NHS Commercial Framework for Medicines

Draft for Engagement

Version 1 (for Engagement)

First Edition

NHS Commercial Framework for Medicines

Draft framework setting out NHS England's proposed approach for working with the pharmaceutical industry in relation to commercial medicines activity.

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Context

1. The Long Term Plan states that as medicine advances, health needs change and society develops, the NHS has to continually move forward. The 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, while also maximising health outcomes for the people of England and value for money for taxpayers.
2. As set out in paragraphs 1.8 – 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. NHS England has already geared up to expand the commercial flexibility offered to the pharmaceutical industry for the best value new treatments, which deliver the greatest clinical benefits at the lowest cost. The increased availability of confidential commercial flexibilities is expected to be beneficial for patients, the NHS, individual pharmaceutical 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 NHS England and reserved for companies aspiring to deliver greater levels of 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 encourage the efficient development and competitive supply of medicines. It also emphasises that such arrangements would normally correspond to medicines that would be 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.
4. The Voluntary Scheme highlights the benefit of open and regular dialogue with pharmaceutical industry representatives and 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.
5. Given this context, and NHS England's increasing role working alongside NICE and industry to support the introduction of clinically and cost-effective medicines, this NHS Commercial Framework for Medicines ("the Framework") has been developed to set out the NHS' approach for commercial activity in relation to branded medicines. It is expected that the framework will be expanded in the future to include, for example, information on the commercial approach for biosimilar and generic medicines. In the meantime, section 3 which details role, responsibilities and engagement will be of interest to all companies.

6. Over the next 10 weeks engagement will be carried out with the pharmaceutical industry and other interested stakeholders on this draft of the Framework. It will then be reviewed and refined, with an expectation of a first edition being published in early 2020. It is intended that this Framework should be a ‘living document’, that is updated over time.

Section 1: Aims and Purpose

7. This Framework sets out 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 into the NHS.
8. The Framework covers the following 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 pharmaceutical 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 commercial flexibilities, and circumstances where they could be considered.
9. The Framework, and the activity it will enable, will support both NHS England and NICE's ambition to deliver patient access to proven, affordable and transformative medicines in a financially sustainable way. For the pharmaceutical industry, it will encourage faster market entry for new treatments and support uptake and adoption where these medicines are priced fairly and responsibly.

Section 2: Core Objectives and Principles

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

Objectives of the NHS Commercial Framework for Medicines

11. The Framework has three core objectives:

    - First, to **drive earlier and more purposeful engagement** between the pharmaceutical industry, NHS England and NICE, to enable better planning at both individual company level and at a wider industry level.
    - Second, to **facilitate timelier and more streamlined discussions about value, affordability and transactability** so technology appraisal decisions, and ultimately patient access, are not unnecessarily delayed, to ensuring early and fast access to new medicines.
    - Third, 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, will understand the full range of commercial options available to them.

Principles Underpinning the Framework

12. The following six principles guide and underpin our commercial activity and are focused on supporting achievement for the above objectives and addressing these three central issues:

    - Ensuring treatments are **clinically and cost-effective** and represent a good use of NHS resources.
    - Ensuring the introduction of clinically and cost-effective treatments are **affordable** for the NHS now and in the future.
    - Ensuring that any commercial arrangements are **transactable** within the NHS so that the value is realised and the burden on the NHS is minimised.

13. **Principle 1: NHS England's commercial medicines activity serves to support NICE's technology appraisal process, rather than act as a substitute 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. 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 in relation to how much it costs the NHS, and whether it represents value for money to the taxpayer). Where issues arise in relation to the economic evidence, whether in relation to cost-effectiveness or affordability, the NHS is able to consider whether commercial arrangements may be able to help resolve those issues.

➔ The relative roles and responsibilities of the organisations is set out in more detail in **Section 3**.

14. **Principle 2: NHS England and NICE will work collaboratively to provide a joined-up way for pharmaceutical companies to engage with the NHS regarding technology appraisals**. We recognise that pharmaceutical companies want and need to be able to have aligned and integrated conversations with NHS England and NICE on addressing issues of value, affordability and transactability in order to achieve the fastest possible access for patients to clinically and cost-effective treatments. Value is assessed through NICE's technology appraisal process. If the potential net budget impact of a medicine is expected to exceed £20 million per year in any of the first 3 years of a technology's use in the NHS, NHS England will engage in commercial discussions to manage its affordability. Transactability is a key element informing any commercial arrangement between the company and NHS England.

    ➔ Further details on the process of engagement and routes to commissioning are set out in **Sections 3 and 4** respectively.

15. **Principle 3: Commercial arrangements must be as simple as possible, minimising the burden on the NHS and front-line staff.** It is vital that all commercial arrangements are transactable within the NHS, both to ensure that the value of products to the NHS is realised and the administrative burden on front line staff is minimised**.** Complex arrangements will only be considered once simple discounts have been fully demonstrated to be unsuitable. Where there is a case for more complex schemes, these will need to be carefully scrutinised, avoiding complex monitoring, disproportionate additional costs and be consistent with NHS financial flows, accounting rules and commissioning arrangements.

