

# **HSCB PROCESS**

# **PHARMACEUTICAL REBATE SCHEMES IN PRIMARY CARE**

**June 2019**

**Version 0.3**

## 1. Purpose

HSCB does not actively seek rebate proposals from pharmaceutical companies; however it is important that a process is in place to assess such proposals if they are offered. The purpose of this paper is to detail the process to be followed by HSCB Integrated Care when considering applications by pharmaceutical companies in respect of proposed Pharmaceutical Rebate Schemes.

Pharmaceutical Rebate Schemes are separate from prescribing policy and guidance and in their nature are short term/terminable. HSCB considers it is not appropriate for pharmaceutical companies to contact any prescribing entity to communicate the existence, or share the content, of any Pharmaceutical Rebate Schemes.

## 2. Background

A Pharmaceutical Rebate Scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine.

In March 2015, HSCB became a member of PrescQIPP which has already established a Pharmaceutical Industry Scheme Governance Review Board and robust process to assess rebates.

<https://www.prescqipp.info/about-prescqipp/>

Membership of PrescQIPP allows HSCB to access the PrescQIPP Review Board's rebate scheme assessments which are based on the clinical, contractual and financial aspects of a scheme.

A HSCB Pharmaceutical Rebate Scheme Review Team (**PRSRT**) has been established to develop and apply a local review process to consider whether or not any individual rebate proposal reviewed and published by PrescQIPP with grey or amber status should be recommended for acceptance by HSCB.

From April 2015, only those rebates that have been reviewed and published by PrescQIPP with grey or amber status will be considered for Northern Ireland. Following assessment by PrescQIPP Pharmaceutical Industry Scheme Governance Review Board, the PRSRT will then apply the local review process to the grey and amber schemes.

<https://www.prescqipp.info/our-resources/webkits/primary-care-rebates/>

### 3. Membership of PRSRT

A full Terms of Reference, including membership details, for the PRSRT is included at Appendix 1.

All information circulated by / discussed within the PRSRT will remain confidential in accordance with PrescQIPP membership.

All members of, and any advisers to, the PRSRT in addition to any other people attending the meeting will be asked to declare any interest or received hospitality in accordance with the Declaration of Interest form (Appendix 2) in advance of each meeting. Any action to be taken on the basis of these declarations will be at the discretion of the Chair. This will remain as a standing item on each agenda.

Any member of the PRSRT who is also a member of the Medicines Optimisation Team (**MOT**) will not be involved in the MOT decision making process on individual rebate schemes.

### 4. Review Process

The various stages in the review process are outlined in the following paragraphs.

#### **Stage 1 Offers**

The starting point for any rebate application to HSCB is an application to PrescQIPP. Applications received directly by HSCB e.g. via [Business.supportwest@hscni.net](mailto:Business.supportwest@hscni.net) or [medicines.management@hscni.net](mailto:medicines.management@hscni.net) , for consideration by the PRSRT will be directed on to PrescQIPP via this link:

<https://www.prescqipp.info/our-resources/webkits/primary-care-rebates/>

#### **Stage 2 Assessment by PrescQIPP**

PrescQIPP will assess these schemes, outlining issues, and highlighting inappropriate schemes. HSCB Medicines Management Team staff will take part in such assessment via teleconference or participate in the PrescQIPP Fast Track Approval Process. As a member of PrescQIPP, all documentation will be made available to HSCB representatives prior to the meeting. Outcomes for all schemes assessed will be published on the PrescQIPP website. Outcomes will be categorised as follows:

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

Schemes assessed as 'Red' will not progress any further in the process.

### **Stage 3 Local Review of Grey and Amber Schemes by PRSRT**

Schemes which have been assessed by PrescQIPP as Grey or Amber will initially be reviewed for appropriateness by HSCB Medicines Management Team staff representatives on the PRSRT taking into account HSCB prescribing practices. Only those schemes deemed appropriate will be presented to the full group for consideration.

Members of PRSRT and Advisers will then consider the PrescQIPP Review Board's comments and will complete the relevant sections of the information summary template (see Appendix 3). Schemes will be reviewed by the PRSRT taking into account the benefits vs. the burden of the proposed schemes; this will, for example, take into account factors such as complexity of the scheme, financial benefits, length of the scheme and local prescribing practice. A legal review of the contract will also be completed by a Representative of BSO Directorate of Legal Services (DLS).

Details of scheme(s) under consideration, plus completed information summary templates (Appendix 3) for each scheme, will be circulated to all members of the PRSRT. Schemes to be considered will be reviewed either at the next PRSRT meeting (PRSRT will meet as appropriate, usually following the PrescQIPP Industry Review Board meeting) or via email and a report will be prepared for review by MOT.

