Pharmaceutical Industry Scheme

OPERATING MODEL v4.6

Governance Review Board

A function of PrescQIPP

Introduction

Primary care rebate schemes are now a common feature within the UK health system, with a significant number of schemes in operation. These schemes are utilised by all devolved nations and by most English commissioners.

In 2012, PrescQIPP (then an NHS programme) established the Pharmaceutical Industry Scheme Governance Review Board (hereby referred to as PISGRB), offering scrutiny and comment on schemes on behalf of subscribed commissioners. This has grown to cover the vast majority of UK commissioners, albeit with differing independent models of assessment in Scotland and Wales, who also contribute to the PrescQIPP system.

This document outlines the processes that the PISGRB follows when assessing primary care rebate schemes which use supplier terms and conditions, and schemes which utilise the PrescQIPP standard terms (Appendix E) and go through the fast track route. This document will act as the master document, outlining:

- PISGRB deliverables / outputs
- Principles, and review / assessment criteria
- Governance
- Membership and responsibilities
- Process stages and timescale
- Stakeholder communication

Company Tips: Throughout this document we have highlighted key information for companies in purple.

PISGRB deliverables / outputs

The primary output of the PISGRB will be an assessment, summarising the evaluations for the scheme submitted. Each PISGRB assessment will also include a **grey**, **amber** or **red** status depending on the outcome of the assessment stage. The classification of the three colours is as follows:

Grey – Scheme considered: No significant reservations

Amber – Scheme considered: Not fully appropriate

Red – Scheme considered: Not appropriate

Principles, and review / assessment criteria

Submitted schemes will need to demonstrate compliance with the following five principles in order to achieve a **grey** or **amber** status:

1. **The therapeutic initiative has a place in clinical practice.**
2. **The arrangements for the scheme are simple and easy for the NHS to implement.**
3. **There is a transparent, sensible plan for payment and tracking.**
4. **The governance on what the scheme is, and is not going to be used for is robust.**
5. **There is a plan for ongoing review.**

We also strongly recommend that rebate schemes adhere to the following principles1:

- **It is preferable for pharmaceutical companies to supply medicines to commissioners using transparent pricing mechanisms, that do not create an additional administrative burden to commissioners (e.g. a reduction in list price).**
- **Health professionals should always base their prescribing decisions on assessments of their individual patients' clinical circumstances. The impact of a rebate scheme is a secondary consideration.**
- **Any scheme offered should not be exclusive. That is there should be no requirement to limit access of other medicines to patients under the scheme.**
- **Where the scheme includes medicines they should be medicines with an EU or UK product licence. Where a medicine has multiple indications the scheme should apply to them all.**
- **Arrangements for the termination of the scheme for both parties are detailed and agreed.**
- **The requirement for volume thresholds within schemes are not encouraged.**
- **There is no requirement for commissioners to divulge any information other than the volume of sales of the manufacturers medicine.**
- **Schemes will be offered to statutory NHS bodies and not to individual GPs or GP practices.**
- **Rebate schemes should be approved through robust local governance processes that include commissioner governance groups / committees or prescribing / medicine optimisation committees.**

Governance and the role of the PISGRB to commissioners and suppliers

The strategic and political acceptability of rebate schemes and their fit with PPRS remains unclear. The ABPI have published a position statement that allows schemes offered freely by the industry but discourages NHS initiatives in this area. In the absence of central government guidance, commissioners have requested that PrescQIPP provide a central governance recommendation which provides expertise and consistency of approach.

As this work is very closely aligned to the objectives of PrescQIPP, it has been agreed that this work will be delivered as part of the subscription to PrescQIPP, which covers the vast majority of UK commissioners. This role is to facilitate commissioner-led decision-making and provide a consistent and fair process for all stakeholders. As previously mentioned Scotland and Wales have their own assessment processes but co-operate and contribute to the PrescQIPP process.

Neither the PISGRB or PrescQIPP have any strategic or financial interest whatsoever in the uptake of schemes by commissioners or any schemes achieving particular scores. The purpose of this group is to provide independent and impartial information and governance that can support local decision-making, and supplements rather than replaces any function performed at a local level.

Any schemes that have not been formally submitted for consideration by the PISGRB, including any schemes that have utilised the PrescQIPP standard terms, are in no way supported by the PISGRB. Whilst it is recognised that such schemes are in circulation, without any formal submission to or consideration by the PISGRB, PrescQIPP will be unable to provide any support or comment to either commissioners or suppliers.

Since the function provided by the PISGRB is governance, provided by peer representatives, the PISGRB will govern itself on all matters relating to the processes, criteria and its recommendations, and will itself ratify all respective amendments to the process. Such decisions and editorial stances will form the mandate which will then be enacted by PrescQIPP's PISGRB delivery team.

