NHS
Kernow
Clinical Commissioning Group

Policy for managing rebates on prescribed products

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Policy for managing rebates on prescribed products

1. Introduction

Retrospective rebates are increasingly being offered by suppliers of products prescribed on FP10 in primary care. This allows suppliers the commercial flexibility to achieve the following:

- Offer NHS organisations a lower price without adjusting list price. This prevents parallel trade and maintains the UK list price as a European reference point;
- Develop a commercial approach specific to individual organisations or groups of organisations.

The concept of rebating is established for some aspects of prescribing, for example, oral nutrition and some secondary care patient access schemes. Manufacturers of new premium price, potentially high volume medicines are also offering rebates to the NHS which could result in significant cost avoidance or greater access for patients. Rebating is also accepted as normal practice in other countries. Rebating may also provide a vehicle for value based pricing in primary care in the future where prices paid are linked to outcomes achieved.

While there are no legal barriers per se, the way in which rebates are handled within an organisation is an important consideration. Risks vary from an organisational 'discomfort' with the concept of rebates to serious breach of European Competition Laws or the Bribery Act. There are, however, potentially significant opportunities to improve the efficient use of the prescribing budget and facilitate access to valuable products for patients. This policy provides a framework for managing rebates in a legal and ethical way.

2. Purpose

This policy provides a framework for managing rebates in a legal and ethical way.

3. Roles and responsibilities

The Chief Officer (Finance): The Director of Integrated Care (Primary Care) will provide oversight of all aspects of this policy to ensure organisational compliance, and provide regular reports to the Finance Committee

Head of Medicines Optimisation: Ensures this policy is adhered to in all decisions relating to acceptance or refusal of rebates. Authorised to sign rebate agreements of behalf of the CCG and ensures rebates are claimed in a timely fashion.

4. Definitions

- **Rebate:** Primary care 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).
- **CCG:** Clinical Commissioning Group

5. Procedure

5.1 Interface with suppliers

5.1.1 Open door policy

The CCG must be able to demonstrate that all suppliers wishing to offer rebates or similar commercial offers are provided with equal access. When appointments are requested and the reason given is to discuss a rebate offer, appointments should always be arranged at the next convenient slot

5.1.2 Set the ground rules

In advance of the meeting suppliers should be provided with a copy of this policy.

5.1.3 Separate commercial from clinical

Most companies separate clinical from commercial calls; however the CCG should always ensure that if commercial offers are being discussed, then no clinical discussions take place in the same meeting. This includes suppliers of non-pharmaceutical products, such as devices, appliances and food products. An exception is when price is being linked to outcomes; in these case discussions clinical should be non-promotional.

5.1.4 No quid pro quo

The CCG must not offer or expect any favourable positioning of a product with respect to local formulary in return for a rebate. Similarly, suppliers should not make guideline or formulary positioning conditional to any rebate offer. To avoid any misunderstandings, meetings pertaining to rebates or other commercial offers must not consider formulary or guidelines status, positioning relative to competitor products or any other actions resulting from the rebate offer. This includes the execution of any switch programmes by the CCG.

Suppliers must not discuss any potential joint working arrangements, medical education goods and services, sponsorship offers or patient support programmes.

An exception is where these are explicitly part of the commercial offer and are included in a legal contract. When any quid pro quo arrangement is suggested, the meeting must be terminated immediately. A written report should be submitted to the Chief Officer (Finance) and Head of Medicines Optimisation.

5.1.5 CCG representation

The meeting should be attended by an employee or representative of the CCG authorised by the Head of Medicines Optimisation and/or Chief Officer (Quality) who is familiar with the content of this policy and the risks to individuals and the organisation.

5.2 Decision making

5.2.1 Initial screening

NHS Kernow Clinical Commissioning Group (NHS Kernow) subscribe to PrescQIPP therefore would consider rebates recommended by PrescQIPP. PrescQIPP are an independent not for profit organisation supporting all subscribed CCGs across England, Wales and Northern Ireland. They have set up well documented process of evaluation of all rebate schemes available and therefore the CCG will use this advice and recommendation as the basis of considering and approving any rebate scheme.

