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# NHS commercial framework for new medicines

6 June 2022

# Contents

# Context

1. The Long Term Plan states that as medicine advances, health needs change and society develops, the NHS has to continually move forward. NHS commercial activity plays a pivotal role in supporting this evolution, ensuring patient access to the most clinically- and cost-effective new treatments and technologies. It maximises health outcomes for the people of England and value for money for taxpayers.

2. As set out in paragraphs 1.8 to 1.11 of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access ('the Voluntary Scheme'), the NHS in England is committed to supporting the introduction of the most clinically- and cost-effective medicines. We – NHS England and NHS Improvement – have already expanded the commercial flexibility offered to the industry for the best value new treatments, delivering the greatest clinical benefits at the lowest cost. We expect this to benefit patients, the NHS, individual companies and the life sciences sector more broadly.

3. The Voluntary Scheme notes that these enhanced commercial arrangements may include complex confidential commercial arrangements, where deemed appropriate by us and reserved for companies aspiring to deliver greater health gain relative to cost. It aims to deliver value for money for the NHS by securing the provision of safe and effective medicines at reasonable prices, and to encourage the efficient development and competitive supply of medicines.

4. It also emphasises that such arrangements would normally be for medicines expected to have value propositions at or below the lower end of the standard National Institute for Health and Care Excellence (NICE) cost-effectiveness threshold range, with greater flexibilities made available for value propositions at even greater levels of cost-effectiveness.

5. The Voluntary Scheme highlights the benefit of open and regular dialogue with industry representatives, and of providing the opportunity for earlier engagement, advice and signposting on the development of new products. This advice and support aims to enable more appropriate uptake of clinically- and cost-effective products to improve patient outcomes, with benefit for industry and patients through accelerating access and uptake.

6. Given this context, and our increasing role working alongside NICE and industry to support the introduction of clinically- and cost-effective medicines, this NHS commercial framework for new medicines ('the framework') has been developed to set out the NHS' approach to commercial activity in relation to branded medicines. While it focuses on new medicines, we will continue to consider the case for developing a related framework for best value biologics (biosimilars) and generic medicines. In the meantime, Section 3, which details roles, responsibilities and engagement, will be of interest to all companies.

7. This framework will be reviewed and updated over time. Further details are provided in Section 6.

# 1. Aims and purpose

8. Supporting improvements in the quality of life and health outcomes for all patients is the overarching purpose of the framework and underpins all NHS commercial medicines activity. The framework sets out how we will work together, with NICE and the industry on commercial medicines activity that supports the introduction of clinically- and cost-effective treatments into the NHS and maximises value for money for taxpayers.

9. The framework has four sections:

   - **Core objectives and principles:** outlining the purpose and principles on which NHS commercial medicines activity will be based.
   - **Roles, responsibilities and engagement:** defining the roles and responsibilities of those involved in commercial medicines activity and detailing how companies can engage with the NHS.
   - **Routes to commissioning:** clarifying the routes to routine commissioning in the NHS, and where commercial activity can occur in those routes.
   - **Commercial options:** outlining the types of commercial options that exist as well as commercial flexibilities, and the circumstances where they could be considered.

10. The framework, and the activity it enables, will support our and NICE's ambition to deliver patient access to proven, affordable and transformative medicines in a financially sustainable way. For the industry, it will encourage faster market entry for new treatments and support uptake and adoption where these medicines are priced fairly and responsibly.

# 2. Core objectives and principles

11. This section sets out the core objectives and principles on which commercial medicines activity will be based.

## Objectives of the NHS commercial framework for new medicines

12. The framework has three core objectives:

    1. To **facilitate timelier and more streamlined discussions about value, affordability and transactability** so that technology appraisal decisions, and ultimately patient access, are not unnecessarily delayed, ensuring early and fast access to new medicines.
    2. To **drive earlier and more purposeful engagement** between our organisation, the industry and NICE, to enable better planning at both individual company and system levels.
    3. To **clarify the commercial flexibilities that may be available to companies** where appropriate. This will ensure that all companies – especially smaller and/or specialist companies with less experience – can understand the full range of commercial options available to them.

## Principles underpinning the framework

13. Six principles guide and underpin our commercial activity. They support the achievement of the above objectives and address three central issues:

    - ensuring treatments are **clinically- and cost-effective** and represents the best use of NHS resources
    - ensuring the NHS can **afford** to introduce clinically- and cost-effective treatments now and in the future
    - ensuring any commercial arrangements are **transactable** within the NHS so that their value is realised and the burden on the NHS is minimised.

14. **Principle 1: NHS England and NHS Improvement's commercial medicines activity serves to support NICE's technology appraisal process, rather than act as a substitute for or alternative to it.**

NICE plays a critical role in ensuring equitable patient access to new medicines and treatments through assessing the clinical- and cost-effectiveness of health technologies in a transparent and consistent way. Its recommendations are based on a review of clinical evidence (which demonstrates how well the medicine or treatment works) and economic evidence (which shows how well the medicine or treatment works relative to how much it costs the NHS, and whether it represents value for money for taxpayers).

Where issues arise in relation to the economic evidence, whether in relation to cost-effectiveness or affordability, we consider whether commercial arrangements can help resolve these.

- The relative roles and responsibilities of the organisations are described in more detail in Section 3.

15. **Principle 2: NHS England and NHS Improvement and NICE will collaborate to provide a joined-up way for companies to engage with the NHS regarding technology appraisals.**

We recognise that companies want and need to have aligned and integrated conversations with us and with NICE to address issues of value, affordability and transactability, to achieve the fastest possible access for patients to clinically- and cost-effective treatments.

NICE assesses value through its technology appraisal process. NICE also assesses affordability by considering the net budget impact of a medicine and, where that is expected to exceed £20 million per year in any of the first three years of its use in the NHS, we engage in commercial discussions to manage the affordability. Transactability is a key element informing any commercial arrangement between the company and us.

- The process of engagement and routes to commissioning are described in Sections 3 and 4 respectively.

16. **Principle 3: Commercial arrangements must be as simple as possible, minimising the burden on the NHS and frontline staff.**

All commercial arrangements must be transactable within the NHS, both to realise the value of products to the NHS and to minimise the administrative burden on

frontline staff. Complex arrangements will only be considered once simple discounts (which facilitate fastest access) have been fully demonstrated to be unsuitable. Where there is a case for more complex schemes, these will need to be carefully scrutinised by us to ensure complex monitoring or burdensome data collection and disproportionate additional costs are avoided, and there is consistency with NHS financial flows, accounting rules and commissioning arrangements.

- Further details are given in Section 5.

17. **Principle 4: Confidential complex commercial arrangements are expected to be considered only for products which represent value at or below the lower end of the standard NICE threshold or other applicable thresholds.**

    The standard cost-effectiveness threshold used by NICE will be retained at the current range (£20,000 to £30,000 per quality adjusted life year [QALY]) for the duration of the Voluntary Scheme.