### **Stage 4 MOT review**

The report developed by the PRSRT detailing all schemes considered will be presented to MOT for approval.

### **Stage 5 Feedback to applicant**

Once a decision is made by MOT, this is recorded formally in the MOT minutes.

#### **If a pharmaceutical rebate scheme is approved by MOT:**

The company will be formally notified of the decision (Appendix 5) by way of a letter notifying the company that HSCB wish to take forward the rebate within primary care in Northern Ireland subject to agreeing the final contract terms and administration detail. All communications in relation to contract administrative detail between BSO DLS and a pharmaceutical company will be facilitated via the [business.supportwest@hscni.net](mailto:business.supportwest@hscni.net) account, unless otherwise agreed between HSCB and the pharmaceutical company.

#### **If MOT does not accept a pharmaceutical rebate scheme:**

Pharmaceutical companies are not routinely informed of the decision. A letter may be sent to the company from the chair of MOT at the request of the company (Appendix 6).

### **Stage 6 Review of decision (if requested)**

Should the applicant have issues with the decision made by MOT, they should submit their comments in writing to the Chair of the MOT who will then initiate a review by a person independent of the process. Each company has 8 weeks from receipt of feedback from MOT to submit their comments to the MOT Chair.

The independent review will then be completed within a further 8 weeks and the company advised of the outcome of the review as soon as possible thereafter.

## **5. Review of HSCB Pharmaceutical Rebate Schemes Operational Process**

The HSCB Pharmaceutical Rebate Schemes Operational Process will be reviewed on a regular basis.

### **Terms of Reference**

#### **Membership of the HSCB Pharmaceutical Rebate Scheme Review Team (PRSRT)**

- HSCB Pharmacy Lead (Chairperson)
- Representative, Medicines Management Information Team, HSCB
- Representatives, Medicines Management Team, HSCB
- Business Support Manager, Integrated Care, HSCB
- Representatives, Business Support, Integrated Care, HSCB
- Representative, Finance (FHS), HSCB
- Statistician, Information & Registration Unit, BSO

#### **Advisers to the Group**

- Representative, BSO DLS
- PrescQIPP Head of Operations

#### **Reporting to the Medicines Optimisation Team (MOT)**

A monthly update report will be presented to MOT detailing progress on all locally reviewed schemes.

#### **Conflict of Interest**

At the start of every meeting, members of the group (and any other people attending the meetings) will be asked to declare any conflicts of interest that may influence any decisions or recommendations of a particular meeting (Appendix 2). Any action to be taken on the basis of these declarations will be at the discretion of the Chair.

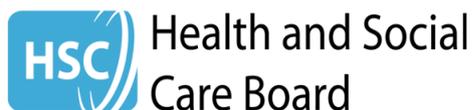
#### **Accountability**

The PRSRT will act as a sub-group of MOT. MOT will be the approval body and will make the decision whether to approve a scheme based on the report and information received from the PRSRT.

### **Third Party Organisations**

The PRSRT will only work with representatives of the company, or clearly designated partner organisations, which are responsible for the scheme and its contents. The main contact should be someone who is able to act as a decision maker on behalf of the company submitting the schemes.

Representatives of PRSRT will not routinely meet with company representatives and all correspondence relating to Pharmaceutical Rebates in Primary Care should be directed through the dedicated email address.



**DECLARATION OF INTERESTS AND RECEIVED HOSPITALITY**

<b>Declared interest or received hospitality</b>	<b>Please state</b>
Directorships, including non-executive Directorships held in private companies or PLCs (with the exception of those of dormant companies)	
Ownership, or part ownership, of private companies, businesses or consultancies held likely or possibly seeking to do business with the NHS	
Majority or controlling share holdings in organisations likely or possible seeking to do business with the NHS	
A position of authority in a charity or voluntary body in the field of health and social care	
Any connection with a voluntary or other body contracting for NHS products or services including: <ul style="list-style-type: none"><li>• share holdings or other interests in pharmaceutical companies</li><li>• receipt of departmental, staffing or personal sponsorship from the pharmaceutical industry</li><li>• engagement by the pharmaceutical industry to provide advice, undertake presentations, lectures or tours of instruction</li></ul>	
Any received hospitality exceeding £50 (this figure is for guidance purposes)	

Name:

Employing organisation:

Signed:

Date:

