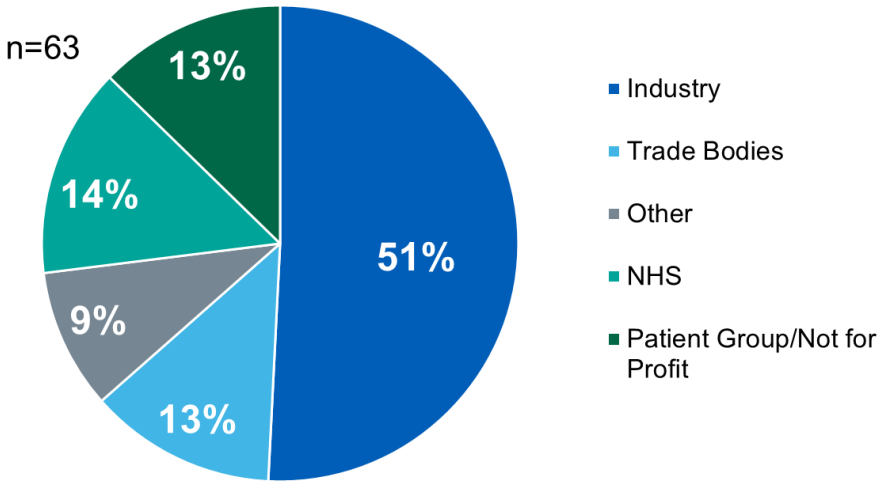
NHS commercial framework for new medicines

Response to engagement

NHS England and NHS Improvement previously asked for comments on our proposed NHS commercial framework for new medicines. We also held an event in London and another in Manchester to enhance our engagement.

Just over half the 63 responses we received were from the industry.



Our thematic analysis considered respondents' frequent themes, less frequent themes and suggested amendments.

This document summarises the feedback and outlines the changes we made to the framework in response to this. We have noted the issues raised on topics outside the engagement questions, e.g. commercial, but do not provide a formal response to these.

Q1. Are the objectives and principles underpinning the framework for medicines clear? Is anything missing?

Respondents warmly welcomed the framework and emphasised the need to ensure that improving patient access and outcomes were at its heart, as well as broad alignment to the Voluntary Scheme.

The frequent themes in responses to Question 1:

- Importance of putting patients at the centre of the framework; the content should focus on improving access and outcomes.
- Need for broad alignment to the Voluntary Scheme and reference in the context to key documentation from the life science sector.
- NHS England and NHS Improvement should take a consistent and fair approach, giving companies a level playing field.
- Clarification needed in relation to commercial flexibility and the lower end of the NICE cost-effectiveness threshold.
- Importance of confidentiality and the Freedom of Information (FOI) status of confidential discounts.
- Further detail on how the framework will support the adoption and uptake of medicines.

Summary of changes to framework based on engagement

- ✓ The framework emphasises the importance of improving outcomes for patients.
- ✓ The framework is fully aligned to the Voluntary Scheme.
- ✓ The framework signals that we take a consistent and fair approach with a level playing field for all companies.
- ✓ The framework makes clear that commercial flexibility is not restricted to medicines with initial value propositions below the lower end of the standard NICE cost-effectiveness range.
- ✓ Addition of wording to set out how we work in accordance with the FOI Act.

✓ Enhanced wording to further clarify that the simplest and fastest way to market is to provide a simple value proposition below NICE's standard cost-effectiveness thresholds.

Our responses to other themes:

- The framework was a commitment in the Voluntary Scheme, and therefore focuses solely on new medicines and does not include details on medical technologies. The case for developing a related framework for best value biologics (biosimilars) and generic medicines will be kept under consideration, as is now stated in the framework. Homecare (and the associated concept of bundling) is not addressed in the framework.
- We are committed to sharing commercial arrangements with devolved administrations as per the Voluntary Scheme requirements.

Q2: Are the respective roles and responsibilities and the processes for engaging with NICE and NHS England and NHS Improvement clear? Where would further clarity be helpful?

Respondents welcomed the framework's definition of the respective roles and responsibilities of NHS England and NHS Improvement and NICE but requested further details, particularly with regard to commercial teams.

The frequent themes in responses to Question 2:

- Request for further detail on the roles and interplay between the commercial teams at NICE and NHS England and NHS Improvement.
- Request for further information on the commercial teams at NICE. NICE Scientific Advice (NSA) and the Office for Market Access (OMA) are fee-based services and this should be acknowledged in the framework.
- Request for further detail on the relative merits of the clinical and commercial surgeries offered by NHS England and NHS Improvement.
- The introduction of a triage process is positive, and further detail on the operational aspects requested.
- The importance of horizon scanning information and UK Pharmascan is well represented in the framework. There was a concern that a focus on patent

expiry and lifecycle management could send out the wrong message to the life-science sector.

- Reassurance that NHS England and NHS Improvement will expand commercial capacity to meet rising demand.
- The importance of engaging with not-for-profit stakeholders such as patient groups and pharmacy groups – particularly during horizon scanning – was emphasised.

Summary of changes to framework based on engagement

- ✓ Provided further detail on the roles and interplay between the commercial teams at NHS England and NHS Improvement and at NICE.
- ✓ Added further detail on the NICE Commercial Liaison Team (CLT), Patient Access Liaison Scheme Unit (PASLU) and Managed Access Team (MAT).
- ✓ Provided further information on the difference between the NHS England and NHS Improvement commercial and clinical surgeries and on the operational detail of the triage service.
- ✓ Reflected the importance of a wide range of stakeholders in making new medicines available to patients.