    Enhanced commercial arrangements would normally be reserved for medicines expected to have value propositions at or below the lower end of the standard NICE cost-effectiveness threshold range, with greater flexibilities made available for value propositions at even greater levels of cost-effectiveness, taking into account any applicable QALY weightings. This refers to the value proposition once any commercial arrangements have been applied.

    - Further details are given in Section 5.

18. **Principle 5: Bespoke commercial arrangements (commercial flexibilities) will be considered on a case-by-case basis.**

    Although this framework describes the types of commercial arrangements that may be available to companies, the different challenges facing different treatments (value, uncertainty, affordability) demand consideration on a case-by-case basis. No previous deals are an indicator of future deals and discretion on whether an acceptable offer has been made and to agree a commercial arrangement ultimately rests with us. We will take steps to ensure that a fair and consistent approach is applied.

- The types of commercial flexibilities and the circumstances when they may be available are described in Section 5.

19. **Principle 6: Commercially sensitive information will be kept confidential at all times.**

We recognise the critical importance of this to industry and, in turn, the benefit to the NHS in terms of securing the best possible deals and value for money for taxpayers. Notwithstanding this principle, and 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. We work in accordance with the Freedom of Information Act (FOI). Where it is in the public interest to withhold commercially sensitive information, such as confidential pricing, requested via FOI, this is exempt from disclosure under FOI.

# 3. Roles, responsibilities and engagement

20. The first two objectives of the framework are to:

    - facilitate timelier and more streamlined discussions about value, affordability and transactability so that technology appraisal decisions, and ultimately patient access, are not unnecessarily delayed, ensuring early and fast access to new medicines for patients.
    - drive earlier and more purposeful engagement between our organisation, the industry and NICE, to enable better planning at both individual company and system levels.

21. This section sets out our and NICE's respective roles and responsibilities and how we work together to enable companies to engage with the NHS about introducing their new medicines and building partnerships. This engagement can happen in different ways across the product lifecycle, and clarity is given about the timing, opportunities and nature of the advice available at different points.

## Roles and responsibilities

### National Institute for Health and Care Excellence

22. NICE has a world-leading role in producing independent evidence-based guidance and advice on the use of medicines. This is an important mechanism for ensuring medicines used in the NHS offer both clinical- and cost-effectiveness (value) to patients and taxpayers.

23. As stated in the Voluntary Scheme, all new active substances in their first indication, and extensions to their marketing authorisation to add a significant new therapeutic indication, are expected to undergo an appropriate NICE appraisal unless there is a clear rationale not to do so. Topics that were previously considered to be out of NICE's remit (specifically HIV and haemophilia treatments) can now be considered for NICE technology appraisal. Therapeutic vaccinations will be considered for NICE technology appraisal, whereas prophylactic vaccinations remain under the remit of the Joint Committee on Vaccination and Immunisation (JCVI).

24. NICE has published a guide to the methods it uses in its technology appraisal programme.

25. NICE also has a key role in enabling engagement with the life science industry, both by providing direct advice and directing enquiries to other appropriate functions within NICE, and to us.

26. In particular, NICE's Office for Market Access (OMA) is the function that helps companies engage with NICE, system partners and wider NHS stakeholders. Companies can engage at any stage of product development to gain valuable insights to inform their market access strategy, including to:

    - identify the most appropriate route to NHS access
    - understand the changing healthcare landscape
    - explore their value proposition.

27. NICE can also provide confidential scientific advice on clinical and economic development plans, as an additional fee-based service, through NICE Scientific Advice (NSA). These complementary teams at NICE (OMA and NSA) operate outside of NICE's guidance-producing programmes and actively collaborate to direct enquiries to the most appropriate function.

28. New medicines are assessed through NICE's technology appraisal process. During that process, there are opportunities for commercial engagement between the company and us. NICE has an important role in helping companies understand the process and timeline for the technology appraisal and facilitating the start of commercial discussions by signposting the company to our Commercial Medicines Directorate.

29. NICE is committed to working closely with us to provide timely information that supports the planning of commercial activity and enables timely commercial discussions between us and the company.

30. Our partnership with NICE is key to ensuring patient access to cost-effective and affordable technologies. In achieving this common purpose, we and NICE will share appropriate information in line with each organisation's own standard principles, respecting confidentiality on all and any matters relating to the information in question.

31. NICE has increased its commercial and managed access capacity and capability. NICE's Commercial Liaison Team (CLT) is responsible for briefing us about all types of technologies undergoing NICE technology appraisal, to inform our commercial discussions. The CLT incorporates the Patient Access Liaison Scheme Unit (PASLU), which advises us on the feasibility, transactability and expected operational success of patient access schemes (PAS). In addition, the CLT project manages the budget impact test (BIT) process at NICE.

32. A pharmaceutical company interested in submitting a PAS or a commercial access agreement proposal should first contact the NICE CLT; they must also consult with CMD at NHSE&I.

33. The Managed Access Team (MAT) focuses on data collection activities for technologies in managed access. MAT also work on the early identification of technologies that potentially require a managed access option.

**NHS England and NHS Improvement**

34. We and our partners set the overall commissioning strategy and clinical priorities for the NHS. We commission some primary care services (although most of this is delegated to clinical commissioning groups [CCGs]), and directly commission specialised services as set out in the Manual for Prescribed Specialised Services.

35. We have an important role in ensuring the best use of public resources and securing the greatest possible health gain for patients from every pound spent. One of the ways we achieve this is through undertaking commercial activities for medicines.

36. Since 2016, we have built on NICE's work by undertaking confidential commercial negotiations for time-limited managed access agreements (MAAs) in the areas of highly specialised technologies (HSTs), oncology drugs in the Cancer Drugs Fund (CDF) and products which meet the BIT, to address uncertainty, value, affordability and risk. From June 2022 this list includes the Innovative Medicines Fund (IMF).

37. As set out in the Voluntary Scheme, we can now consider commercial arrangements in more circumstances than before (e.g. to address both cost-effectiveness and affordability issues) and with more flexibilities, such as when a company wishes to offer a value proposition at or below the lower end of the

standard NICE cost-effectiveness threshold range. There are now a number of examples that demonstrate this flexibility.

