Pharmaceutical Industry Scheme

Governance Review Board

A function of PrescQIPP

GUIDANCE ON CONTRACTUAL ASSESSMENTS

When submitting schemes to the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board (PISGRB), companies planning to submit a primary care rebate scheme (PCRS) often request further clarification on how they can build schemes fit-for-purpose for commissioners within the NHS. Whilst the PISGRB neither supports nor promotes the uptake of PCRS - in fact the group's role is to facilitate a process to find issues with schemes for commissioners and highlight them - it is understandable that companies will wish to change their schemes in light of negative scoring or commentary. At no stage does the PISGRB seek to negotiate or request amendments to schemes, however, it is willing to review updated or amended schemes. For further information on the construction, standard timelines and processes please refer to the PISGRB Operating Model. [1]

Frequently, when running the PISGRB we encounter common misassumptions from companies within the schemes, around our scoring, which often results in the companies deciding to adjust their scheme for re-review. For each of the three areas of the assessment process (Clinical, Contractual and Financial) there will be a minimum threshold to pass that area, achieved from the sum of scores within the questions. To support clarity and understanding around these schemes, we have undergone an exercise to elaborate on our scoring criteria, and the feedback that we receive from commissioners around schemes being inappropriate, unwieldy or burdensome. Please note that we will consider whatever schemes the companies decide to submit, and if they achieve grey or amber then we're content to progress as-is with scoring and commentary to reflect the elements of the scheme.

The Contractual Assessment

Below, you will find a breakdown of the twelve questions that make up the Contractual Assessment, which are outlined in the PISGRB Operating Model.[1] The questions are provided as-is, however, for a selection of the questions we have provided further commentary in green.

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 automatically fail and the review process will stop.

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 commissioners. 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).

PrescQIPP commentary. This is a key area where companies struggle to produce helpful and appropriate schemes, often due to significant input from the company's legal team without sufficient consideration of who will be expected to understand and agree these schemes. Most medicines commissioning

teams do not have legal expertise immediately available, and are therefore unable to confidently process and understand contracts that are very legalistic. Whilst legality is of course necessary, and significant detail of all conditions understandable, expecting commissioners to sign up to very legal schemes is problematic. Often when we provide our formal response, with scoring and commentary, companies frequently complain around our suggesting that commissioners obtain legal advice before signing a legalistic scheme. However, if a company produces a long technical contract written by a legal department, then it makes sense that the commissioner would similarly need to get advice. We feel it would be inappropriate for us not to make this recommendation.

This is not to say that we recommend insufficient contracts - quite the opposite - but that companies properly consider the content and length of the scheme and whether it is in plain English. We have seen a number of examples that achieve both of these goals, and are confident that this is very possible with prior consideration.

An alternative approach is to adopt a standard contract that the NHS understands. Scotland have produced an NHS version that they are mandating. PrescQIPP are familiar with this document.

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 CCG 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.

PrescQIPP commentary. As different schemes will be more or less difficult to implement, it would be inappropriate for us to suggest a specific timescale to apply to all proposed schemes, however, there are some points that companies should consider when designing schemes:

1. As with any contract your scheme will define the commitment that you are looking to make. Whilst situations can change in the market, timescales for an unqualified exit by the company effectively undermines the proposed contract length, i.e. a two year contract with a one month notice period is effectively a one month rolling contract. Consequently the PISGRB will consider the unqualified notice period to be the length of the contract.
2. In this difficult fiscal landscape implementing and administering any schemes taps upon a finite human resource. If you know that achieving any returns from the scheme will require significant work by the commissioner, then it would make sense to reflect this in the overall length of the scheme.

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.

PrescQIPP commentary. FOI requests regarding PCRS schemes are increasingly creating significant workload for medicines teams. Historically many contracts have requested that the company is informed whenever an FOI indirectly or directly refers to their scheme. If commissioner X has 10 live PCRS in place, and receives 2 FOI requests per week asking what schemes the commissioner is signed up to, with similar FOI conditions this equates to 20 e-mails per week to companies.

Going forward we're changing our stance to consider the administrative burden that conditions within schemes can create. Below are some relevant elements to consider.