All potential rebate offers should then be presented to the Medicines Optimisation Programme Board (MOPB).

Decision making processes should be clinically led and 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.

The group will appraise the offer considering the following issues:

- Current formulary / guideline status of the product / existing care pathways;
- Licensed indications (and those of alternative products);
- Duration of the rebate;
- Structure of the rebate – a straight discount or something more complex;
- Administration costs and burden to the NHS;
- Patent expiries of product or alternatives;
- Cost of change if currently low usage;
- Impact on community pharmacy;
- Branded versions of category M generics;
- Brief review of evidence and perceived benefit – clinical effectiveness, safety and tolerability, patient acceptability, pathway impact, cost;
- Estimate of potential savings;
- Potential impact on secondary care;
- NICE TAG decisions / guidance.

The group should decide at this point if acceptance of the offer is in the interest of the organisation. If a decision is made not to proceed, the reasons should be carefully documented and fed back to the supplier.

5.2.2 Action plan

The Head of Medicine Optimisation will formulate an action plan which is then overseen by MOPB and must include:

- Need for a formulary submission;
- Need to consult with stakeholders;
- Management of confidentiality requirements;

- Outline plans for a switch programme if relevant;
- Discussion with stakeholder and CCG commissioning manager regarding pathway redesign opportunities if relevant;
- Communication / education plan.

5.2.3 Formulary submission

If a formulary submission is required, this should be submitted to the Cornwall Area Prescribing Committee Technical Working Group (CAPC TWG) as usual. The rebate arrangements should be considered when cost is usually discussed considering, 'rolling forward' any position generated by the MOPB, but taking account of any confidentiality requirements (see section six). Any person present who has been involved with the commercial discussion with the supplier should declare this at the meeting and should not take part in any clinical discussions at TWG. Clarity may be provided on the rebate structure if applicable.

5.2.4 Prescribing decisions

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.

5.2.5 Product licence

Any medicine considered under a 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.

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.

5.2.6 Rebates on non-formulary products

There are some potential scenarios where formulary inclusion is not supported but the rebate offered is significant. As a general rule rebates agreements should not be entered into for non-formulary products. Any departure from this position should be discussed at Quality and Safety Committee and the decision fully documented. Similarly decisions to decline a rebate offer which could deliver significant savings should also be fully documented.

5.2.7 Category M products

Rebate schemes are not appropriate for medicines in Category M and some medicines in Category C of the Drug Tariff, because of the potential wider impact on community pharmacy reimbursement. Advice should be sought from Head Medicines Optimisation for any category C products.

5.2.8 Volume based rebates

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

A volume based scheme should only be agreed if clinically appropriate and in line with local formulary and prescribing priorities. However, the administrative burden of monitoring such a scheme should be carefully considered.

6. Contracts

Head of Medicine Optimisation and Chief Officer (Finance) should ensure that a formal written contract is in place, signed by CFO 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.

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.

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.

The CCG 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.

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 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.

7. Commercially sensitive information

In many cases, rebate details will be commercially sensitive. In particular, suppliers will wish to avoid disclosure to competitor companies and to payer bodies in other countries.

7.1 Meeting minutes

No prices should be included in the minutes of meetings which are available to the public, for example those published on the internet site. Prices should ideally be communicated verbally at relevant meetings.

7.2 Sharing of information with prescribers and other stakeholders

It is important that prescribers and other stakeholders, for example secondary care clinicians and pharmacists, are aware of the efficiency opportunities provided by specific rebates. However, the risk associated with leakage of prices should be weighed against the benefits of informing prescribers. A plan for each product will be formulated by Head of Medicines Quality, discussing approach with suppliers where required. Any confidentiality agreements must be adhered to; this may include the requirement not to disclose specific rebate details to other CCGs, provider trusts or other external bodies. This aspect will be reviewed with further experience.

7.3 Freedom of Information (FOI) requests

Section 43 of the Freedom of Information Act provides exemption from the right to know [disclosure of information] when 'release of the information is likely to prejudice the commercial interests of any person. (A person may be an individual, a company, the public authority itself or any other legal entity.)'