    ➔ Further details can be found in **Section 5**.

16. **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 - £30,000 per Quality Adjusted Life Year [QALY]) and not changed for the duration of the Voluntary Scheme. Enhanced commercial 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, taking into account any applicable QALY weightings.

    ➔ Further details can be found in **Section 5**.

17. **Principle 5: Bespoke commercial arrangements (commercial flexibilities) will be considered on a case-by-case basis**. Although the types of commercial schemes that may be available to companies are described in this Framework,

the different challenges facing different treatments (value, uncertainty, affordability) demands 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 NHS England.

➔ Further details on the types of commercial flexibilities and the circumstances when they may be available can be found in **Section 5**.

18. **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 tax payers. 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.

Section 3: Roles, Responsibilities and Engagement

19. The first two objectives of the Framework are to:

    - Drive earlier and more purposeful engagement between the pharmaceutical industry, NHS England and NICE, to enable better planning at both individual company level and at a wider industry level.
    - Facilitate more timely and streamlined discussions about value, affordability and transactability so technology appraisal decisions, and ultimately patient access, are not unnecessarily delayed.

20. This section sets out the respective roles and responsibilities of NICE and NHS England and how we will work together to enable pharmaceutical 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 these different points.

Roles and Responsibilities

National Institute for Health and Care Excellence

21. 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 by the NHS offer both clinical and cost-effectiveness (value) to patients and taxpayers.

22. 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. NICE expects to achieve this from April 2020. The methods that NICE uses can be accessed here.

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

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

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

25. NICE is also able to provide scientific advice on technical questions through NICE Scientific Advice (NSA). These complementary teams at NICE (OMA and NSA) both operate outside of NICE's guidance-producing programmes and actively collaborate to direct enquiries to the most appropriate function.

26. It is through NICE's technology appraisal process that new medicines are assessed. During that process, there are opportunities for commercial engagement between the company and NHS England. NICE has an important role in helping companies to understand the process and timeline for the technology appraisal and facilitating the introduction of commercial discussions by signposting the company to NHS England's commercial medicines directorate.

27. NICE is committed to working closely with NHS England to provide timely information and intelligence to support the planning of commercial activity and enable timely commercial discussions between the NHS and the company.

NHS England

28. NHS England and its partners sets the overall commissioning strategy and clinical priorities for the NHS. NHS England commission some primary care services (although most of this is delegated to CCGs) and directly commission specialised services (such as treatments for rare conditions).

29. NHS England has an important role in ensuring the best use of public resources and securing the greatest possible health gain for patients for every pound spent. One of the ways that this is achieved is through undertaking commercial activities on medicines.

30. Since 2016, NHS England has built on NICE's work by undertaking confidential commercial negotiations for time-limited managed access agreements in the areas of Highly Specialised Technologies (HSTs), oncology drugs in the Cancer Drugs Fund (CDF) and for products which meet the Budget Impact Test (BIT), to address uncertainty, value, affordability and risk.

31. As set out in the Voluntary Scheme, NHS England are now able to consider commercial arrangements in more circumstances than before, for example to address issues of both cost-effectiveness and affordability, and with more flexibilities, 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.

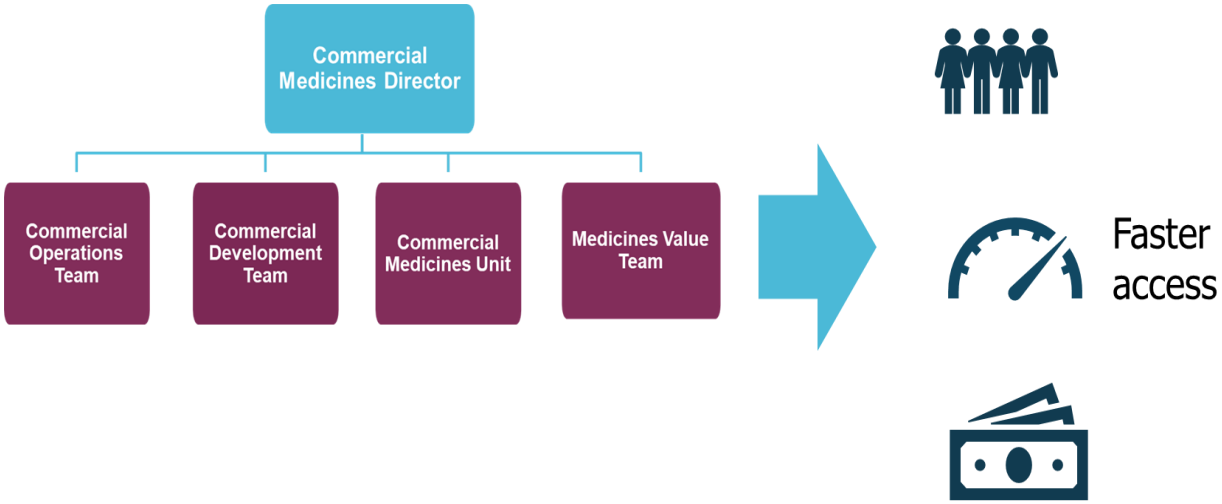
32. NHS England has increased its commercial capacity and capability in order to support this, and is proactively working with NICE and the pharmaceutical industry to:

    - encourage companies to engage with horizon scanning; creating opportunities for early engagement;
    - have a single point of contact for all commercial enquiries, with a triage system in place to direct the enquiry;

- have more planned and consistent engagement with the pharmaceutical industry representative bodies; and
- enable timely and structured commercial discussions where relevant and appropriate.