Membership and responsibilities

Membership of the group will be composed of the PISGRB delivery team and representatives from across the UK commissioning organisations subscribed to PrescQIPP. The named delivery team is:

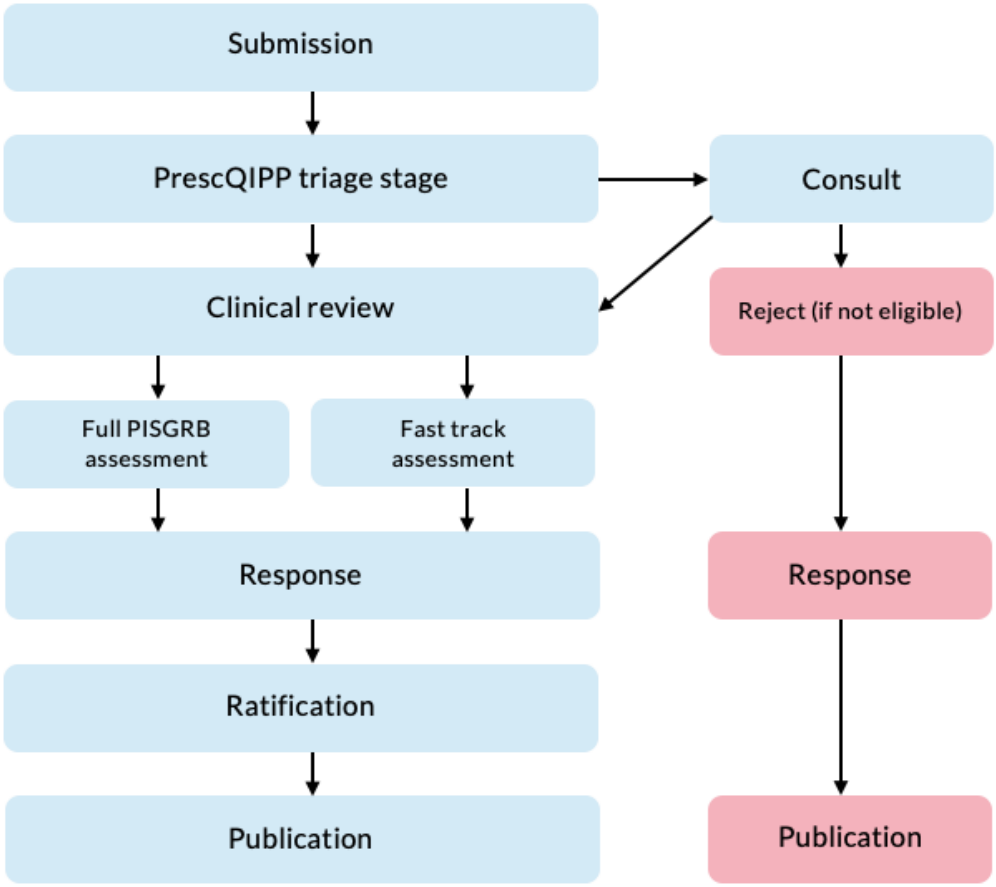
- Karen Homan, Associate Director of Medicines Optimisation (**Role**: Project Lead)
- Katie Smith, Director of Clinical Quality (**Role**: Evidence Review)
- Kevan Wind, Non-Executive Director and Chair of Primary Care Rebates (**Role**: Chair)
- Kirsty Shadbolt, Senior Project Manager (**Role**: Project Manager)
- Vicky Gibson, Senior Pharmacist - Clinical Quality (**Role:** Evidence Review)

Within both the traditional PISGRB assessment meeting and fast track virtual assessment routes, the delivery team will provide the scheme details and supporting information to the subscriber representative group in order to facilitate the assessment process. In order for any assessments to be quorate, five representatives will be required to consider the scheme and be involved in assessments. For each assessment, any conflicts of interest will be declared and where conflicts exist for that scheme, the representative will abstain from participating in the assessment. Together the delivery team and subscriber representatives will form the PISGRB. For further information around the group terms of reference please see Appendix F.

Process stages and timescales

The stages, timescales and available options for companies vary depending on whether the PISGRB standard terms, and associated fast track process are used, or the company choose to submit their own bespoke scheme. In the details below we will outline each stage with some key points that companies should consider.

Stage 1. Submission stage



During this stage companies will need to decide what contract they're looking to submit, and then formally submit it to the PISGRB Project Manager via e-mail at rebates@prescqipp.info. Should you have any questions that you would like to address please feel free to send these beforehand, however, we will not accept requests for meetings by companies seeking support on composing schemes. Please note that under no circumstances will any members of the PISGRB agree to sign any confidentiality or non-disclosure agreements, as it impedes PrescQIPP's ability to process the scheme. This is non-negotiable.

Companies will have the option to submit their own bespoke scheme, or a scheme adhering to the PISGRB standard terms. Whilst we are willing to accept both formats, use of the standard terms has resulted in less PISGRB assessment meetings being organised, and depending on the submission date, bespoke schemes may take 4-5 months to complete the process.