It may be acceptable to confirm or deny that specific information is held by the CCG, however the CCG may still be exempt from providing this information if disclosure is likely to prejudice the supplier.

It should not be assumed that the CCG understands the potential commercial impact of disclosure on the manufacturer or supplier. The company concerned should be contacted before any potential disclosure of confidential commercially sensitive information under FOI especially where this is subject to a confidentiality clause within a contract. Expert / legal advice should be sought if necessary.

FOI 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

Any directive from the Information Commissioners Office to disclose information will be adhered to.

Any FOI requests should be discussed with the Finance Director and Information Governance lead before any response is made.

8. Use of rebates

It is vital that any funds received by the CCG as part of a rebate or similar commercial agreement are managed in a transparent, legal and ethical way. Oversight for any spending plans, redistribution of funds and control of destination budgets will be provided by the Finance Committee.

As a general rule, no prescriber or adviser should be in a position to benefit personally from the level of rebate received by the CCG. This means personal payment or 'empire building.'

Examples of unacceptable practice:

- A GP LES for diabetes is funded by an insulin rebate. The higher the rebate payment, the more funds available for the LES;
- The medicines management team create a budget for special projects. All rebates are paid into this budget and the team can use this for short term posts.

Examples of acceptable practice:

- All rebates are paid to the practice prescribing budget in line with each practices prescribing patterns;
- A diabetes 'invest to save' project is approved by the CCG. The business case includes an investment which is offset by a rebate scheme. The projected savings are in line with analysis of appropriate use and the project funding is secure even if rebate savings are not fully realised. Any surplus is not automatically allocated to the project.

9. Payment mechanisms

A clear process for generating the required information should be determined for each rebate agreement which will be managed by the medicines optimisation team and their management accountant. This should include:

- Information required;
- Reporting intervals;
- Generation of purchase orders if required;
- Invoicing arrangements.

10. Switch programmes

Any programmes which aim to 'switch' patients medicines or other prescribed items undertaken as a result of rebate schemes should incorporate the principles listed in the DH document – 'Strategies to achieve cost effective prescribing.'

11. Use of third party organisations

Any third party organisations, for example commercial 'brokers' or Commissioning Support Services should adhere to the principles described in this document.

12. Training

No specific training requirements. All staff who may be involved in managing rebate schemes must be familiar with the content of this policy.

13. Monitoring the compliance and effectiveness of this Policy

Annual reports will be provided to the Finance and Performance Committee. Frequency of reports will be reviewed against the size of the CCG portfolio of rebate schemes.

