BIA response to NHS Commercial Framework for New Medicines consultation

Background

NHS England has published a consultation document which sets out proposals for updating the NHS Commercial Framework for New Medicines. The proposals include:

- indication-specific pricing arrangements and the circumstances in which they will be considered
- a reflection of the Competition and Markets Authority prioritisation statement on combination therapies
- embedding the provisions and principles supporting patient access schemes into the Commercial framework for new medicines

The consultation is open until 25 September 2024. You can access the consultation here.

Consultation questions

Section 1: Indication-specific pricing arrangements

Q1: To what extent do you agree or disagree with the criteria proposed for the circumstances when NHS England will consider indication-specific pricing arrangements?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/NA

Please provide any further comments here:

The BIA welcomes NHS England's focus on indication-specific pricing (ISP) in this consultation, and the recognition that an increasing number of new medicines are found to provide clinical benefits to several different groups of patients. We also welcome the recognition that ISP may result in increased access to new indications for a given medicine, with the potential of increasing therapeutic options for patients to optimise their care and clinical management.

We understand that ISP can result in higher costs for NHS England in some circumstances, however we believe that further consideration is required of the benefits of ISP, and other commercial flexibilities, to patients, including improved clinical outcomes, with consequential benefits for the NHS and broader society. Health systems may also benefit from ISP through increased competition and more granular value-based budget management at the indication level. Furthermore, NHS England should recognise that ISP would not necessarily result in increased spending on medicines, as if a product does not launch in a future indication due to commercial unviability, patients would instead be treated with alternatives which might have a similar or even higher price due to potentially less competition at an indication level. It is also important to consider that there are a number of existing budget control mechanisms, including the cap on NHS spending on branded medicines through VPAG, and the Budget Impact Threshold (BIT), the purposes of which are designed to facilitate patient access to cost-effective medicines in a sustainable way that does not inflate the NHS budget.

We are concerned that the proposed criteria for the circumstances in which NHS England will consider ISP remain unchanged from the previous arrangements, and will therefore limit the increased application of ISP. We believe that changes to the criteria are required to enable broader application of ISP for products that require it, in order to increase patient access to cost-effective treatments. Furthermore, retaining the preference for uniform pricing is at odds with the approach NICE takes to evaluating each indication on its own merits to ascertain the level of value offered and therefore a cost-effective price, recognising that different indications bring different levels of value.

We are particularly concerned that the requirement for products to "represent value at or below the lower end of the standard NICE threshold" could be especially punitive for access to innovative treatments for rare diseases, where the inherent nature of the patient population, paucity of data and consequential higher levels of uncertainty means that such medicines tend to sit at the higher end of the ICER threshold. This could limit rare disease patients access to innovative treatments and exacerbate health inequalities in the NHS. Smaller companies may also be disproportionately impacted by this criterion, as discounts of this magnitude are less likely to be economically viable to support a commercial launch in the UK. NHSE should remove this requirement, and instead consider the value of each indication at the cost-effectiveness threshold established by NICE when making decisions on ISP.

The BIA believes that a broader approach to ISP is required to ensure that NHS patients can benefit from faster and broader access to innovative new medicines. The UK is increasingly out of step with other countries operating ISP models, and our members have reported cases where the current approach to ISP in England has impeded access for a follow-on indication that is widely available in other European countries. The issues with the current limited approach to ISP is also demonstrated in recent analysis of NICE appraisals between 2016 and 2023 which found that terminations disproportionately impact products with multiple indications.[1]

A broader and more formalised approach to ISP would enable companies to prioritise the UK as a launch market, by enabling companies and NHS England to apply commercial flexibilities at an indication level that is cost-effective, offers good value to the NHS and is commercially viable. This

[1] Review funded by Sanofi presented at ISPOR 2023. Available at: https://www.ispor.org/docs/default-source/euro2023/isporeurope23mitchellhta133poster132056-pdf.pdf?sfvrsn=753ac94e_0with

would result in UK patients having faster and broader access to potential treatment options, improving clinical outcomes with consequential benefits for the NHS and society.

The requirement for products to meet all four of these criteria is in itself restrictive, which could result in a number of viable treatments not qualifying for commercial flexibilities if a product does not wholly satisfy each criterion, therefore potentially limiting patients access to innovative treatments. See below our feedback on each of the proposed criteria:

1. *The indication meets an unmet clinical need*

   We agree that ISP should be limited for products which address unmet clinical need, however we believe that this should be interpreted to include products beyond the first to market in a particular indication, rather than only those with no active comparator treatments available. Further clarity is required on how companies should demonstrate unmet need, including the types of evidence which will be considered as sufficient to satisfy this threshold, and the role of patients and clinicians in contributing to assessments of unmet need.

2. *The company can demonstrate with a high degree of confidence that uniform pricing would reduce the total revenue for a medicine across all indications*

   This is potentially more restrictive than the current criteria, which does not specify that this must be demonstrated "with a high degree of confidence" seemingly implying a very high evidentiary standard and which can be inherently difficult for companies to forecast. There is a risk that this could result in a tightening of the criteria for ISP, and further detail is required on what the threshold of "a high degree of confidence" would mean in practice in terms of the types of evidence that would be considered as sufficient, and over what time period this would be assessed. NHS England should also explain the rationale for using this criterion to establish if a product is eligible for ISP.