Guide for companies - What to submit

Do Submit

- The completed submission form (if you're using the standard terms this is included in the document).
- The contract (either the completed standard terms or your own) that would be provided to the NHS organisation - this will need to be a final contract and not a suggested guide to terms.
- The commercial details of the scheme - we cannot assess the scheme without them.
- Any other relevant, necessary supplementary materials (such as claim forms, letters or explanations for commissioners which are part of the scheme).

Do NOT Submit

- Supplementary promotional information around the drug or related evidence - the scheme will undergo a comprehensive independent clinical evidence review.
- Supplementary data.
- Presentations, flyers etc. these will not be circulated to the PISGRB members.
- Requests or mandates for non-disclosure to PISGRB members - as a policy we will not share any information to any parties outside of the NHS circulation, but as part of the PISGRB process, we will be sharing with NHS colleagues within the PrescQIPP subscription area.
- Stipulations around schemes only being available to certain areas. For the sake of equity, all schemes must be available to all commissioners covered by PrescQIPP.

Stage 2. PrescQIPP triage stage

Once the submission has been received, the PISGRB delivery team will review the scheme to ascertain whether it is eligible for progression, and if so what route it will go through. The following will be considered:

Is the scheme eligible for assessment? (if not then the scheme will be rejected)

- Is all of the required information present?
- Is the scheme legal?
- Is the scheme available to all PrescQIPP subscribers in the UK, with consistent conditions and without excluding criteria or conditions (e.g. formulary positioning)?
- Would the scheme realistically yield any financial benefit for the NHS? (e.g. a scheme relating to a minimally prescribed product, with a low rebate percentage and the expectation that commissioners would be unlikely to add to formularies may not be worth the group's consideration). If the PISGRB delivery team believe a scheme should be rejected on the grounds of financial yield, PISGRB members will be consulted for objections. If any members object then the scheme will proceed for review.

Is the scheme eligible for the fast track assessment process?

- Does it fully utilise the PISGRB standard terms, without amendment, or supplementary clauses that undermine the scheme?
- Is it in any way a growth based scheme? (not eligible for fast track)
- Have extra conditions or terms been added to the scheme details that undermine the scheme in any way?

Following the triage stage the company will be updated regarding the route, or reasons for the scheme being rejected. The decision will not be negotiable however companies will be given the opportunity to amend their scheme and resubmit. Depending on the chosen route, the scheme will be formally logged and progressed to the next stage of the respective route. If the scheme is fast track then it will commence the fast track process, or if the scheme is PISGRB assessment then it will be granted a slot at the next available PISGRB assessment meeting.

If it is helpful a phone call can be arranged with the PISGRB delivery team to explain and discuss any potential issues identified by triage.

Stage 3. Clinical review stage

Once the triage stage is complete, the proposed scheme will be submitted for a clinical review (normally undertaken by a member of the PISGRB delivery team). The review provided will consider the areas covered in Appendix D (covering licensed uses, alternative treatments, relevant NICE guidance etc., following a standard search pattern to include BNF, SPC and NICE), to establish whether the product has a place in therapy or not.

This is an independent process and we will not accept any of the following from companies:

- Requests for any meetings or discussions with the independent reviewer before, during or after the review.
- Requests for the review to be shared at any stage.
- Any evidence that the company wishes to share.

In addition to the clinical review, when schemes have been assigned to the fast track process, additional advisory commentary will be supplied to support virtual assessment, and mirror that advice that would usually be provided in the PISGRB assessment process.

The review will be returned to the Project Manager for submission to the PISGRB members before the meeting.

Stage 4. Assessment via PISGRB assessment or fast track assessment routes

At this stage the scheme will now progress via its designated route. Please refer to the relevant section and appendices below for guidance.

PISGRB assessment route

The PISGRB assessment meetings are usually scheduled depending on the number of schemes requiring assessment at any given time. With the introduction of the fast track route, meetings have become more infrequent however, the PISGRB will endeavor to hold meetings no longer than 4-5 months apart. Considering the large geographic range of PrescQIPP subscribers, meetings will either be held physically with some representatives joining virtually via teleconference to ensure the meeting is quorate or completely virtually via teleconference. Meetings are never recorded.

The agenda of each PISGRB assessment will consist of five major parts (four of which being part of the proposed scheme's process) being:

- **Discuss review** – The PISGRB members will discuss the proposed scheme, and the findings of the xlinical review and financial scoping.
- **Generate questions** – Prior to the company meeting (if the company has agreed to attend) any questions that have been deemed necessary will be generated by the group and asked by the group's chair.
- **Company meeting** – If the company has agreed to attend, they will be given a 20-minute slot to respond to any questions around the proposed scheme. In some cases where there are elements that support the needs of the NHS (e.g. inability to fulfil statutory obligations such as FOI) the PISGRB will offer feedback to the company. This is in no way a negotiation but often companies seek to offer changes to the terms for consideration, which can be tentatively accepted by the group, in lieu of any changes. In all cases this will need to be clearly defined by the company. Under no circumstances will the group request changes or respond to company requests for what language or changes the group would like to see.
- **PISGRB assessment** – Using the PISGRB assessment tool provided in Appendix A, the PISGRB will perform the clinical, contractual and financial assessment, followed by a discussion, and agreement, on the status and other recommendations/comments to be included in the PISGRB assessment. If, because of the company meeting, the company has offered prospective amendments to the scheme, the PISGRB will agree an 'as-is' score and a tentative score if the changes are satisfactory, along with an agreement for the chairperson to consider whether the changes are akin to the agreed amendment offered by the company.
- **Lessons learned** – This element will not form part of the process of assessing the proposed schemes, however each meeting will be concluded by compiling any lessons learned, and noting any necessary other inclusions / amendments to this operating model.