38. We have increased our commercial capacity and capability to support this, and are proactively working with NICE and the industry to:

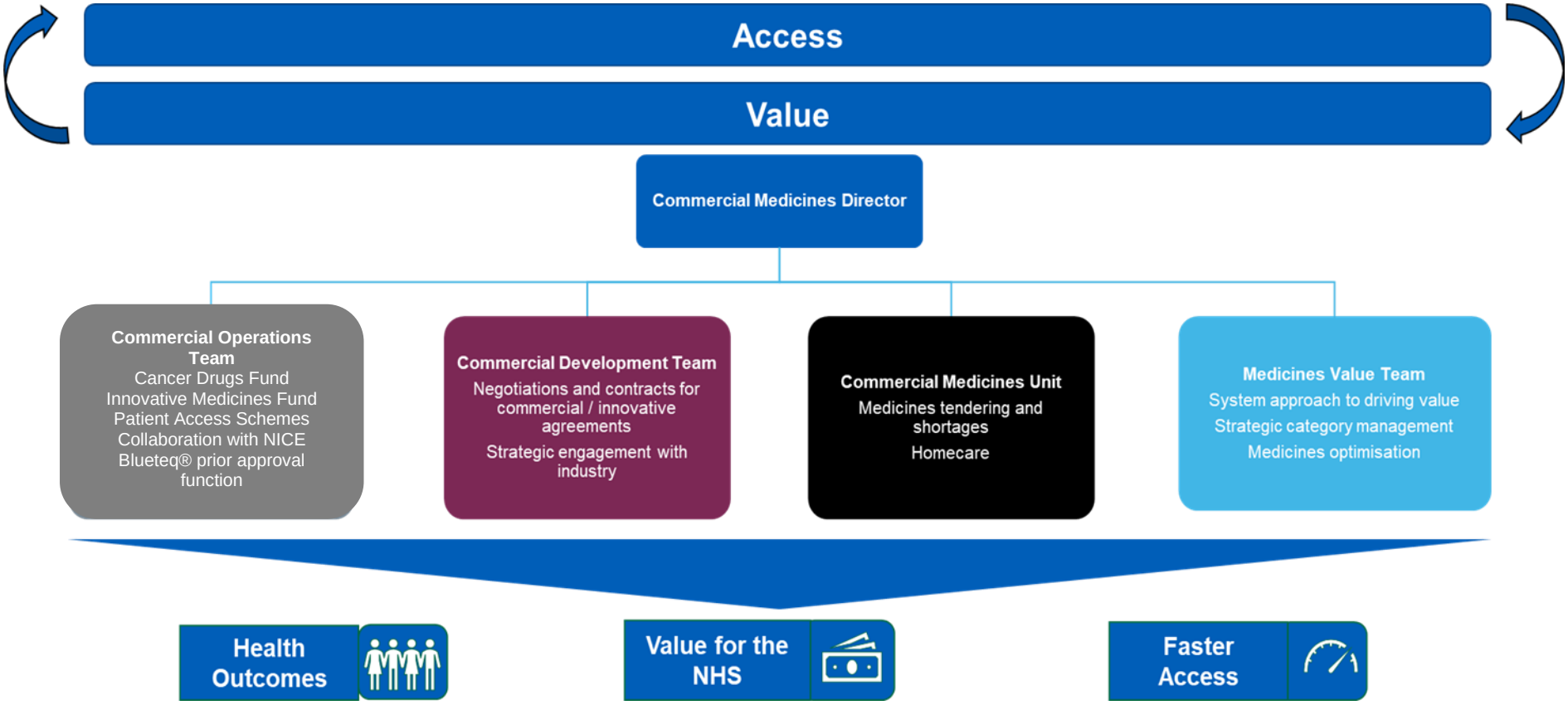
- encourage companies to engage effectively with horizon scanning activity
- create more opportunities for early engagement
- have a single point of contact for all commercial enquiries through england.commercialmedicines@nhs.net, with a triage system in place to direct the enquiry
- have more planned and consistent engagement with the industry representative bodies
- enable timely and structured commercial discussions where relevant and appropriate.

39. Our Commercial Medicines Directorate seeks to balance access and value across the product lifecycle. The directorate seeks to engage with the relevant commissioning functions to prepare the healthcare service for the implementation of new medicines, which is particularly important given the increased propensity to require corresponding changes to how clinical services are organised. **Figure 1** below explains what the Commercial Medicines Directorate encompasses.

40. In addition, we host the Accelerated Access Collaborative (AAC). This is responsible for co-ordinating activities across the AAC partner organisations, aiming to make the UK one of the most pro-innovation healthcare systems in the world. This includes:

- supporting the development of innovative products and overcoming system-wide barriers to access
- driving the uptake and spread of the best value innovations across the NHS
- identifying and supporting innovations that will deliver the greatest benefits for patients.

**Figure 1: Commercial Medicines Directorate**



## Process of engagement

41. Improved and proactive engagement with companies will enable all parties to build trusting relationships, understand the opportunities for aligning strategic objectives and seek opportunities of mutual benefit. The engagement will also look to the medium and longer terms to address issues of value, affordability, commercial risk and supply, to deliver optimal access and sustainability for the NHS and our stakeholders.

42. We and NICE have established processes for providing advice to companies across the product lifecycle. This framework enables these existing approaches to be more fully aligned, providing clarity on these opportunities, their timing and the nature of the advice available.

43. **Figure 2** below outlines the opportunities that companies have to engage with us and NICE; more detail on each is given below.

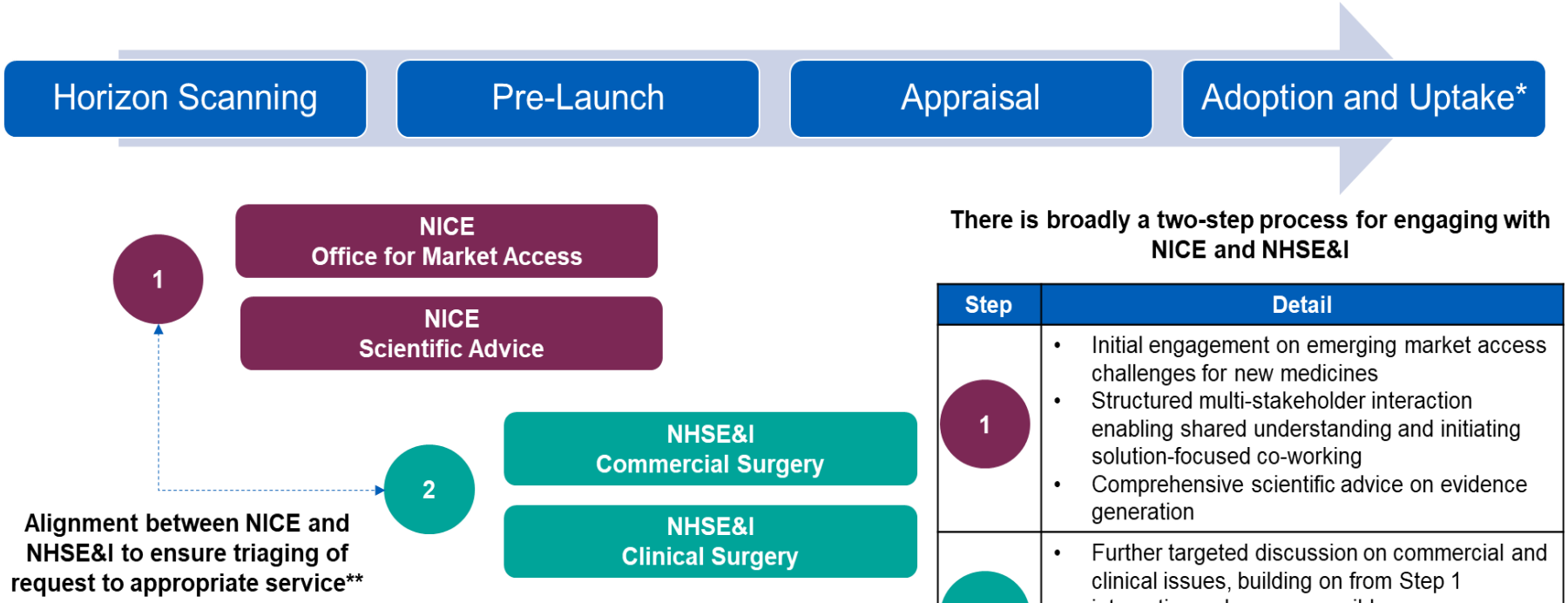
### Engagement with NICE

44. NICE provides early engagement opportunities for companies through OMA and NSA. These are complementary, fee-for-service offers that sit outside NICE's formal guidance-producing processes. These services operate on a not for profit basis and in accordance with government requirements for managing public money.