14. References

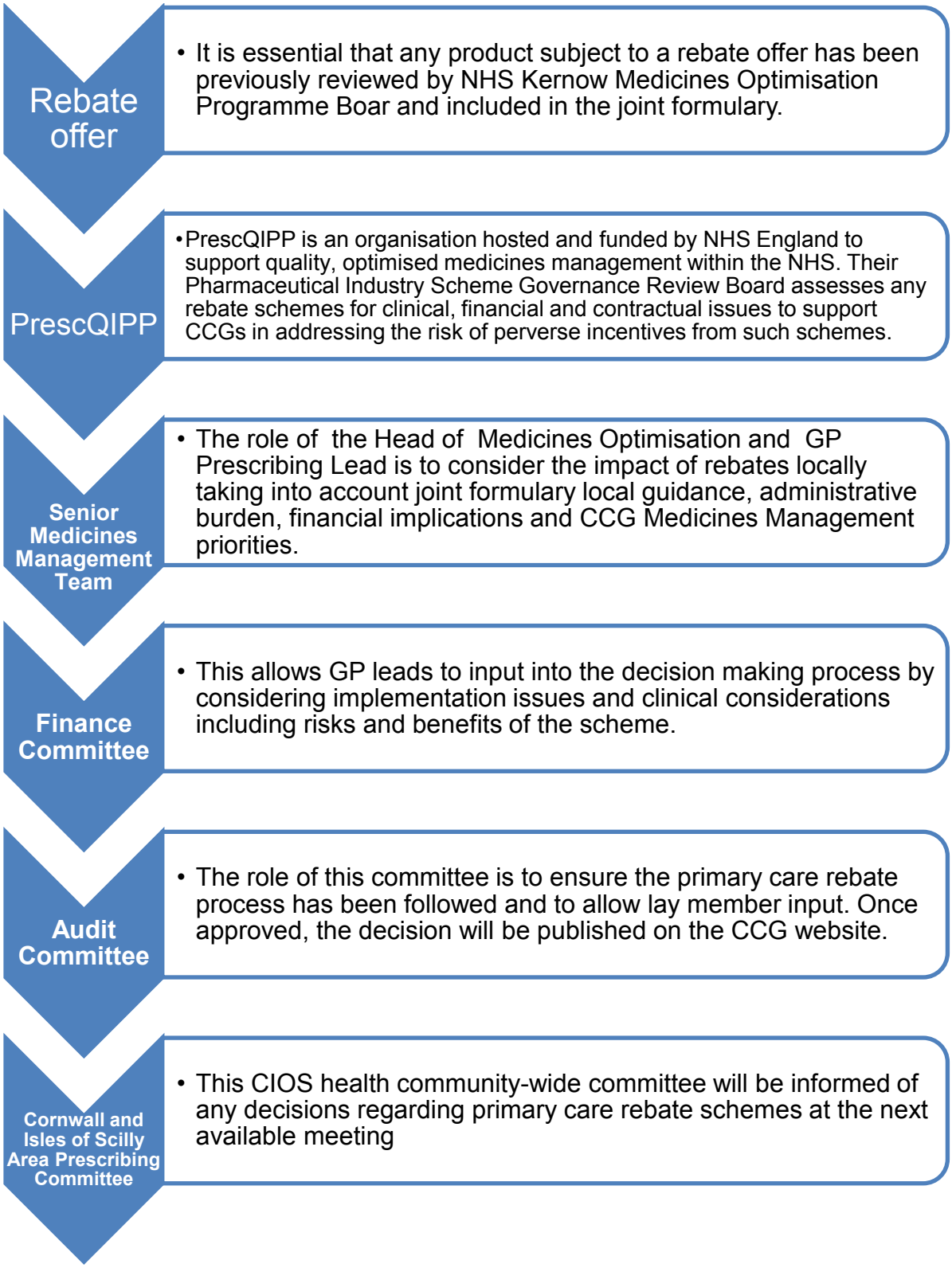
- London Procurement Programme Legal Response from DAC Beachcroft LLP – Personnel Communication;
- Department of Health. Strategies to Achieve Cost-Effective Prescribing (2010);
- London Procurement Partnership (2013) Principles and Legal Implications of Primary Care Rebate Schemes;

15. Acknowledgements

The following were used as the basis of this policy:

- Principles and Legal Implications of Primary Care Rebate Schemes. London Procurement Programme, 2012. Available from: http://www.lpp.nhs.uk/_store/documents/pcrs_principles_updated_feb_13.pdf Accessed 9/4/13]
- Ethical Framework for Considering Rebate Agreements from Pharmaceutical, Nutrition and Device Companies. Greater Manchester Commissioning Support Unit, 2013.
- PrescQIPP Pharmaceutical Industry Scheme Governance Review Board, 2014.

Appendix one
Primary care rebate scheme approval process



Appendix 2
Primary care rebate scheme decision form

Confidential

Product	
Manufacturer	
Contact details	

Brief details of rebate scheme	

Assessment criteria	**Yes or no?**
If the product is a medicine, is it licenced in the UK?	
The product does not have a negative decision from NICE?	
The contract does not include any requirement for a directive or guideline to be given to health care professionals to prescribe the specific product?	
The rebate scheme is not designed to increase off label use of the drug?	
If the product is a device or nutritional supplement is it contained in the current Drug Tariff?	
If it is not a medicine, it has not been excluded from use within primary care?	
If the product is a vitamin and classed as a food supplement, is it recommended for use in HaRD CCG?	
The rebate scheme does not require exclusive use of a specific brand?	
The product is not contained in Category A or M of the Drug Tariff?	
The rebate scheme is not linked directly to a requirement for an increase in market share or volume of prescribing?	
The rebate scheme does not prevent consideration of other schemes?	
There is no requirement to submit additional information beyond the volume of prescribing of the product?	
There is no requirement to collect patient specific data?	