Some preparatory tips for scheme providers attending company meeting:

- The meeting will last no more than 20 minutes for a single scheme's Q&A. If the company has separate multiple schemes this will usually be accommodated within one meeting with no more than 20 minutes for each.
- Please do not prepare a presentation or offer other printed materials or supplementary items.
- As is the case throughout the whole process the PISGRB will not agree to any confidentiality conditions or non-disclosure agreements (NDAs) for any aspect. We will however respect the commercial nature of the scheme at all times.
- You can have up to three representatives (if third part facilitated include at least one senior representative from the client company). We recommend that people who are able to make decisions around the scheme attend the meeting.
- The meeting is solely to discuss the scheme submitted. We will not discuss any other topics.

Fast track route

The fast track process normally delivers an assessment and formal response to companies submitting schemes within 4-6 weeks of submission. As this process will be solely applied to schemes utilising the PISGRB standard terms (download the standard terms: https://www.prescqipp.info/our-resources/webkits/primary-care-rebates/), many of the contractual fields will be pre-scored and result in a shorter assessment (see the fast track assessment sheet template in Appendix B).

The assessment process will be performed virtually over two weeks, largely mirroring the PISGRB assessment process, via a survey, sent to PISGRB members. To support consistency and parity each assessment question within the survey will include the framework criteria, advisory comments from the PISGRB Chair and Clinical Reviewer, then with the option for PISGRB members to vote on which score they would assign.

Once the two week deadline has passed, and the quorate has been achieved, the PISGRB delivery team will review the responses to ascertain whether a consensus has been achieved. For each question if the majority (67.7% or above) assign the same score this will then be assigned. For those questions where this is not the case, the Chair will consult the comments, contact the respondents to understand their views, provide supplementary information and reach an assessment via e-mail (in some cases by tabling a recommendation). This may then result in a quicker round of voting on the contested questions, or a conference call with the objective to achieve the required majority.

Finally, once scoring has been achieved the PISGRB Chair will provide any additional commentary and the draft final assessment will be compiled.

Stage 5. Response stage

Once scoring has been achieved through either the PISGRB assessment or fast track route, and any amendments offered by the company have been completed, a formal response will be offered to the company, with an overview of how the scheme has fared in each of the three scoring areas, along with any comments. As the scheme owner, the company will then be asked to ratify the decision allowing PrescQIPP to publish the scheme items, and then to provide any final versions (e.g. in a PDF watermarked format) along with a redacted non-confidential version of the scheme.

Please note that the full scoring, clinical assessment and data produced during the earlier stages will not be shared with the company, and decisions during the assessment stages are final and non-negotiable.

If the company is happy to proceed and has provided all required materials then a final response letter (see Appendix G) will be communicated and the scheme will progress to the delivery stage.

If however, the company is unhappy with the final scoring and / or commentary then the company fully reserves the right to withdraw the scheme (or abstain from ratifying) or request that we take the scheme back for review and possible future resubmission. Whilst the PISGRB will not publish any documents submitted by the company, without ratification, we reserve the right to publish the assessment or comments around the

scheme being withdrawn if it is considered to be in the best interests of PrescQIPP subscribers.

In the instance of a **red** or **amber** status being assigned, the company will have the right to lodge an appeal, providing extra information / evidence to support any objections. The PISGRB may request that the company attend a meeting to answer questions around the appeal.

Stage 6. Delivery stage (publication, communication and management)

The PISGRB assessment will be made available to subscribed commissioners via the restricted rebates area of the PrescQIPP website, with commissioners being informed of the scheme's availability. PrescQIPP also produce a monthly rebate monitoring tool for commissioners to scope potential financial returns, and to support the claim process.

What we publish on the PrescQIPP website's subscriber area

- The PISGRB assessment (once ratified) with scoring.
- Both commercial (as submitted with pricing details) and redacted non-confidential version of the scheme.
- The independent clinical evidence review.
- The submission form (for PISGRB assessment route).
- Any other agreed working materials (e.g. claim forms).

Please note that the above is mandatory for all schemes, and will not be negotiable - in particular around the limiting of commercial details.

Offering schemes to commissioners

Once the scheme has been ratified and published, the company will be welcome to offer and receive sign-up requests to / from any subscribed commissioner, utilising the response letter and in reference to the scheme completing the PISGRB process.