45. OMA helps companies engage with NICE, system partners and wider NHS stakeholders. Company queries are systematically 'unpacked' through preparatory discussions to facilitate a structured and extended 'safe harbour' engagement meeting across multiple stakeholders. This enables confidential, free-flowing, peer-to-peer conversations, which can act as a basis for ongoing engagement with stakeholders.

46. While companies can engage at any stage of product development to gain insights to inform the development of their ongoing market access strategy, OMA engagement offers maximum benefit when undertaken early in the market access and reimbursement process. We are a key participant in OMA engagement meetings.

**Figure 2: Engagement opportunities with NICE and NHS England**




**There is broadly a two-step process for engaging with NICE and NHSE&I**

| Step | Detail |
|---|---|
| 1 | • Initial engagement on emerging market access challenges for new medicines<br>• Structured multi-stakeholder interaction enabling shared understanding and initiating solution-focused co-working<br>• Comprehensive scientific advice on evidence generation |
| 2 | • Further targeted discussion on commercial and clinical issues, building on from Step 1 interactions wherever possible<br>• Surgeries tend to be closer to appraisal and focus on practical, commissioning related issues |

* We and NICE both offer advice at later stages of the product lifecycle. Requests are triaged appropriately.

** Acknowledging that confidentiality plays a role in what information can be shared.

47. NSA provides advice on scientific and technical questions at key points in the technology development process, including trial design, early modelling plans, additional data collection and model validation. Companies frequently engage with both OMA and NSA as they offer different types of insights, both of which are beneficial in the market access and reimbursement pathway.

48. NICE OMA and NSA services can be used in the product development to adoption journey. In the rare instances where a company considers there is a barrier to accessing these services, we would strongly encourage it to get in contact to discuss how the relevant service could be tailored to resolve this.

49. Companies can find the relevant contact forms to engage with NICE OMA here, and with NSA here.

**Engagement with NHS England and NHS Improvement**

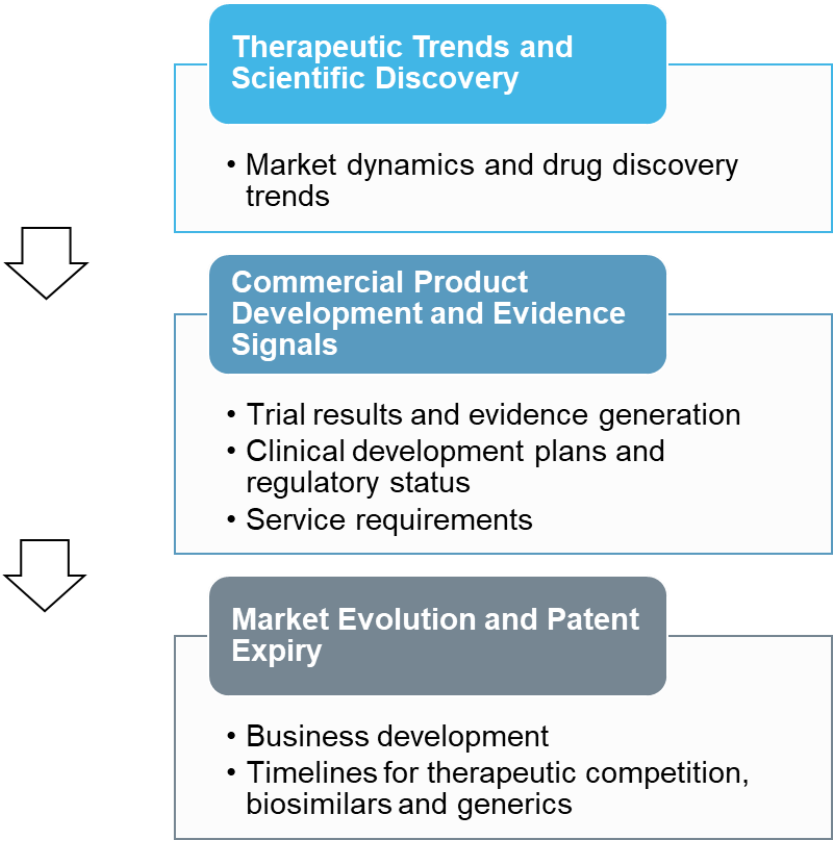
50. We offer surgeries to discuss a variety of commercial issues facing companies. We bring together the relevant expertise and skill-mix to discuss the issues effectively. These meetings often take place closer to the NICE technology appraisal than OMA meetings/NSA, and provide the opportunity for more focused discussion, with NICE as an additional participant.

51. Companies and patient groups can also engage with us on clinically related matters through clinical stakeholder surgeries. These surgeries were set up in 2014 as a way for companies and patient groups to engage with us. Requests for clinical stakeholder surgeries are managed via the triage system.

52. Effective horizon scanning is essential to allow the NHS to understand the products it will likely be using and give an indication of their likely impact on patients, existing pathways and services, and budgets. It also provides an indication of the future commercial environment, so that the NHS can be ready to respond as markets evolve.

53. Companies are encouraged to make information available at all stages of product development, to inform horizon scanning. This is set out in **Figure 3**.

**Figure 3: Horizon scanning across the product lifecycle**




54. UK PharmaScan is the single national database repository of information about all new medicines and all significant new indications to be launched in the UK. It is used by us, NICE and devolved national health technology appraisal (HTA) bodies to inform their horizon scanning activities.

55. Companies are expected to submit timely, accurate and comprehensive information to the fullest extent possible on all medicines in development using UK PharmaScan, and to keep this up to date. Information on patent expiry and potential timing of competition entry, such as biosimilars or generics, is also vital and the NHS will seek clarity from companies on this. Companies should ensure they are registered to use the system, have appointed leads in their organisation for keeping the system up to date, and respond to requests about horizon scanning information in a timely manner.

56. For further information about registering or using UK PharmaScan, please use https://www.ukpharmascan.org.uk/login or email contactus@ukpharmascan.org.uk.

57. UK PharmaScan will be further developed and enhanced to meet the evolving horizon scanning requirements of the system. This will ensure it remains the primary source of information for all relevant agencies to drive improved financial, clinical, assessment and service planning around the introduction of new medicines.

58. We and NICE also acknowledge the vital role organisations such as patient groups, medical research charities and pharmacy play in horizon scanning across the product lifecycle.