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Considerations:

PrescQIPP Pharmaceutical Industry Scheme Governance Board assessment		
No. of years scheme is available? (Is it >2 years?)		
Estimated potential savings (per patient and for HaRD population per annum)?	£ /pt/annum	£ /NHS Kernow/annum
Have any other contractual or legal issues been identified during the evaluation?		
Further information, for example: • Administrative burden • Governance issues • Freedom of Information issues • Any other pertinent issues		
Recommendation		
Rationale		
Evaluation carried out by (name, title and date):		
Reviewed by (name, title and date):		

Finance Committee decision

The Committee does / does not support the decision to agree to this primary care rebate scheme.

Title	Name	Signature	Date
FC Chair			
CCG Chief Finance Officer			

Date sent to Audit Committee:

Appendix three
Equality Impact Assessment

Name of policy to be assessed	Policy for managing rebates on prescribed products		
Section	Prescribing and Medicines Optimisation	**Date of Assessment**	07/03/2017
Officer responsible for the assessment	Georgina Praed	**Is this a new or existing policy?**	New
1. Describe the aims, objectives and purpose of the policy.			
The policy aims to provide the legal and ethical framework for managing rebates offered by the pharmaceutical industry. The policy outlines an internal decision making process.			
2. Are there any associated objectives of the policy? Please explain.			
Sets out roles and responsibilities. Sets out process for management.			
3. Who is intended to benefit from this policy, and in what way?			
The CCG will benefit financially.			
4. What outcomes are wanted from this policy?			
Set a clear process which is legal and ethical, and which reinforces that decision making processes should be clinically led and 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.			
5. What factors/ forces could contribute/ detract from the outcomes?			
Risks vary from an organisational 'discomfort' with the concept of rebates to serious breach of European Competition Laws or the Bribery Act.			
6. Who are the main stakeholders in relation to the policy?			
NHS Kernow.			
7. Who implements the policy, and who is responsible for the policy?			
Head of Medicines Optimisation and Chief Financial Officer, NHS Kernow			

8. What is the impact on people from Black and Minority Ethnic Groups (BME) (positive or negative)?
Consider relevance to eliminating unlawful discrimination, promoting equality of opportunity and promoting good race relations between people of different racial groups. Issues to consider include people's race, colour and nationality, Gypsy, Roma, Traveller communities, employment issues relating to refugees, asylum seekers, ethnic minorities, language barriers, providing translation and interpreting services, cultural issues and customs, access to services.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
9. What is the differential impact for male or female people (positive or negative)?
Consider what issues there are for men and women e.g. responsibilities for dependants, issues for carers, access to training and employment issues, attitudes towards accessing healthcare.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
10. What is the differential impact on disabled people (positive or negative)?
Consider what issues there are around each of the disabilities e.g. access to building and services, how we provide services and the way we do this, producing information in alternative formats and employment issues. Consider the requirements of the NHS Accessible Information Standard. Consider attitudinal, physical and social barriers. This can include physical disability, learning disability, people with long term conditions, communication needs arising from a disability.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
11. What is the differential impact on sexual orientation?

Consider what issues there are for the employment process and training and differential health outcomes amongst lesbian and gay people. Also consider provision of services for e.g. older and younger people from lesbian, gay, bi-sexual. Consider heterosexual people as well as lesbian, gay and bisexual people.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
12. What is the differential impact on people of different ages (positive or negative)?
Consider what issues there are for the employment process and training. Some of our services impact on our community in relation to age e.g. how do we engage with older and younger people about access to our services? Consider safeguarding, consent and child welfare.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
13. What differential impact will there be due religion or belief (positive or negative)?
Consider what issues there are for the employment process and training. Also consider the likely impact around the way services are provided e.g. dietary issues, religious holidays, days associated with religious observance, cultural issues and customs, places to worship.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
14. What is the impact on marriage of civil partnership (positive or negative)? NB: this is particularly relevant for employment policies
This characteristic is relevant in law only to employment, however, NHS Kernow will strive to consider this characteristic in all