Please note that as a neutral governance function, PrescQIPP does not endorse, approve or support particular schemes. Marketing such statements will result in the PISGRB withdrawing the assessment and communication on the PrescQIPP website.

Whilst we are happy for the result of your scheme to be referenced, we do not agree to our resources being used for marketing purposes. When referencing your rebate scheme assessment we suggest the following wording can be used:

"The [insert company name and scheme name] scheme has been through the PrescQIPP assessment process and has achieved a [grey / amber / red] status."

Note for commissioners

Through offering schemes for assessment by the PISGRB, the schemes are in effect being passively offered to all subscribers. Therefore commissioners can have confidence that they can contact companies about the scheme and that this in no way represents solicitation.

Please note that the contract reviewed by the PISGRB is solely the one that should be offered to any PrescQIPP subscribers for the sake of equity and collectivism of risk, and without any further conditions being applied (i.e. a requirement for the product to be on formulary). In all cases the offering of schemes that are commercially or contractually different in any way will be considered as an undermining of the agreed terms by the company. In the event of this being actively done the scheme will be suspended and commissioners will be informed of this, with an explanation. As is covered below, companies should consider changes in advance and contact the PISGRB delivery team as soon as possible to discuss any version updates.

Process for updating schemes

Over time companies may wish to update schemes. As has been covered above, PrescQIPP will not allow different or updated versions to be offered until they have completed consideration by the PISGRB. For minor updates this will be considered by the PISGRB delivery team, and if it is not believed to affect any of the scores will be updated and communicated to the wider PISGRB for objections. If however, this could result in scoring changes this will need to be considered (usually virtually by the PISGRB) to achieve a quorate agreement.

In the event that the scheme is totally revised either commercially or contractually then we would recommend that this is treated as a new superseding submission by the company.

Sharing this operating model

This document is intended to outline the process, terms and assessment criteria for both commissioner and scheme provider, and as such is published for use without restriction. However, we would appreciate if any significant adaptations reference the source of this work. If companies wish to use this for any commercial or marketing purposes, we would appreciate if it could be used in its entirety to avoid any information being taken out of context.

Appendix A - PISGRB assessment sheet template

Pharmaceutical Industry Scheme
Governance Review Board
A function of PrescQIPP

ASSESSMENT v2.0

Board Date		Approved Name (+Brand)	

Clinical Assessment (Below 0 equates to a fail)		Range (Good to Bad)					
	Question	+2	+1	0	-1	-2	Total
1	Is the intervention evidence based?				FAIL		
2	What is the status of the intervention compared to current therapy? **Inferior efficacy will render the Clinical Assessment an automatic fail.**						
	Equal efficacy						
	Superior efficacy						
3	Is this a cost effective healthcare intervention?						

Contractual Assessment (Below 0 equates to a fail)		Range (Good to Bad)					
	Question	+2	+1	0	-1	-2	Total
1	Does the scheme require limited access to other medicines for patients?				FAIL		
2	Is any information required from the NHS organisation, other than the volume of sales?				FAIL		
3	What is the length of the deal (incl. company notice period) vs market uncertainties?						
4	Is the contract simple, understandable and free of legal jargon?						
5	Are there clear arrangements for the NHS organisation exiting?						
6	Are there sufficient details to support FOI?						
7	Are there significant penalty clauses?						
8	Does the contract allow for communication with ALL relevant stakeholders?						
9	Is the scheme directly linked to a requirement for increased market share or volume of prescribing?						
10	Could the deal be interpreted as a bundle or portfolio of **different** products?						
11	Does the scheme seek to limit the freedom of the NHS organisation in any way?						
12	Is there resilience of supply of relevant products?						

Financial Assessment (Below +1 equates to a fail)		Range (Good to Bad)					
	Question	+2	+1	0	-1	-2	Total
1	How big is the potential financial benefit?						
2	Does the scheme require significant NHS resource to realise the benefits?						
3	Is the benefit achievable?						

Final Scoring and Comments	Total Score	
	Clinical	
	Contractual	
	Financial	
Overall Status	SCHEME CONSIDERED: NOT FULLY APPROPRIATE	

Appendix B - Fast track assessment sheet template

STANDARD TERMS ASSESSMENT v4.0

Pharmaceutical Industry Scheme
Governance Review Board
A function of PrescQIPP

Board Date		Approved name (+Brand)	

Clinical Assessment (Below 0 equates to a fail)		Range (Good to Bad)					
	Question	+2	+1	0	-1	-2	Total
1	Is the intervention evidence based?				FAIL		
2	What is the status of the intervention compared to current therapy? Inferior efficacy will render the Clinical Assessment an automatic fail.						
	Equal efficacy						
	Superior efficacy						
3	Is this a cost effective healthcare intervention?						

Contractual Assessment (Below 0 equates to a fail)		Range (Good to Bad)					
	Question	+2	+1	0	-1	-2	Total
1	Is any information required from the NHS organisation, other than the volume of sales?				FAIL		
2	What is the length of the deal (incl. company notice period) vs market uncertainties?						
3	Could the deal be interpreted as a bundle or portfolio of different products?						
4	Is there resilience of supply of relevant products?						