59. We and NICE will draw on all available information, including that requested through participation in clinical and commercial surgeries. Access to this accurate and timely information will enable rapid commercial decisions and facilitate commissioning as efficiently as possible.

60. A cross-functional Horizon Scanning Steering Group (HSSG) has been set up and is working to enhance and optimise NHS horizon scanning, reaffirming the commitment set out in the Voluntary Scheme. The National Institute for Health Research Innovation Observatory (NIHRIO) will work alongside stakeholders such as the NHS Specialist Pharmacy Service (SPS) to provide a central horizon scanning platform for intelligent, timely analysis that aligns with AAC goals.

**Getting in contact**

61. Companies can contact both us and NICE directly.

62. We have developed a triage function to enable faster and more consistent engagement between the NHS and companies. It provides a single point of engagement for all commercial queries. We anticipate this will help give patients faster access to the most innovative or best value new treatments. The triage system can respond to specific enquires and requests with helpful and relevant advice, as well as signpost companies to advice.

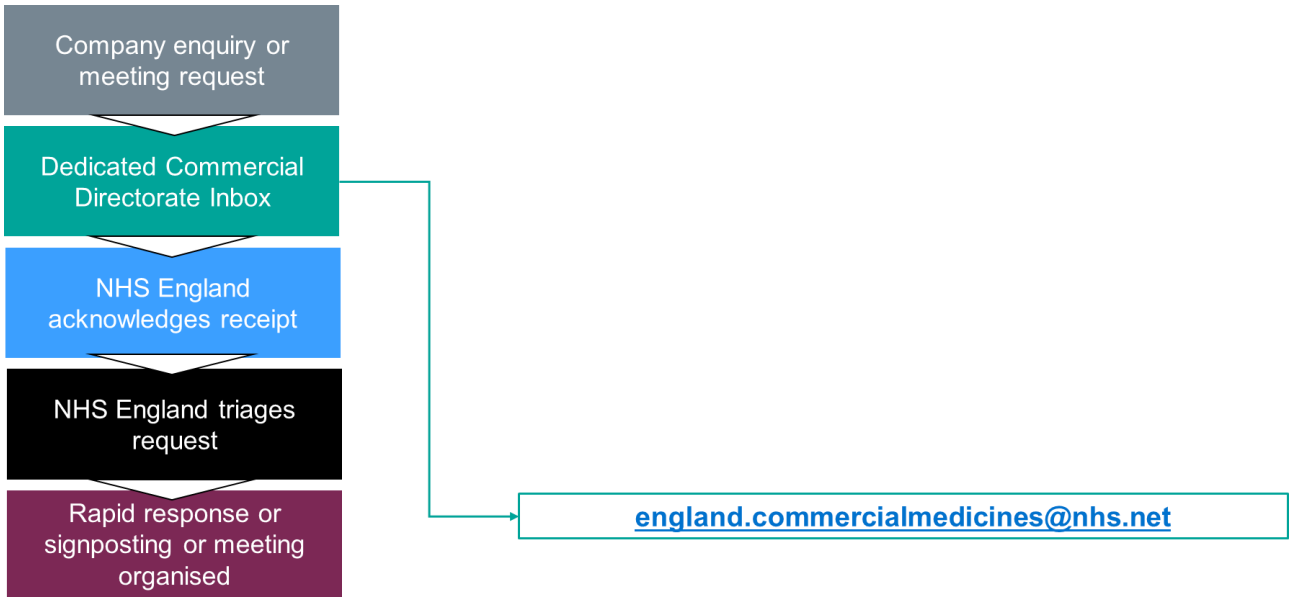
63. The triage function aims to:

- resolve enquires in a timely fashion
- arrange a meeting or teleconference where appropriate
- signpost and redirect enquiries outside the Commercial Medicines Directorate when necessary.

64. Typical outcomes for companies engaging with us through the triage function are resolution of their query, advice on who to engage with or a tailored commercial or clinical surgery arranged.

65. The way the triage function operates is summarised in **Figure 4**.

**Figure 4: NHS England and NHS Improvement – triage system**



# 4. Routes to commissioning

65. As set out in the previous section, the main route for commissioning medicines is expected to be via a NICE technology appraisal. NICE's technology appraisal is the standard route for medicines being recommended for use in the NHS in England. In very limited circumstances, medicines may go through other routes to become routinely commissioned in the NHS. These routes are summarised in **Figure 5** below.

## Regulatory approval and early engagement

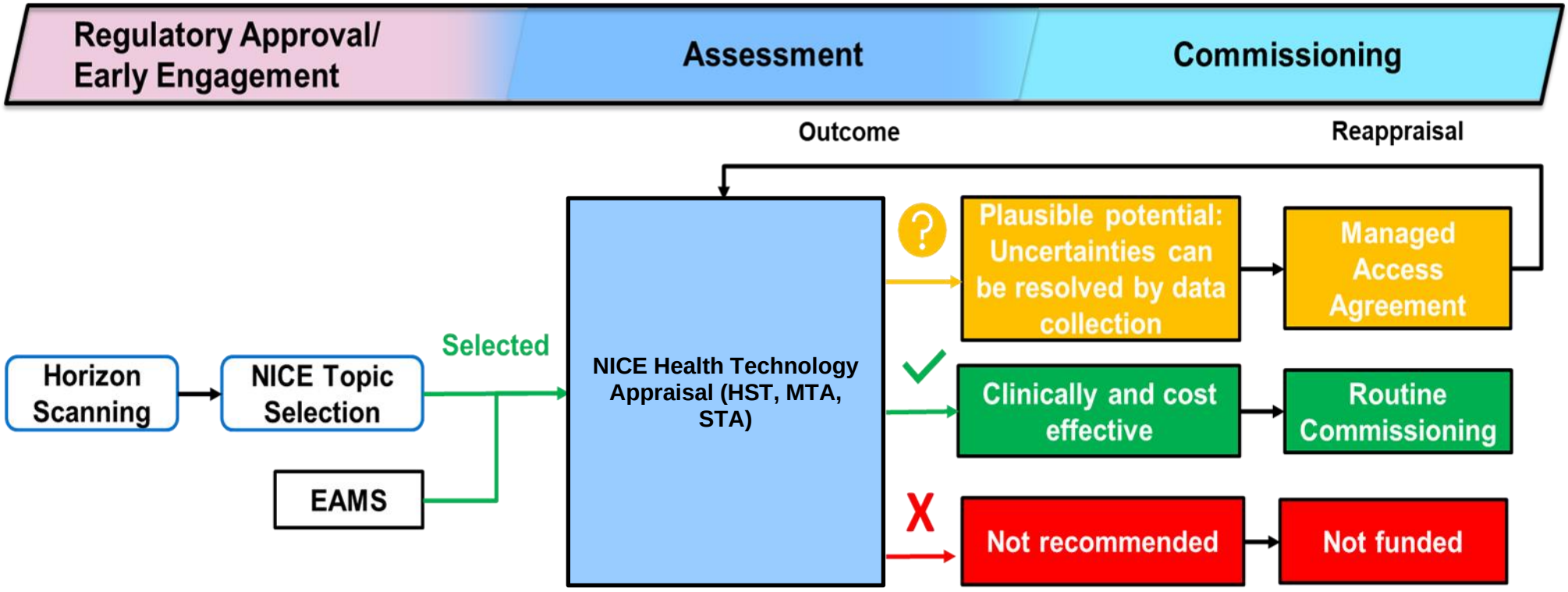
66. The route to commissioning begins with companies providing horizon scanning information through UK PharmaScan. Companies can then engage early with us and NICE, as set out in the previous section.