Our responses to other themes:

- Further consideration will be given to the request for performance metrics for the framework as part of an ongoing dialogue with stakeholders.
- Requests from companies to have debrief sessions post-negotiations will be considered on a case-by-case basis. Given the potential volume of such requests, companies will need to give a clear reason for requesting such a session.

Q3: Are the routes to commissioning and funding new treatments within the NHS clear?

Overall, there was a positive response to the way the framework is laid out, supported by clear diagrams, and the routes to commissioning in the NHS in England for new medicines.

The frequent themes in responses to Question 3:

- Request for details explaining the exceptional situations when medicines are not assessed by NICE.
- Reassurance that the framework was not actively promoting the off-label use of medicines.
- Request for further information on when managed access agreements (MAAs) can be delayed beyond 90 days at NHS England and NHS Improvement's discretion.
- Request for additional information on how and when NHS England and NHS Improvement will determine whether a hospital product will be funded via tariff or pass through reimbursement would be helpful.

Summary of changes to framework based on engagement

- ✓ Provided clear explanation of the updated remit for NICE.
- ✓ Provided further information on the off-label usage of medicines.
- ✓ Provided explanation that the statutory funding is related to NICE technology appraisals and highly specialised technologies recommendations, not clinical guidelines or medical technologies guidance.

Our responses to other themes:

- The framework includes a simplified and stylised schematic of routes to commissioning in the NHS. Further detail could be added to this but at the expense of simplicity.
- The framework covers the flexibilities that apply to topics going through the NICE technology appraisal process. Where topics are not selected for a NICE technology appraisal or are off-label indications, it will be for the relevant

commissioning body (NHS England and NHS Improvement or individual CCGs) to reach a policy position on whether the treatment will be routinely commissioned or not. In the case of NHS England and NHS Improvement-commissioned specialised services, the existing and published service development policy and methods will be followed (further details).

Q4: Is the framework of commercial options available clear? Where might further clarity be helpful?

Respondents acknowledged the complexity associated with commercial options and were supportive of the framework's approach in giving companies information on the available opportunities and providing reassurance on confidentiality.

The frequent themes in responses to Question 4:

- Highlighted that not being able to set a different price for a new indication to correspond with its value as assessed by NICE remains a potentially challenging issue for companies.
- Request for the inclusion of more complex commercial models that go beyond the status quo and futureproof the framework against technologies such as advanced therapy medicinal products (ATMPs).
- Complex schemes can put a significant administrative burden on NHS staff and therefore simple schemes should be encouraged.
- Respondents thought it important to explain how the commercial options would work alongside the Conservative manifesto commitment of an Innovative Medicines Fund.

Summary of changes to framework based on engagement

- ✓ Wording on uniform pricing fully aligns with the Voluntary Scheme.
- ✓ Content makes clear the implications of exiting a MAA on pricing.
- ✓ Confirmed the review arrangements for the framework.

Our responses to other themes:

- The framework confirms that when exiting a MAA, the price of the drug can be higher or lower.
- We acknowledge that the number of oncology combinations is likely to increase in future, and in partnership with NICE remain committed to supporting the Association of the British Pharmaceutical Industry's (ABPI) efforts on this topic.

Q5: What is missing from the framework? and Q6: What additional information could be included?

Overall, respondents thought the framework was a robust and detailed document. Respondents did suggest it could be enhanced with some further information.

The frequent themes in responses to Questions 5 and 6:

- Suggestion that the framework would benefit from an escalation and case review process.
- Request for a data section detailing how the NHS plans to enhance the infrastructure to make use of real world evidence (RWE).
- Suggestion that governance and standards could help with the auditing of the framework.
- Request that evidential standards should be adhered to for information used to underpin assumptions in commercial negotiations.
- Request for further details on the lifecycle of the product (e.g. NHS England and NHS Improvement Commercial Medicines Unit contracting processes).
- Suggestion that the plan for future iterations of the framework and a timetable for review are included.
- Request that success metrics and key performance indicators (KPIs) for the framework are included.

Summary of changes to framework based on engagement

- ✓ Addition of detail on escalation process.
- ✓ Confirmed the review arrangements for the framework.
- ✓ The framework is compatible with ongoing policy developments.

Our responses to other themes:

- Further details of the triage process are provided in the framework, at a level deemed appropriate for a national strategy document.

Q7: Are you aware of any impact this framework might have on health equalities?

Generally, responders considered the framework would not adversely impact on health inequalities.

The frequent themes in responses to Question 7:

- Suggestion that technologies for rare diseases are disadvantaged. This was based on two main concepts:
  - small companies (that develop drugs for rare diseases) may be unable to afford OMA/NSA fees
  - NICE thresholds could potentially disadvantage technologies for rare diseases.

Summary of changes to framework based on engagement

- ✓ All patients (including those with rare diseases) have the right to fair, equitable and cost-effective interventions.
- ✓ Provided information on the fee element of NICE OMA and NSA services and that these services operate in accordance with government requirements for managing public money.

Our response to another theme:

- Consistent with the Voluntary Scheme, we will work with companies and the devolved administrations to confidentially share, wherever possible, commercial arrangements, recognising the reach of the NHS across the UK and the interests of UK taxpayers.

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