This scheme utilises the PrescQIPP Standard Terms of Agreement for Primary Care Rebate Schemes, meaning that a number of the contractual questions are pre-scored, and thus automatically pass. The numbers above have been retained in accordance with the standard assessment questions.

Financial Assessment (Below +1 equates to a fail)		Range (Good to Bad)					
	Question	+2	+1	0	-1	-2	Total
1	How big is the potential financial benefit?						
2	Does the scheme require significant NHS resource to realise the benefits?						
3	Is the benefit achievable?						

Final Scoring and Comments	Total Score	
Example	Clinical	
	Contractual	
	Financial	
Overall Status	**e.g. SCHEME CONSIDERED: NO SIGNIFICANT RESERVATIONS**	

Appendix C - Guidelines for assessment sheet

Clinical assessment (0 required to not fail)

Is the intervention evidence based? Relates to the published evidence on efficacy and safety of the product as assessed by a clinical evidence review. A scheme with strong evidence (e.g. a positive NICE TA) would score +1. Sufficient evidence 0. Evidence which is equivocal or negative will be failed.

What is the status of the intervention compared to current therapy? A medicine should be chosen on its clinical attractiveness rather than price and a scheme should not be a way of making an inferior medicine be chosen over more appropriate clinical choices. Inferior efficacy (-1); Equal efficacy (0); Superior efficacy (+1)

Does the cost and efficacy make the treatment cost effective? The cost effectiveness is based on the list price of the product, not the rebated price. Is the treatment cost - Lowest within range (+1); Amongst the lowest (0); Not amongst lowest (-1)

Contractual assessment (0 required to not fail)

Does the scheme require limited access to other medicines for patients? It is probably anticompetitive behaviour to require that other medicines have limited availability as part of the scheme. Any such schemes will be failed.

Is any information required from the NHS organisation, other than the volume of sales? It is inappropriate to require managerial or financial information other than the volume sales of the product from the commissioner. Any scheme that requires more than the sales data will be failed.

Is the contract simple, understandable and free of legal jargon? The contract commissioners are required to sign should ideally be understandable to a lead pharmacist (who will have to sign it).

What is the length of the deal (incl. company notice period) vs market uncertainties? To reap the full benefits of many of these schemes a commissioner may have to influence clinical practice. This takes time and the term of the contract should align with that timeframe. **The notice period for the company is effectively the term length if notice is free from any conditions.**

Are there clear arrangements for the NHS organisation exiting? Whilst it is helpful for a commitment from the company to the NHS, a commissioner will want to be able to extricate themselves from any arrangement within a reasonable time should circumstances change.

Are there sufficient details to support FOI? It can be helpful to have the confidentiality of commercial arrangements laid out clearly but a commissioner would need to have detailed instructions about who and how to contact the company given the tight time frame for responses.

Are there significant penalty clauses? Obviously penalty clauses for the NHS would not be welcomed in such an arrangement.

Does the contract allow for communication with ALL relevant stakeholders? It is important that whilst keeping commercial information confidential outside the NHS a commissioner is able to share information within the NHS. e.g. to GP's within the commissioner, to PrescQIPP and other commissioners, to the DH or to NHS England.

Is the scheme directly linked to a requirement for increased market share or volume of prescribing? Whilst thresholds and volume targets are not disqualified it is illegal to incentivise a GP to prescribe and any payments must be distanced from the prescribing decision.

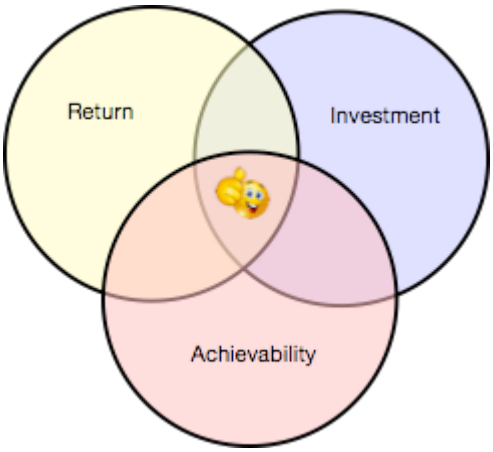
Could the deal be interpreted as a bundle or portfolio of products? Even if the arrangements pass the legal test of not being anticompetitive (in which case the scheme should be failed), bundling of products complicates and confuses the clinical decisions to be made.

Does the scheme seek to limit the freedom of the NHS organisation in any way? Some schemes look to direct the savings accrued into spending on specific projects. Others demand frequent meetings or uptake of a specific training or marketing initiative. These types of activities are unwelcome.

Is there resilience of supply of relevant products? The availability of the product should match the likely uptake should the scheme be adopted widely in the NHS.

Financial assessment (+1 required to not fail)

The financial category covers three areas of considerations – what you could get, what you have to do to get it, and how likely it is you'll get it. Consequently we have three questions to try and sum this up.