67. NICE selects the topics it will produce technology appraisal guidance on. NICE manages this process on behalf of the Department of Health and Social Care (DHSC). Selected topics are recommended to the Secretary of State for Health and Social Care for formal referral: NICE can only begin to appraise a technology once this has occurred. Further information on topic selection can be found here.

68. The Early Access to Medicines Scheme (EAMS) aims to give patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have marketing authorisation, when there is a clear unmet clinical need. The EAMS operates within the current regulatory structure and is voluntary and non-statutory.

69. Once licensed, NICE (and equivalent bodies in the devolved administrations) will appraise medicines for routine use that have been through the EAMS. Companies can use the evidence collected as part of the EAMS to support the appraisal.

**Figure 5: Schematic of routes to commissioning new medicines/indications in the NHS in England***




*All New Active Substances in their first indication, and extensions to their Marketing Authorisation to add a significant new therapeutic indication, will undergo an appropriate NICE appraisal, except where there is a clear rationale not to do so.

## Assessment

70. All new active substances in their first indication and extensions to their marketing authorisation to add a significant new therapeutic indication, are expected to undergo an appropriate NICE appraisal, unless there is a clear rationale not to do so. Medicines selected for NICE appraisal can be routed through one of the following processes:

    a. **Single technology appraisal (STA)** – this technology appraisal assesses asingle drug or treatment.
    b. **Multiple technology appraisal (MTA)** – this technology appraisal assessesseveral drugs or treatments used for one condition.
    c. **Cost comparison process –** shorter than the STA and does not formally use the technical engagement step.
    d. **Rapid review process –** Can be requested within 16 weeks of the final guidance publication to consider new PAS or commercial access agreement proposals.
    e. **Highly specialised technologies (HST)** – this technology appraisal assessesa single drug or treatment for very rare conditions.

    Further information on the NICE technology appraisal processes can be found in the NICE health technology evaluations: the manual (2022).

71. From April 2020, there may still be a few instances where topics are not selected for a NICE technology appraisal or are off-label indications. In such circumstances, 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 for specialised services, the existing and published service development policy and methods will be followed (further details).

72. Note that the framework does not advocate the use of off-label indications or suggest companies promote off-label usage of their medicines. Further information can be found on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

## Commissioning of services

73. We, ICBs and CCGs (depending on who the responsible commissioner is) are legally obliged to fund and resource medicines recommended by NICE's technology appraisals (the statutory funding requirement). This legal requirement is reaffirmedin the NHS Constitution that states that patients have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if theirdoctor believes they are clinically appropriate.

74. When NICE recommends a treatment for routine commissioning, the NHS must make sure it is available 'as an option' within 90 days (unless otherwise specified) of its final guidance being published. This means that if a patient has a disease or condition and the doctor responsible for their care thinks that the technology is the right treatment, it should be available for use, in line with NICE's recommendations.

75. In certain circumstances, when there is outstanding clinical and consequently financial uncertainty, and these can be plausibly addressed by data collection, a managed access approach via a MAA may be appropriate. Any MAA must formally be agreed between us, NICE and the relevant company. If and when agreement is reached, commissioning in line with the terms of the MAA will start (for CDF and IMF, interim funding is available; otherwise it will usually be within 90 days after final guidance). The statutory funding requirement does not apply to MAAs.

    Further details on this and other commercial options are set out in Section 5.

76. Although the NHS commissions most treatments available to it, some will not be available routinely as NICE has not recommended them as clinically- and cost-effective and, therefore, they do not represent an appropriate use of NHS resources.

77. However, a clinician may believe that their patient's clinical situation is so different from that of other patients with the same condition that they should have their treatment paid for when other patients would not. In such cases, NHS clinicians can ask the relevant commissioner (NHS England and NHS Improvement or CCGs), on behalf of a patient, to fund a treatment that would not usually be provided by the NHS for that patient. Such a request is called an individual funding request (IFR) and more details about this policy can be found here.

# 5. Commercial options

78. This section sets out the commercial options that may be available to companies, and that we and NICE may pursue in particular circumstances. The fastest (and preferred) route to market in England is for companies to propose simple discounts via a PAS.

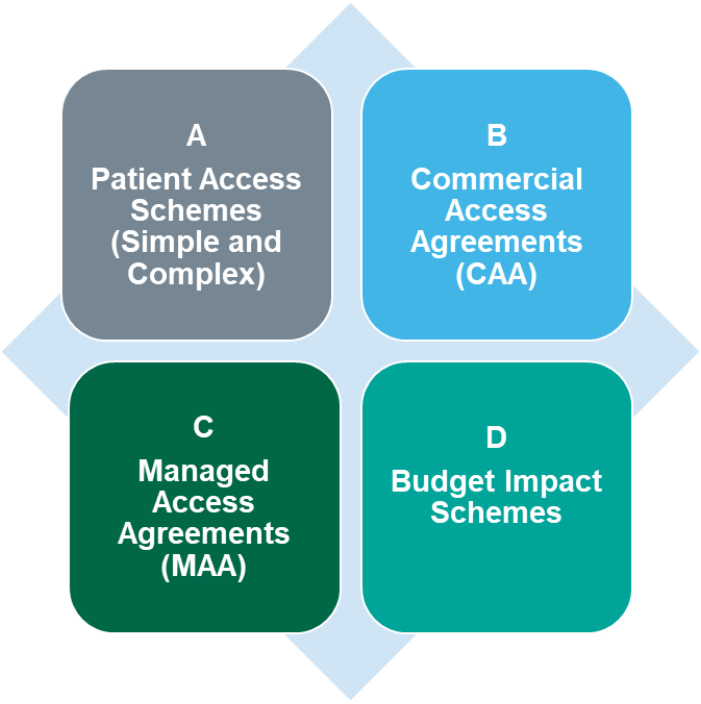
79. This section fulfils the framework's third objective: to clarify the commercial flexibilities that may be available to companies where appropriate. This will ensure that all companies – in particular, smaller and/or specialist ones with less experience – understand the full range of commercial options available to them.

80. The framework of potential commercial options:

- **supports companies in presenting a value proposition to NICE** that is considered clinically- and cost-effective within the relevant threshold
- **offers companies the potential opportunity to enter into complex and confidential agreements**, beyond a simple discount, where that results in an enhanced value proposition being presented to NICE that is at or below the lower end of the relevant clinical- and cost-effectiveness threshold
- **offers companies the opportunity to discuss the potential for a confidential commercial solution where there may be unusual or unique circumstances** that make launching a product particularly challenging or commercially unviable
- **provides companies with a confidential commercial mechanism where NICE believes there is significant uncertainty** surrounding the clinical- and consequently cost-effectiveness of a treatment and where there is plausible potential for that treatment to be clinically- and cost-effective
- **supports companies and us to work together to identify confidential commercial solutions for addressing NHS affordability challenges** that may arise from otherwise clinically- and cost-effective treatments.