## HSCB/PHA Process for Managing Declarations of Interest August 2013

Type of interest	Outcome
<p><b>A specific personal pecuniary interest</b> involves a current personal payment, which may either relate to the manufacturer or owner of a product or service being evaluated. This may include consultancy work, fee-paid work or direct share-holdings in the 12 months preceding the meeting at which the declaration is being made.</p>	<p>A person declaring a personal specific pecuniary interest <u>shall take no part in proceedings</u> as they relate to the intervention or matter and will normally leave the meeting until the matter has been concluded. In exceptional circumstances he or she may, at the discretion of the chair, be permitted to remain for the discussion where their expertise is specifically required to inform the other members in their discussions. This expert advice shall be restricted to the giving of factual and objective information before withdrawing from the meeting until a decision/vote is taken or the discussion has concluded.</p>
<p><b>A non-specific personal pecuniary interest</b> involves a current personal payment, which may either relate to the industry or sector from which the product or service comes. This may include consultancy work, fee-paid work or direct share-holdings in the 12 months preceding the meeting at which the declaration is being made.</p>	<p>A person declaring a personal non-specific pecuniary <u>may take part in the proceedings</u> unless, exceptionally, the chair rules otherwise.</p>
<p><b>A non-personal pecuniary interest</b> involves payment which benefits a department or organisation for which a person has managerial responsibility, but is not received by the person themselves. For example, charities or self-help organisations might receive funding such as sponsorship money or educational grants from the healthcare industry, which might be considered as affecting the objectivity of people working for the organisation N.B it is not always easy to know whether an organisation receives funding or payment from the healthcare industry, and you are not expected to make exceptional efforts to find out about such payments</p>	<p>A person declaring a non-personal specific pecuniary interest <u>may take part in the proceedings</u> unless he or she has personal knowledge of the intervention or matter either through his or her own work, or through direct supervision of other people's work. In either of these cases he or she should declare this interest and not take part in the proceedings except to answer questions</p> <p>A person declaring a non-personal non-specific pecuniary interest <u>may take part in proceedings</u> unless, exceptionally, the chair rules otherwise.</p>
<p><b>A specific personal family interest</b> relates to the personal interests of a family member and involves a current payment to the family member of the employee or member. The interest is regarded as <b>specific</b> when it relates to the manufacturer or owner of a product or service being evaluated. This may include consultancy work, fee-paid work or direct share-holdings in the 12 months</p>	<p>A person declaring a personal specific family interest <u>shall take no part in proceedings</u> as they relate to the intervention or matter and will normally leave the meeting until the matter has been concluded. In exceptional circumstances he or she may, at the discretion of the chair, be permitted to remain for the discussion where their expertise is specifically required to inform the other members in their discussions. This expert advice shall be restricted to</p>

<p>preceding the meeting at which the declaration is being made.</p>	<p>the giving of factual and objective information before withdrawing from the meeting until a decision/vote is taken or the discussion has concluded.</p>
<p>A <b>non-specific personal family interest</b> relates to the personal interests of a family member and involves a current payment to the family member of the employee or member. The interest is regarded as <b>non-specific</b> when it relates to the industry or sector from which the product or service comes. This may include consultancy work, fee-paid work or direct share-holdings in the 12 months preceding the meeting at which the declaration is being made</p>	<p>A person declaring a non-specific personal family interest <u>may take part in the proceedings</u> unless he or she has personal knowledge of the intervention or matter either through his or her own work, or through direct supervision of other people's work. In either of these cases he or she should declare this interest and not take part in the proceedings except to answer questions</p>

Notes:

### **Personal interest**

A personal interest involves payment to the member personally. The main examples are:

- a) Consultancies: any consultancy, directorship, position in or work for the pharmaceutical industry which attracts regular or occasional payments in cash or kind
- b) Fee-Paid work: any work commissioned by the pharmaceutical industry for which the member is paid in cash or kind
- c) Shareholdings: any shareholding in or other beneficial interest in shares of the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence or financial management

### **Non-personal interests**

A non-personal interest involves payment which benefits a department for which a member is responsible, but is not received by the member personally. The main examples are:

- a) Fellowships: the holding of a fellowship endorsed by the pharmaceutical industry
- b) Support by the pharmaceutical industry: any payment , other support or sponsorship by the pharmaceutical industry which does not convey any pecuniary or material benefit to a member personally but which does benefit his/her position or department e.g.
  - a. A grant from a company for the running of a unit or department for which a member is responsible
  - b. A grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the member is responsible. This does not include financial assistance for students
  - c. The commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible

**Clinical Issues Information Summary****Scheme Title:**

<b>NO.</b>	<b>ISSUES</b>	<b>INFORMATION</b>
1	Assessment outcome by PrescQIPP i.e. amber (not fully appropriate) or grey (no significant reservations). Include any additional comments made at time of assessment	
2	Name of Drug Company	
3	Name of Drug  Generic/Proprietary	
4	NI Formulary Inclusion:	
5	Current Place in Therapy (e.g. as per NICE, Managed Entry process)	
6	Clinical Endorsement (NI) – e.g. NICE/SMC/HSCB/PCE	
7	Patent Expiry (as per UKMi database)	
8	Dispensing Information (Last 12 months):	
9	Spend:  No. of Prescriptions:	
10	Additional Clinical Information	