How big is the potential financial benefit? Considers both the magnitude of the potential savings against the full subscription base of PrescQIPP – considering who benefits vs. the size of the return.

		Range of beneficiaries		
		All or many	Some	Few
Size of return	Significant	+2	+1	0
	OK	+1	0	-1
	Insignificant	-1	-1	-1

Does the scheme require significant NHS resource to realise the benefits? If Q1 considers return, this question considers the holistic investment by the commissioner. This could include:

- The human or financial resource in order to implement as project to realise return.
- The time required to administer the scheme or fulfil the conditions (e.g. burdensome FOI requirements; scheme admin or meeting requirements)

Is the benefit achievable? Considers the likelihood of realising the return. If the return is guaranteed this will score positively; whereas a product where it is difficult or unlikely to realise any of the proposed benefits will score negatively. Factors could include possible clinician objection or changing clinical practice in a contentious area or to an agent with which the commissioner and GPs have little clinical experience. Also whether the scheme is based on growth and the likelihood of growth within the product's market may be factored.

Appendix D – Evidence review template (for submission to PISGRB)

Information provided by the Evidence Reviewer to the PISGRB

Medicine / trade name	
Manufacturer	
Medicine class	
Indication	
Formulation and strength	
Dose and frequency	
Length of treatment	
Current place in therapy	
Treatment alternatives	
Future alternatives	
Patent expiry	
List price	
Rebate price	
NICE guidance or national guidelines on use?	
Other relevant evidence	
Incidence of condition and potential use per 100,000 population	
Does the product have a place in therapy / practice?	
Date of last revision	
Cost of intervention vs other therapeutic alternatives	
PrescQIPP subscriber spend and average spend per commissioner	
References	

Appendix E - PrescQIPP standard terms of agreement for primary care rebate schemes guidance

The PrescQIPP standard terms of agreement for primary care rebate schemes offers a standard contract that pharmaceutical companies may wish to utilise as a part of their submission to PrescQIPP's Pharmaceutical Industry Scheme Governance Review Board (PISGRB).

Within the document we have provided a set of contractual terms adapted from the those designed by NHS National Services Scotland (to whom we are grateful), which we have amended to match the differing requirements within the commissioning areas that PrescQIPP cover, and the facilitative role that PrescQIPP undertakes for those commissioners. In preparing the terms of agreement in the contract below we have worked with the NHS and industry to ensure that the terms are robust and fair to both the commissioner and supplier and wider industry / health system.

On the first page of the template we have created some key questions that will allow you to explain the components of your scheme, followed by the standard terms. These standard terms have been pre-scored within the contractual assessment, with only a few remaining questions to be considered. Within the context of the standard terms, which will allow for a much quicker assessment process, the terms cannot in any way be edited. As before if your company chooses to use either your own terms and conditions or an adaptation of the standard terms this can be accommodated via our long-standing PISGRB assessment process although this will take longer. For eligible standard terms your scheme will be taken through a fast track process after triaging. Schemes will not be eligible for the fast track route if: the scheme is a growth based scheme or other commercial offering that is not simple (i.e. flat and purely financial), or further terms supplied within the scheme setails section undermine the standard terms.

However, the standard terms do not include a termination clause (other than for contract breach). If you wish to add a termination period for either the commissuioner or the supplier please add these details in the 'Other details around administering the scheme' section. This section also allows for detail around financial administration of the scheme. Please do not include any promotional or marketing information within the submission, or supply any additional documents, letters or addendums that contain additional terms or requirements. We will accept simple claim forms to support administration. As you will be adopting the standard terms please do replace our logo and footer with whatever you require, and feel free to watermark, but do not remove the note and source text on page 2 of the template.

Finally, please refer to the PISGRB operating model for more information on processes, timescales, scoring, assessment criteria and principles.

For the avoidance of doubt, in light of the absence of clear national guidance around primary care rebates, at no point does the use of standard terms in any way change the nature or role of PrescQIPP's PISGRB or the ownership of the scheme or its 'contract'. In other words whilst the terms below should hopefully support better consistency, clarity and assurance, and reduction of workload for both parties, the scheme itself will always belong to the supplier, and be part of a direct relationship between the supplier and NHS commissioner. Furthermore, the provision of these standard terms in no way changes PrescQIPP's neutral position around rebates, nor constitutes endorsement or positive approval of any schemes. Our role is and continues to be to support equity, good governance and transparency on behalf of the NHS whilst rebate activities exist.

On behalf of the PrescQIPP CIC facilitated Pharmaceutical Industry Scheme Governance Review Board.

Download the full standard terms: https://www.prescqipp.info/our-resources/webkits/primary-care-rebates/

Appendix F – PISGRB operational terms of reference

Objectives

As a member of the Pharmaceutical Industry Scheme Governance Review Board (PISGRB) all representatives agree to uphold the following aims and values:

- Fair, unbiased and objective approach to all activities, acting neutrally to individual schemes or schemes in general.
- Representing the wider views and needs of primary care commissioners in the UK.
- Supporting patient needs, views and safety within all PISGRB activities.
- Respectful of any commercially sensitive information provided for the use of PISGRB activities.
- Respectful of all views, and the collective aim to reach agreement by consensus.