81. A single commercial solution may be needed to address more than one of the points set out above. The commercial options (see **Figure 6** below) that can be considered and which are discussed in more detail below fall into four broad categories.

**Figure 6: Accessing commercial options**




## A. Patient access schemes (simple and complex)

82. PASs are the starting point or default option for companies to consider when developing their value proposition for appraisal by NICE. They provide a mechanism for companies to improve the cost-effectiveness of a treatment under appraisal beyond that driven by its list price.

83. Unless a treatment is to be considered by NICE at list price, companies should always include a PAS in their initial evidence submission to NICE to ensure sufficient time for full consideration in advance of the appraisal committee meeting.

84. There are two types of PAS:

- simple PAS (confidential)
- complex PAS (transparent).

**Simple patient access schemes**

85. Simple PAS are confidential and provide a fixed price or percentage discount on the list price that is applied at source. **These are always the preferred option**, in line with the principles set out in Section 2, as they require less monitoring by all parties and minimise the administrative burden on NHS organisations. They also

ensure that where VAT is incurred it applies at the lowest level of the effective net price.

86. Importantly, simple discounts apply consistently across all indications for a given technology. This is consistent with the Voluntary Scheme, which confirmed that the health service in England does not operate blended pricing or pricing by indication. In practice, this means that a simple PAS discount may increase the discount within an existing PAS – that is, where the technology being appraised for a particular indication is already routinely commissioned for a different indication.

87. We took over responsibility for agreeing PASs from DHSC in April 2018.

88. The PASLU advises us on the feasibility of a PAS. As a simple PAS involves a more rapid review than a complex PAS, both the NICE CLT's advice (via PASLU) and our approval are faster. Importantly, note that our agreement to a PAS should not be seen as a willingness to pay at the proposed level of discount.

89. The advice from the NICE CLT (via PASLU) informs the decision on whether the proposed PAS can be considered as part of a NICE technology appraisal. It is for NICE to determine whether the level of discount being offered by the company represents a clinically- and cost-effective use of NHS resources.

**Complex patient access schemes**

90. In contrast to a simple PAS, a complex PAS is not confidential. By definition, it will involve a more complex reimbursement proposal that, in turn, will be more complex to administer within the NHS. The requirement for transparency is to ensure the administrative burden and cost to the service of implementing such schemes is minimised and helps ensure the value of the treatment, as determined by NICE, is achieved.

91. If a company chooses to propose a complex scheme, there needs to be a strong rationale to justify its use and an indication of how the associated risks will be shared equitably between us and the company. VAT consequences associated with the proposed scheme must also be accounted for within the proposal to ensure the full financial benefits of the scheme are realised by the NHS.

92. As with a simple PAS, the NICE CLT (via PASLU) advises us on the feasibility of implementing the proposed scheme. For a complex PAS, this will inevitably be a

more involved process, including consultation with the NHS and an operational review of commercial arrangements to ensure the benefit can be realised.

93. PASs extant as at 31 December 2018 have been maintained in accordance with their terms as per the 2014 Pharmaceutical Pricing Regulation Scheme.

## B. Commercial access agreements (CAAs)

94. Unlike complex PASs, which are transparent, CAAs are confidential. In line with the principles set out in Section 2, such agreements are at our discretion, with the default arrangement of offering a PAS (simple or complex) always being available to companies.

95. There are currently two circumstances when we may consider entering into a CAA with a company:

- where the company wants to propose an enhanced value offer
- where there are unusual or unique circumstances that mean launching a product is considered particularly challenging or commercially unviable.

**Enhanced value offers**

96. The Voluntary Scheme sets out the following:

"Enhanced commercial arrangements may include complex confidential commercial arrangements, where deemed appropriate by NHS England and reserved for where companies aspire to deliver greater levels of health gain relative to cost. Arrangements would normally correspond to medicines that would be expected to have value propositions at or below the lower end of the standard NICE cost effectiveness threshold range, with greater flexibilities made available for value propositions at even greater levels of cost effectiveness, plus any applicable QALY weightings."

**Table 1** gives example formats for CAAs. Each would be considered on a case-by-case basis.

**Table 1: Example formats for confidential commercial arrangements***

| Scheme type | Description |
|---|---|
| Budget cap | Maximum budget impact for a product (or products) beyond which a central rebate is payable. |
| Price/volume agreement | Price agreed for set volume of patients and then reductions staged based on additional patient numbers, or company pays back the full amount (similar to budget cap). |
| Cost sharing | The company funds initial cost of therapies such as offering the first month for free. |
| Stop/start criteria | Rules on eligibility criteria for when patients should start/stop therapy. |
| Outcomes-based agreement/payment by results | Discount or rebate applied if a product does not perform as expected or for non-responders. |

*NB: This list is not exhaustive, and a combination of schemes can be applied.

### Unusual or unique circumstances

97. We recognise that there can be unusual or unique circumstances surrounding the NICE technology appraisal of a particular treatment that make its launch challenging or commercially unviable. The merit or otherwise of developing and agreeing bespoke commercial solutions in such circumstances will be considered on a case-by-case basis.

98. The NHS in England will continue to adopt uniform pricing by medicine; it does not operate blended pricing or pricing by indication. In cases where uniform pricing would reduce the total revenue for a medicine from introducing additional indications, other forms of commercial flexibility may be considered for medicines that have a strong value proposition. In these cases, commercial flexibility would only be considered where the level of clinical effectiveness is highly differentiated and substantial in all indications under consideration.

99. The Voluntary Scheme also recognises that realising the full potential health benefits from combination drug therapies can be challenging given the requirement for commercial confidentiality and the need to maintain competition. They may, therefore, require bespoke commercial solutions.

100. In this respect, we and NICE will continue to:

- support the Association of the British Pharmaceutical Industry (ABPI)'s efforts to find solutions to enable companies to engage with one another where health-improving combination therapies face challenges coming to market
- provide feedback on ABPI's proposed solutions to allow company-to-company engagement, to ensure that the combined cost of combinations can be developed for NICE technology appraisal, at the standard NICE threshold, in line with competition law.

101. In the UK, the Competition and Markets Authority (CMA) represents the sole competent authority and scheme members will need to satisfy themselves that the commercial aspects of bringing combination therapies to the market are compliant with relevant legislation.

102. There may be other unusual or unique circumstances, beyond those considered here, that may justify bespoke commercial flexibilities, and these will be looked at on a case-by-case basis.