1. **FOI contact** - One simple element that can really help teams to support an FOI request is provision of a point of contact (e-mail) for any queries for the commissioner to send through. FOI requests have short timescales and it's helpful to get clarity.

2. **Imposition of timescales** - When receiving an FOI request the commissioner has 20 days to respond to the request. Requesting / committing to a 7 day period for the company to answer questions is fair. Stating that a CCG must share the FOI request within X days; that the company will need to approve any responses before they are shared, or anything that makes it difficult or impossible to satisfy the FOI request and the contract is not fair. Our scoring will reflect this.
3. **Commercial / non-commercial** - Commissioners are bound by law to share all contractual arrangements that are not commercial when responding to an FOI request. In other words, everything but the percentage, (or percentages if growth based), financial return from scheme (although they are required to share the overall amount if it doesn't allude to a certain percentage) and length of the contract. Everything else they are required to send. Therefore, communication with the company is not required and is therefore an unnecessary administrative burden. Requests by companies to be informed of requests for non-commercial information or in restricting sharing of non-commercial information is therefore scored negatively.
4. **Redacted non-commercial contracts** - for any new or updated schemes we now require a non-commercial or redacted copy of the contract. In line with the above points this helps medicines teams differentiate - beyond all doubt - between commercial and non-commercial details, and allows them to proactively or reactively respond to such FOI requests. Schemes and their assessments can no longer be ratified and published without this document.

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.

PrescQIPP commentary. This relates to both commercial and non-commercial information. In order to appropriately sign up to or administer schemes the commissioner should not be restricted from communicating information with appropriate and relevant stakeholders. These include:

- PrescQIPP or another body who works in a similar way for the commissioner relating to PCRS.
- Other commissioners - encouraged to ensure equity and propriety.
- Commissioning support units the commissioner works with, or any other similar bodies the commissioners have agreements to support
- GPs - if commissioners are not allowed to share this information with GPs it could suggest impropriety, which should not be the case. Whilst different areas take different approaches, for the purpose of assurance it makes sense that commissioners are allowed to share this information.
- NHS England and the Department of Health - if requested.

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.

PrescQIPP commentary. Bundles, baskets, portfolios etc. will be viewed unfavourably if the scheme requires signing up to a collective of different products (this does not include different strengths of the same drug). Similarly a rebate based on growth of product volume is straying towards incentivisation to prescribe and becomes more problematic for a CCG to sign up to.

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.

PrescQIPP commentary. The above refers to any conditions that a company might include to make the commissioner do or not do something beyond signing up to the scheme, or the hidden or indirect cost of signing up to the scheme. Some examples that would be negatively scored could include:

- Requests for regular meetings or events (this obviously increases the administrative burden).
- Circulation of marketing materials or required communication, publication or promotion relating to the PCRS.
- Specifying how or where any returned monies are used.

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.

PrescQIPP commentary. Assurance around resilience of supply is increasingly important, with many issues occurring around stock issues. Whilst this is not a contractual element we will seek assurance that any significant increase or spike in demand could be managed by the company. Especially important for smaller companies. The information that would help provide assurance would include:

a) The supply channel(s) you use to distribute your medicine or device.

b) The number of weeks stock you hold in the country.

c) The site of manufacture.

d) The lead time from request for manufacture to stock reaching the supply channel (manufacturing lead time).

e) Any other comment you might have.

In Summary

This document has sought to provide some clarity around the Contractual scoring within the Pharmaceutical Industry Scheme Governance Review Board assessment process, as this is often an area where companies seek to make the most changes to their schemes before publication. We'd strongly recommend that companies consider the above before submitting schemes to be assessed. We have also refrained from providing commentary on the Clinical and Financial assessment areas as this often varies depending on the product and the commercial offer, however, we'd recommend that companies do read the PISGRB Operating Model[1] in full to understand the process that will be applied to submitted schemes, and which also contains all the assessment questions for the three areas.

References

1. Pharmaceutical Industry Scheme Governance Review Board Operating Model v3.0 https://www.prescqipp.info/projects/pharmaceutical-industry-scheme-governance-review-board#primary-care-rebate-board-operating-model

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