aspects of its work. Consider what issues there may be for someone who is married or in a civil partnership. Are they likely to be different to those faced by a single person? What, if any are the likely implications for employment and does it differ according to marital status?
No impact identified. Decision making processes should be clinically led and 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.
How will any negative be mitigated?
No impact identified
15. What is the differential impact who have gone through or are going through gender reassignment, or who identify as transgender?
Consider what issues there are for people who have been through or a going through transition from one sex to another. How is this going to affect their access to services and their treatment when receiving NHS care? What are the likely implications for employment of a transgender person? This can include issues such as privacy of data and harassment.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
16. What is the differential impact on people who are pregnant or breast feeding mothers, or those on maternity leave?
This characteristic applies to pregnant and breast feeding mothers with babies of up to six months, in employment and when accessing services. When developing a policy or services consider how a nursing mother will be able to nurse her baby in a particular facility and what staff may need to do to enable the baby to be nursed. Consider working arrangements, part-time working, infant caring responsibilities.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
17. Other identified groups:

Consider carers, veterans, different socio-economic groups, people living in poverty, area inequality, income, resident status (migrants), people who are homeless, long-term unemployed, people who are geographically isolated, people who misuse drugs, those who are in stigmatised occupations, people with limited family or social networks, and other groups experiencing disadvantage and barriers to access.
No impact identified. Decision making processes should be clinically led and 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.
How will any negative impact be mitigated?
No impact identified
18. How have the Core Human Rights Values been considered in the formulation of this policy/strategy? If they haven't please reconsider the document and amend to incorporate these values. • **Fairness;** • **Respect;** • **Equality;** • **Dignity;** • **Autonomy**
This policy does not impact upon Human Rights values.
19. Which of the Human Rights Articles does this document impact?

The right:	**Yes / No:**
• To life	No
• Not to be tortured or treated in an inhuman or degrading way	No
• To liberty and security	No
• To a fair trial	No
• To respect for home and family life, and correspondence	No
• To freedom of thought, conscience and religion	No
• To freedom of expression	No
• To freedom of assembly and association	No
• To marry and found a family	No

• Not to be discriminated against in relation to the enjoyment of any of the rights contained in the European Convention	No
• To peaceful enjoyment of possessions	Yes
a) What existing evidence (either presumed or otherwise) do you have for this?	
Article 1 – Protection of property: Protocol 1 Article 1 ensures that a person's belongings are not unfairly interfered with. It can include the right to carry on a business and this may arise in the context of Performers List decisions or decisions relating to NHS Kernow's pharmacy list.	
20. How will you ensure that those responsible for implementing the Policy are aware of the Human Rights implications and equipped to deal with them?	
The Human Rights Statement and Guidance accompanies the Equality Impact Assessment guidance and Comprehensive Impact Assessment guidance, to provide comprehensive information for staff. These policies are available for staff on the NHS Kernow website and have been proactively disseminated via the staff bulletin.	
21. Describe how the policy contributes towards eliminating discrimination, harassment and victimisation.	
No impact identified.	
22. Describe how the policy contributes towards advancing equality of opportunity.	
No impact identified.	
23. Describe how the policy contributes towards promoting good relations between people with protected characteristics.	
No impact identified.	
24. If the differential impacts identified are positive, explain how this policy is legitimate positive action and will improve outcomes, services or the working environment for that group of people.	
No impact identified.	
25. Explain what amendments have been made to the policy or mitigating actions have been taken, and when they were made.	
No amendments identified.	
26. If the negative impacts identified have been unable to be mitigated through amendment to the policy or mitigating actions, explain what your next steps are.	
No impact identified.	

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Signed (completing officer) : 

Date: 13 March 2017

Signed (Head of Section): 

Date: 12/07/2017

Please ensure that a signed copy of this form is sent to both the Policies Officer with the policy and the Equality and Diversity lead.