## C. Managed access agreements (MAAs)

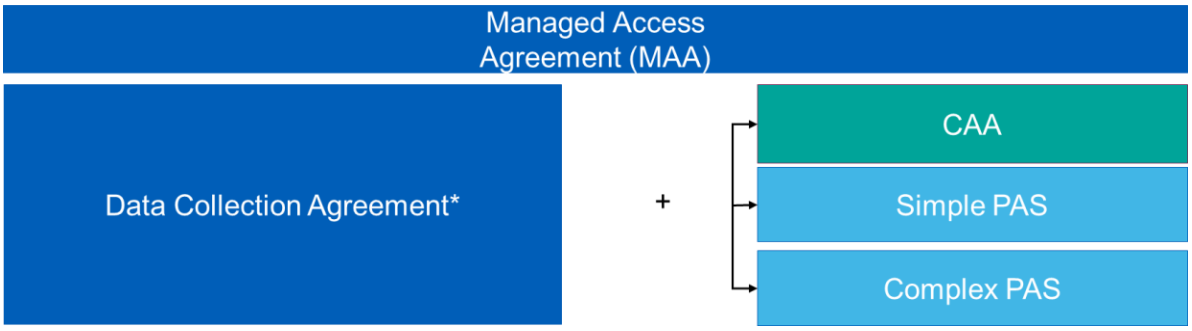
103. There are situations where uncertainty exacerbates the challenge for NICE in its technology appraisals. In general, there are two main sources of outstanding uncertainty at the time of appraisal:

- clinical uncertainty
- (and as a consequence) financial uncertainty.

104. Where such uncertainty exists, NICE can recommend that we and the company explore an MAA. This would only happen when there is plausible potential for a medicine to satisfy the criteria for routine commissioning, and there is uncertainty surrounding the clinical data and consequently the cost-effectiveness estimates on which to make such a recommendation.

105. MAAs consist of two key components (**Figure 7**): a data collection agreement to mitigate clinical uncertainty (as defined by the NICE Appraisal Committee), and either a commercial access agreement or a PAS.

**Figure 7: MAAs explained**




* This captures the time-limited clinical element, which needs to be incorporated into the MAA.

106. MAAs are an interim commissioning position with a committed future date for reappraisal, which may result in routine commissioning; they are therefore time-limited.

107. MAAs require the company's agreement to offer the treatment at a cost-effective price for the duration of the MAA. There are exit clauses in place as part of each MAA, including the obligation to maintain funding and existing patient access should any reassessment result in a negative decision. It should be noted (as with the CDF and IMF) that it is possible, when exiting the MAA, for the price of the product to be higher or lower, depending on the reappraisal outcome.

108. To date, MAAs have been most frequently used in the context of the CDF, and for NICE HST guidance where very small patient numbers can lead to significant uncertainty in the clinical evidence being presented.

109. Further detailed information in relation to the operation of the CDF can be found here.

110. Although MAAs have most commonly been seen within the CDF and HST appraisals, this is not an exclusive position and NICE may recommend their use in a broader set of circumstances. However, one of the key constraints to overcome when considering the possibility of a MAA is whether data collection has the potential to collect data on the relevant health outcomes and resolve the uncertainties.

## D. Budget impact schemes

111. We have a responsibility to ensure that any commissioned new technologies do not present an affordability challenge for the wider NHS.

112. If the potential net budget impact is expected to exceed £20 million per year in any of the first three years of a technology's use in the NHS, we will engage in commercial discussions with relevant companies as an alternative to requesting a variation to the statutory funding requirement. The purpose of these commercial discussions is to mitigate the affordability challenge of immediately funding the technology for other NHS services. If an agreement between us and the company is not reached, we may then request a variation to the statutory funding requirement.

113. The degree of additional value expected from application of the BIT will take into account two main dimensions:

- overall cost impact to the NHS in each of the first three years
- any likely direct competition to or external impact on that market that may mitigate any spend by the NHS.

**Escalation**

114. If, in commercial discussion between us and a company under the terms of this commercial framework, we or the company consider a failure to reach agreement could be escalated to reach a mutually acceptable commercial arrangement, either we or the company may escalate the disagreement as described below.

115. Initially, the Level 1 negotiators (for us, the head of the Commercial Development Team or deputy; and for the company, the most senior national manager or deputy with knowledge of the escalation issue) meet within 14 calendar days to discuss the point of escalation and seek agreement if possible, provided that the discussions (and all and any subsequent levels of escalation) are strictly limited to the original issue for escalation.

116. If no agreement is reached at this stage, we or the company may refer the point of escalation to the Level 2 negotiators (for us, the Commercial Medicines Director; and for the company a senior independent company representative, e.g. at global level) not previously involved in the commercial discussion.

117. Level 2 negotiators meet within 14 calendar days to discuss the unresolved point of escalation and seek agreement if possible.

118. If we cannot reach agreement with the company following the meeting of the Level 2 negotiators, the relevant commercial discussion will be treated as having come to an end.

# 6. Updating the framework

119. The framework is a national strategy document setting out the NHS' approach for commercial activity in relation to new medicines. We envisage that the framework will be discussed as part of the Voluntary Scheme operational review meetings between the DHSC, ourselves and the ABPI.

120. We believe that it is essential that the framework has the stability of a long-term strategy but remains up-to-date to reflect key developments that impact on its implementation. As the framework fully align with the Voluntary Scheme, we will review it following any relevant updates to the Voluntary Scheme or any other relevant policy changes.

# Glossary

| | |
|---|---|
| AAC | Accelerated access collaborative |
| BIT | Budget impact test |
| CAA | Commercial access agreement |
| CCG | Clinical commissioning group |
| CDF | Cancer drugs fund |
| CLT | NICE Commercial Liaison Team |
| CMA | Competition and Markets Authority |
| EAMS | Early access to medicines scheme |
| FOI | Freedom of information |
| HSSG | (NHS England and NHS Improvement) Horizon Scanning Steering Group |
| HST | Highly specialised technology |
| JCVI | The Joint Committee on Vaccination and Immunisation |
| MAA | Managed access agreement |
| MAT | NICE Managed Access Team |
| MHRA | Medicines and Healthcare products Regulatory Agency |
| MTA | Multiple technology appraisal |
| NICE | National Institute for Health and Care Excellence |
| NIHRIO | National Institute for Health Research Innovation Observatory |
| NSA | NICE scientific advice |
| OMA | Office for Market Access |
| PAS | Patient access scheme |
| PASLU | Patient access scheme liaison unit |
| QALY | Quality-adjusted life year |
| SPS | Specialist Pharmacy Service |
| STA | Single technology appraisal |

# Further information

- Accelerated Access Collaborative
- Early Access to Medicines Scheme

- Office for Market Access (NICE)
- PASLU (NICE)
- NICE Scientific Advice Service
- NICE health technology evaluations: the manual (2022)
- Cancer Drugs Fund
- Innovative Medicines Fund

# References

Documents that have informed the NHS commercial framework for new medicines:


- Department of Health and Social Care (2018) The 2019 Voluntary Scheme for Branded Medicines Pricing and Access
- The National Archives (2000) Freedom of Information Act (2000)
- NHS England (2019) NHS Long Term Plan
- Wellcome Trust (2016): Accelerated access review: final report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