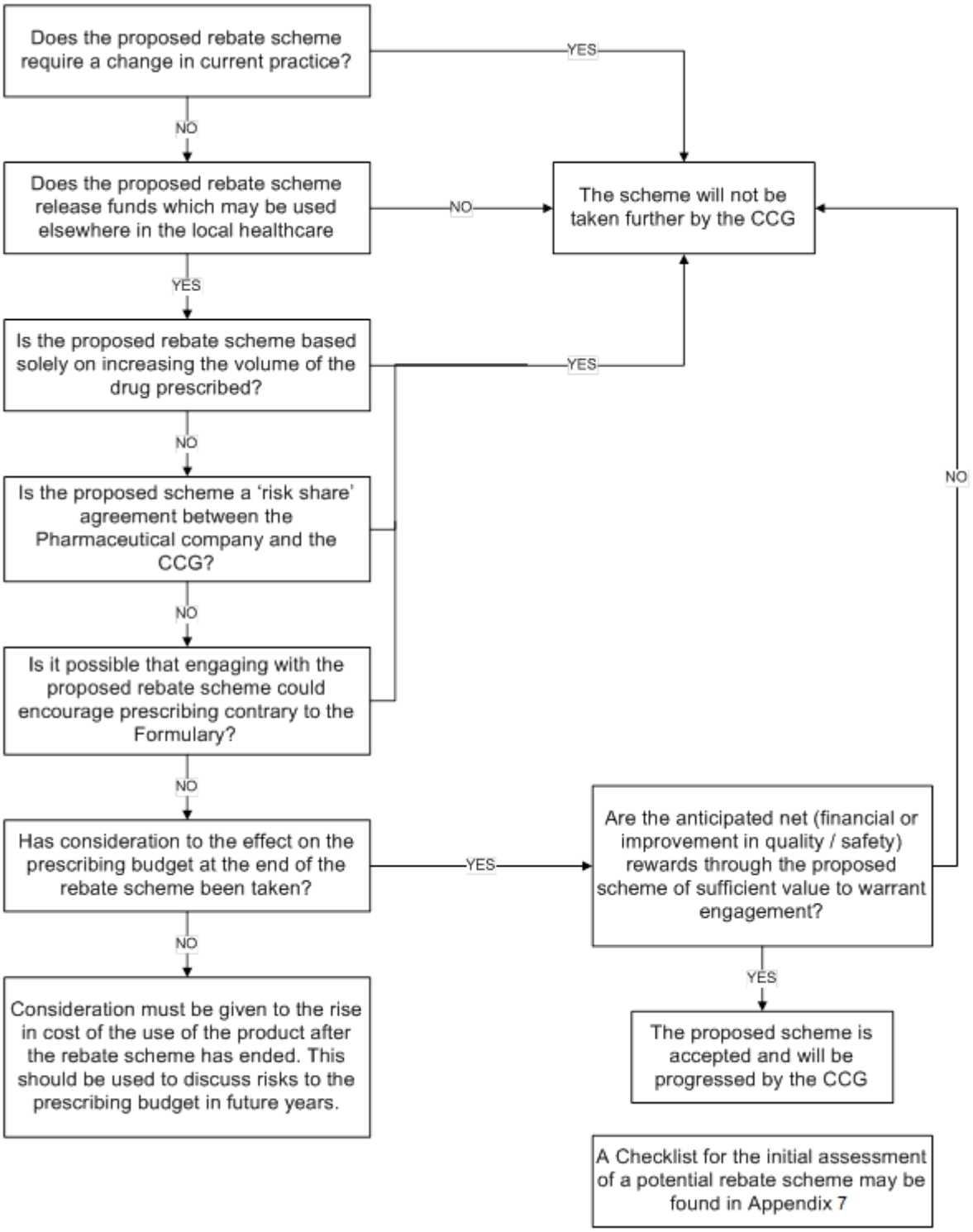
In view of this, Primary Care Organisations (PCO) should look critically at the wider ramifications of any potential rebate schemes on NHS budgets and future NHS service provision before entering into local agreements.

The PPRS does not extend to non-branded medicines or other items which may be prescribed on the NHS; this includes POM medicines. Depending upon the detail of the rebate scheme, it will be important to consider other relevant issues. If a company is offering an arrangement that is of added value to a PCO, for example, it supports implementation of one of the PCO's prescribing policies, or optimises patient's use of their medicines, there may be a benefit.

Before entering into any such arrangement a PCO may want to consider:
1. PCO/Practitioner administration burdens
2. Longevity of any such arrangements
3. Resilience of supply of relevant products
4. Accessibility of supply for community pharmacies and in particular whether there are any extra costs to community pharmacy which may not be particularly transparent (for example out of pocket expenses, increased stock holdings, use of a different supplier which amongst other things increases administration burdens.)
5. The need to obtain adequate independent legal advice to ensure there are no specific difficulties for example the Bribery Act, competition law and/or rules around procurement.
6. Access to robust data about product use and costs, taking into account administration burdens, needing to combine data sources when any historic or product comparison are needed and patient confidentiality requirements.

Ultimately, it is for individual NHS organisations to determine whether they should participate in such arrangement.

Appendix 2: Screening questions when considering a rebate scheme



Appendix 4: BaNES CCG Principles on Pharmaceutical Rebate Schemes

Background

Pharmaceutical rebate schemes are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded medicine(s).

Following a paper considered by the CCG Board in November 2015 a set of principles of good practice have been accepted by BaNES CCG, and are outlined below.

- It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms, which do not create an additional administrative burden to the NHS.

- 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.

- Any rebate scheme must be compatible with the effective, efficient and economic use of NHS resources

- The CCG 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 DH's controls on pricing made under the 2006 Act, the Medicines Act, the Human Medicines Regulations 2012, the Bribery Act, EU law and the public law principles of reasonableness and fairness.

Principles

A. Product related

1. Before any consideration of price the role of the medicine and place in the pathway should have been established by the BCAP Formulary Group
2. Information about rebate schemes will not be promoted to prescribers in BaNES so health professional are always able to base their prescribing decisions on the assessment of their patients' clinical circumstances
3. Any medicines considered for a rebate scheme will be licensed in the UK. Rebate schemes will not be linked to particular indications for use
4. All medicines in rebate schemes will be for use consistent with the marketing authority of the medicine

B. Rebate scheme related

1. Rebate schemes will be agreed following governance process agreed by the Board
2. The administrative burden to the NHS of setting up and running schemes must be factored against the likely financial benefit
3. Rebate schemes will be agreed at a CCG level only
4. Schemes encouraging exclusive use of a medicines will be avoided
5. 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 http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx
6. Rebates schemes should not be linked to requirements to increase market share

7. Formal written contracts should be in place, signed by both parties to ensure the terms of the scheme are clear
8. Rebate schemes should have a right to terminate on notice with a sensible period e.g. 3 to 6 months
9. 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

C. Information and Transparency

1. The CCG will make public via its website the existence of any rebate schemes and its principles
2. The CCG will not enter into any rebate schemes which preclude them from considering other schemes offered by others
3. There should be no requirements to collect or submit data other than volume of use as derived from ePACT data
4. Any rebate schemes must meet the requirements of the Data Protection Act, patient confidentiality must never be compromised
5. CCG will not enter into schemes that require them to provide information about competitors market share
6. Freedom of Information. Information about rebate schemes the CCG are engaged with and the total value of income received from rebate schemes by the CCG will be made available on the CCG website. All other aspects of FOI requests will be covered in the contract
7. Details of rebate schemes will be allowed to shared within the NHS and should be part of the rebate contract

Date: November 2015