**Completed By****Date**

## Contracting/Administrative Issues Information Summary

**Scheme Title:**

NO.	ISSUES	INFORMATION
1.	Length of contract	
2.	Nature of opt out/termination clause:	
3.	Is the administration of the scheme straightforward/ routine?  If no, please state why?	
4.	Are contract monitoring arrangements for the rebate in line with routine HSCB processes (quarterly in arrears upon submission of invoice)?  If not, what are the arrangements?	
5.	Any other relevant comments	

**Completed By**

**Date**

## Financial Issues Information Summary

**Scheme Title:**

NO.	ISSUES	INFORMATION
1	Description/process of the rebate	
2	Estimated level of annual rebate	
3	Arrangements for claiming rebate in line with HSCB processes (quarterly in arrears upon submission of invoice)?  If not the above, please state?	
4	Any other relevant comments	

**Completed By**

**Date**

### Summary of outcome

For internal use	
<b>Scheme title</b>	<b>Internal reference no</b>
<b>Date considered by HSCB Rebate Group</b>	
<b>Recommendation made</b>  <b>To be considered by MOT</b>	
<b>Date of MOT meeting and outcome</b>	
<b>Date communication sent to company</b>	

**Completed By.....**

## **Appendix 4**

### **Sample Acceptance Letter for Schemes Accepted for Use in Northern Ireland**



#### **Integrated Care Office - West**

Gransha Park House  
15 Gransha Park  
Clooney Road  
LONDONDERRY  
BT47 6FN

Tel : 028 95361082

Fax : 028 95361166

Web Site :

[www.hscboard.hscni.net](http://www.hscboard.hscni.net)

Dear

#### **PHARMACEUTICAL REBATE SCHEME – [TITLE OF SCHEME]**

HSCB (Health and Social Care Board) is a member of the PrescQIPP. As a result the HSCB have utilised the PrescQIPP process within their Operational Process for the Review of Pharmaceutical Rebate Schemes in Primary Care.

<http://www.hscboard.hscni.net/our-work/integrated-care/pharmacy-and-medicines-management/>

A local review has been undertaken of rebate schemes currently published on the PrescQIPP website and a decision was made by the Medicines Optimisation Team (MOT) on *DATE* that we wish to avail of the rebate scheme submission for [TITLE OF SCHEME].

Please note that acceptance of this scheme is conditional upon agreeing:

- Amendments to contract as set out in Appendix 1
- Data used to calculate rebate will be dispensing data as provided by Business Services Organisation
- Data will be provided to companies by the end of the following quarter (an example of the format of the quarterly monitoring report is provided Appendix 2)

I would be grateful if you can advise of next steps. Please note that this proposal has been assigned the reference RS\*\*\*. Any communication should be made through the following email address [business.supportwest@hscni.net](mailto:business.supportwest@hscni.net) and should include the reference RS\*\*\* in the title.

Yours sincerely

**Chair of MOT (Medicines Optimisation Team)**

***RS\*\*\* TITLE OF SCHEME***

**Required Amendments to contract**

This Agreement is acceptable provided the following amendments can be made:

*[Insert proposed amendments from HSCB BSO DLS]*



## Appendix 5

### Sample Refusal Letter for Schemes Not Accepted for Use in Northern Ireland



#### **Integrated Care Office - West**

Gransha Park House

15 Gransha Park

Clooney Road

LONDONDERRYBT47 6FN

Tel : 028 95361082

Fax : 028 95361166

Web Site : [www.hscboard.hscni.net](http://www.hscboard.hscni.net)

Dear

#### **PHARMACEUTICAL REBATE SCHEME – [TITLE OF SCHEME]**

HSCB (Health and Social Care Board) is a member of the PrescQIPP. As a result the HSCB have utilised the PrescQIPP process within their Operational Process for the Review of Pharmaceutical Rebate Schemes in Primary Care.

<http://www.hscboard.hscni.net/our-work/integrated-care/pharmacy-and-medicines-management/>

A local review has been undertaken and a decision was made by HSCB Medicines Optimisation Review Team (MOT) on *DATE* that we do not wish to avail of the rebate scheme submission for [TITLE OF SCHEME].

Should you have any issues with the decision made by MOT, please submit comments in writing via the following email address – [business.supportwest@hscni.net](mailto:business.supportwest@hscni.net). HSCB will then initiate a review by a person independent of the process.

Yours sincerely

**Chair of MOT (Medicines Optimisation Team)**