3. *Sufficient data is available within existing NHS systems to make such arrangements operationally feasible*

   We understand the need for sufficient data to be available to make ISP arrangements operationally feasible and support the use of Blueteq data to support the implementation of ISP for innovative rare disease medicines directly commissioned by NHS England. However, a pragmatic approach is required to enable the broader rollout of ISP over the coming years. Alternative models, including weighted average pricing based on estimated usage, could be considered to enable patient access for indications where data is limited. We also recommend that ongoing and planned work to improve NHS data should be reviewed to ensure they can support the transaction of commercial flexibilities including ISP, as it has the potential to promote better collection of health data and improve transparency on medicines use through appropriate monitoring of drug utilisation per indication.

4. *The cost-effective price is highly differentiated for all indications under consideration*

   Further clarity is required on what constitutes a highly differentiated price and anticipated outcomes for treatments that are, for instance, approved through cost comparison, as well as

further detail on the rationale for the inclusion of this criterion. It is important that this criterion is not interpreted as requiring all indications to satisfy the £20,000 per QALY threshold which would not reflect multi-indication products with significantly different patient outcomes and value propositions. We believe that the criterion should encourage commercial agreements that produce more value for the NHS than if there was no agreement.

Q2: To what extent do you agree or disagree that the criteria provide clarity on the circumstances in which NHS England will consider indication-specific pricing arrangements?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/NA

Please provide any further comments here:

A number of the proposed criteria would benefit from further clarity, as set out in our previous answer. It is particularly unclear how companies should demonstrate unmet clinical need, and what constitutes a "highly differentiated" price. NHS should also provide a rationale for the inclusion of each criteria, as well as the "at or below" requirement.

We recognise the provision of clarity needs to be balanced with the need to retain some flexibility within the commercial framework in order to facilitate effective negotiations. With this in mind, NHS England should establish clear processes to ensure that commercial flexibilities are applied in a fair manner across different companies and indications. NHS England should also share anonymised information about the reasons for acceptances and refusals of requests of ISP, which would provide learnings for industry.

We agree that early engagement, including on products entry to the appraisal process, between NHS England, NICE and companies has a crucial role to play in enabling companies to understand the potential for commercial flexibilities for a specific treatment. NHS England should establish clear processes to facilitate formal early engagement with companies so that eligibility in principle can be determined, potential barriers can be overcome and any delays in the process can be avoided. This would help to accelerate reimbursement decisions and patient access.

Section 2: Combination therapy pricing

Q3: To what extent do you agree or disagree that NHS England should support the CMA's position statement to enable company-to-company engagement over combination therapies?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/NA

Please provide any further comments here:

The CMA's statement enabling company-to-company engagement over combination therapies provides a key step forward in supporting patient access to combination therapies in the UK. NHS England should support the statement to enable this to be implemented, and has a crucial role to play in the provision of NHS data as well as facilitating early engagement with companies to avoid any delays to patient access.

We welcome the consideration of ISP alongside combination therapies, as ISP and other commercial flexibilities can play an important role is supporting access to combination therapies. Commercial flexibilities should be automatically considered for companies that have successfully facilitated a cost-effective commercial agreement under the CMA framework.

Q4: To what extent do you agree or disagree with the proposed approach for data sharing, where necessary, to facilitate company-to-company commercial agreements for combination therapies?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/NA

Please provide any further comments here:

The proposed approach for data sharing will enable companies to facilitate commercial agreements in line with the negotiation framework set out by the CMA.

NHS England should provide further information about the factors they will consider in deciding whether to provide data to facilitate a commercial agreement for a combination therapy. It should also clarify when in the NICE evaluation process companies should engage with NHS England if they anticipate a requirement for NHS data sharing and what the costs of data reports are expected to be.

We also recommend that ongoing and planned work to improve NHS data should be reviewed to ensure they can support the transaction of commercial flexibilities, including for commercial flexibilities.

Q5: To what extent do you agree or disagree that there are circumstances where the CMA's position statement would not support commercial arrangements for combination products?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree
- Don't know/NA

Please provide any further comments here:

The CMA's statement only supports commercial arrangements for some types of combination therapies and will not be able to facilitate access to all combination therapies that could benefit patients. However, it presents an important step forward to facilitating greater access to combination therapies in cases where there is a sufficient business case for the companies to enter into commercial discussions. In cases where the challenges for an effective combination cannot be resolved through commercial dialogue, flexibility in NICE methods and early engagement would be welcome in instances when the application of NICE's standard procedures would otherwise result in a negative outcome.

Section 3: Embedding patient access scheme provisions and principles

Q6: To what extent do you agree or disagree with the proposal to embed the PAS provisions and principles from the 2014 PPRS in the framework?

- Strongly agree
- Agree
- Neither agree nor disagree

- Disagree
- Strongly disagree
- Don’t know/NA

Please provide any further comments here:

We support the proposal to embed the PAS guidance and principles in the framework to ensure companies submitting PASs have the complete information in the framework.

We understand that changes to the PAS principles are not in within the scope of this consultation. However, we believe that the next commercial framework consultation provides an opportunity to consider potential changes to the PAS principles to support patient access to innovative new medicines.