Minimum required membership of the PISGRB for a meeting to be formed:

- Five senior subscriber representatives from primary care organisations subscribed to PrescQIPP (although more may attend).
- Chair (or nominated deputy).
- Director of Clinical Quality.
- Project Manager.
- Specialist Procurement Pharmacist or Associate Director of Medicines Optimisation.
- Other people may be invited to the meetings where relevant for a particular discussion e.g. Specialist Clinical Pharmacists.

For meetings to be quorate, at least nine members should be present at each meeting, five of which being subscriber representatives.

Role of group members

In order to make best use of the time and expertise of the members and to facilitate timely decision making, members will be expected to:

- Accept ownership of advice / recommendations produced by the group.
- Undertake work as necessary in preparation for meetings.
- Commit to actively participate at meetings in the preparation of the recommendations and to achieving consensus based on the expertise of the individuals.
- Commit to active participation in finalising guidance documents, recommendations and decisions by providing timely feedback on drafts of any documents circulated.
- Communication between meetings primarily by email.
- Commit to regular attendance at meetings to ensure continuity and balance of input into recommendations.
- Declare at the meeting any outside interests, which might have a bearing on your actions, views and involvement in discussions within the group.

Conflict of interest

All members of the group and any other people attending the meetings will be asked to declare any conflicts of interest that may in influence any decisions or recommendations of a particular meeting. Any action to be taken on the basis of these declarations will be at the discretion of the Chair.

Recommendations

The numerical weighting to questions, and resulting comments / recommendations resulting from the PISGRB will be reached by consensus in the group, based on the available information and expert advice.

The PISGRB provides an advisory governance function. It is not a decision making group and has been formed to provide impartial assessments of submitted schemes. Collectively the view of the PISGRB is neither to support nor oppose rebates, therefore it is not appropriate for the group to give a positive endorsement to any scheme. The aim of the group is to assess schemes based on the information submitted and identify any issues with them, communicating ratified outcomes.

Accountability

The PISGRB will act as a project within the range of deliverables by PrescQIPP and therefore report directly to the PrescQIPP Board of Directors, Council of Members and subscribers.

Third Party Organisations

The PISGRB will allow for third party facilitation during the submission stages, however representation by individuals from the originating company will be required at any meetings.

Following ratification of the assessment, and communication of the outcomes, the PISGRB will not have any involvement around any resulting promotion of the schemes beyond the agreed impartial methods in the operating model. No further detail, or materials will be provided by the PISGRB.

Appendix G– Sample response letter

Pharmaceutical Industry Scheme Governance Review Board - Scheme Response

Pharmaceutical Industry Scheme
Governance Review Board
A function of PrescQIPP

Scheme Name	
Company	
Board Date	

Date:

Dear ,

I am writing to you in response to the scheme, above, updated to the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board. Following careful consideration, your scheme has been awarded with the following status and comments. Please note that irrespective of the outcome, the board does not provide endorsement, positive reviews or formally support primary care rebate schemes, but instead provides a governance framework for commissioners, pointing out any features of the scheme that commissioners may wish to consider when they decide themselves whether to sign up or not. Their final decision will be based on this assessment in accordance with local governance processes. The outcome of your scheme reflects the scores applied to a number of questions, with the comments relating to specifc points of concern or interest.

Final Scoring and Comments	Total Score	
XXXXXX	Clinical	+1
	Contractual	0
	Financial	0
Overall Status	SCHEME CONSIDERED: NOT FULLY APPROPRIATE	

In line with the terms set out in the operating model (see www.prescqipp.info), the board is happy for this letter to be used, without restriction. However, this document must only be for schemes which are an exact match to the one submitted to the board, and shared with commissioners on the PrescQIPP website. Please note that using this document or referencing the above outcome for offerings that do not match the scheme (including the contract) will result in your scheme being removed from the website, the decision being made null-and-void, and a communication to all PrescQIPP commissioners that your company has offered inequitable, preferential agreements. This specifically includes differing prices or rebate amounts, outside of that submitted. Please note this does not relate to historic agreements offered before your submitting the scheme or the date of this letter or offered to commissioners prior to them joining PrescQIPP. If you have any questions relating to this, or feel that there are specific variables, which are in the spirit of the process, then please do not hesitate to contact us.

Whilst we are happy for the result of your scheme to be referenced, we do not agree to our resources being used for marketing purposes. When referencing your rebate scheme assessment we suggest the following wording can be used:

"The [insert company name and scheme name] scheme has been through the PrescQIPP assessment process and has achieved a [insert status colour, e.g. amber] status."

If aspects of your scheme change over time, we are happy to receive updated agreements, however, if the changes are significant, then these will be referred to the Board to ensure that the scoring is still consistent.

On behalf of:

Kevan Wind, Chairman of the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board