

NHS Commercial Framework for Medicines – Frequently Asked Questions (FAQs)

First Edition

Date: 1st November 2019

Introductory Questions

1. What is the commercial framework and why has it been published?

The Commercial Framework was a commitment set out in the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (“Voluntary Scheme”). The Commercial Framework establishes how NHS England will work together with NICE and the pharmaceutical industry on commercial medicines activity that is intended to support the introduction of clinically and cost-effective treatments for patients into the NHS.

2. How long is the engagement period and how can I engage?

The formal engagement exercise is for ten weeks (closing on Friday 10th January 2020) and will include stakeholder events in London and Manchester. Further details about the events will be published on the consultation web page shortly. A maximum of two people per organisation will be accepted per event.

Please note that any material submitted outside of the engagement questions will not be formally considered.

3. How will NHS England take into account my comments?

NHS England will consider all comments received during the engagement that relates to the engagement questions and publish a formal response in due course. Depending on the extent of the comments received, a thematic approach to the response may be produced.

4. When will the final version be published?

The aim is to publish the Commercial Framework in early 2020. The exact date of publication will depend on the extent of the revisions required after the formal engagement exercise closes on Friday 10th January 2020.

5. Is the engagement limited to pharmaceutical/biotechnology companies?

No. NHS England welcome comments from all organisations or individuals with an interest in the Commercial Framework.

6. I have an imminent commercial query – can I engage before the Commercial Framework is finalised?

Yes. The NHS England Triage system is operational. Please email your enquiry to england.commercialmedicines@nhs.net.

7. What is the process once I have submitted a commercial query to the NHS England Triage system and when can I expect a response?

NHS England will send an acknowledgement to confirm that the query has been safely received and is being considered.

The time for a formal response will depend on the nature of the enquiry and the current caseload. As the commercial capacity at NHS England evolves, the aim in future is to have a service-level agreement (SLA) with timelines for response.

Detailed Questions

8. The Commercial Framework focuses on branded new medicines – will future editions extend to include generic medicines and biosimilars?

The Commercial Framework was a commitment set out in the Voluntary Scheme. It is therefore appropriate that the first edition of the Commercial Framework focuses primarily on pricing and access issues associated with branded medicines.

NHS England will consider the inclusion of generic medicines and biosimilars in future editions of the Commercial Framework, or in alternative documentation as required.

9. The Commercial Framework is a first edition – what is the timeline for updating the document?

The updating of the Commercial Framework will be at the discretion of NHS England and will require dialogue with stakeholders such as NICE and the Department of Health and Social Care. The commercial environment is evolving rapidly; however, updating the framework must be balanced with the requirement to have a transparent and stable operating environment.

10. Can you provide further information on early engagement? For example, is it possible to engage with the Office for Market Access (OMA), NICE Scientific Advice (NSA) and NHS England?

NHS England and NICE have established processes for providing advice to companies across the product lifecycle. In the Commercial Framework, we have clarified these opportunities and encourage industry to engage throughout the product development process.

OMA engagement offers maximum benefit when undertaken earlier in the product development process, while NHS England surgeries often take place closer to the NICE appraisal and tend to focus on implementation issues. By engaging with NICE and NHS England in this way, companies can undertake a 2-step approach that: -

1. Optimises the opportunity to expose and explore the full range of market access challenges relating to a technology through structured multi-stakeholder interaction, gaining shared understanding and solution focused co-working.
2. Leads to further, more targeted discussion on any commercial, clinical and service delivery issues, building on the activity outlined above.

NICE and NHS England support and participate in each other's processes in this stepwise approach and work closely to triage requests appropriately.

11. How will horizon scanning evolve under the Commercial Framework?

Horizon scanning is a vital tool to understand the future healthcare environment and is a cornerstone of the emerging commercial strategy at NHS England. The Voluntary Scheme reaffirms the commitment to enhance the NHS' horizon scanning capability. A cross-function Horizon Scanning Steering Group (HSSG) is coordinating activity to meet this commitment.

Companies are encouraged to engage with UK *PharmaScan* and provide timely, accurate and relevant data to ensure the NHS can optimise the delivery of new medicines to patients.

12. How is the NHS going to manage combination therapies moving forward?

As set out in the Voluntary Scheme, realising the full potential health benefits from combination drug therapies can be challenging, given the need for commercial confidentiality and the requirement to maintain competition. NHS England and NICE will work with the Department of Health and Social Care to continue to support and comment on any solutions proposed by the Association of the British Pharmaceutical Industry (ABPI).

13. What should a company take into account before making a commercial offer to NHS England as part of the NICE appraisal process?

Among the commercial proposals available to companies, a simple confidential discount (a simple patient access scheme [PAS]) remains the preferred offer. More complex arrangements are available in certain circumstances, and companies should note that as complexity increases, so does the requirement to demonstrate increased value.

14. Will the Commercial Framework allow complex arrangements such as harnessing Real-World Evidence (RWE) to support reimbursement?

NICE's health technology evaluation review, due to be published in late 2020, will be considering how RWE is utilised.

15. Can you further clarify the difference between a managed access agreement (MAA) and a commercial access agreement (CAA)?

MAAs consist of two key components - a Data Collection Agreement to mitigate clinical uncertainty (as defined by NICE Committee) and either (a) CAA (see below) and /or (b) a simple PAS.

CAAs are a commercial-financial arrangement to enhance the value proposition for a medicine. They are agreed directly through engagement with NHS England and can be in addition to a simple PAS discount.

A CAA can therefore be part of a MAA or a standalone commercial-financial arrangement.