33. The 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. The commercial medicines directorate encompasses:

Figure 1: Organogram of commercial medicines directorate



34. In addition, NHS England host the Accelerated Access Collaborative (AAC). The AAC is responsible for coordinating 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; and
- identifying and supporting innovations that will deliver the greatest benefits for patients.

Process of Engagement

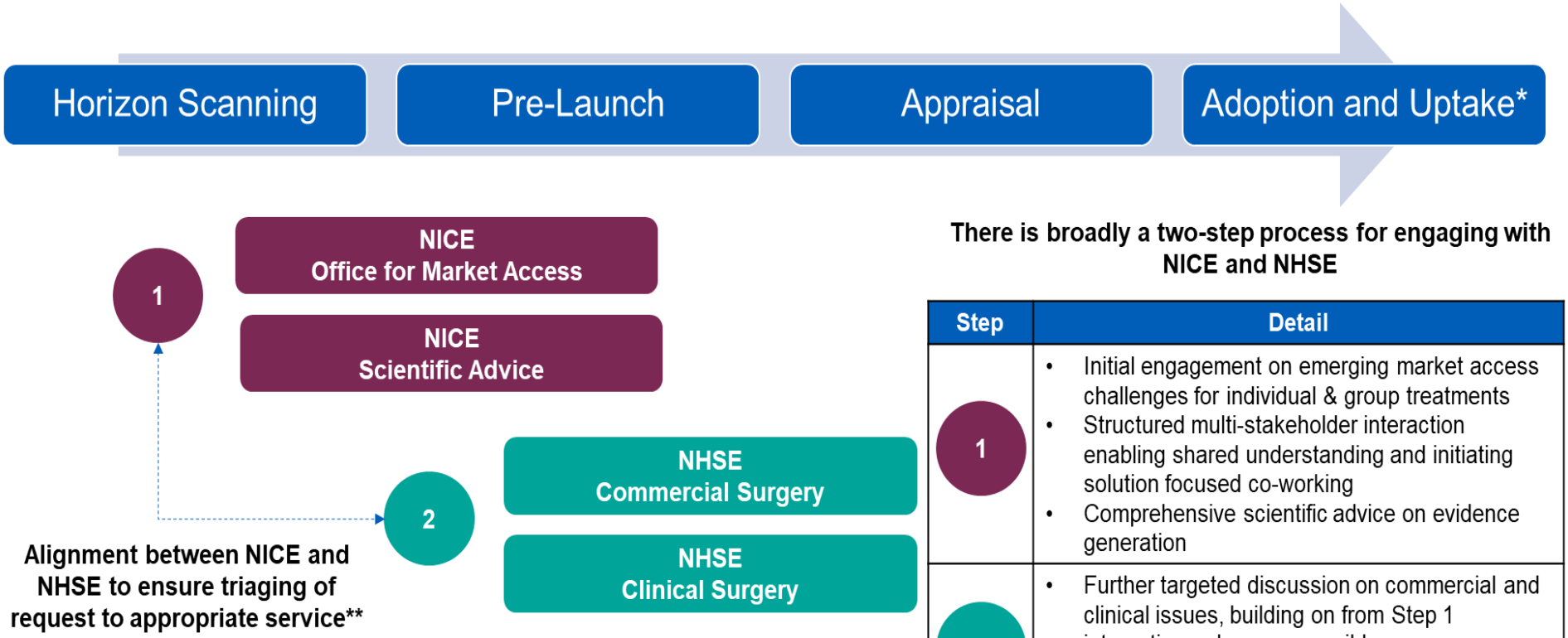
35. Improved and proactive engagement with companies will enable all parties to build trusting relationships, understand the opportunities for aligning strategic objectives and seek out opportunities of mutual benefit. The engagement focus will also look to the medium and longer terms to address issues of value,

affordability, commercial risk and supply, in order to deliver optimal access and sustainability for the NHS and our stakeholders.

36. NHS England 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.

37. The following schematic outlines the engagement opportunities that companies have with NHS England and NICE and more detail on each step is set out below.

Figure 2: Engagement Opportunities with NICE and NHS England



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

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

*Both NICE and NHSE&I offer advice at later stages of the product lifecycle and requests are triaged appropriately

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

Step 1: Engagement with NICE

38. NICE provide early engagement opportunities for companies through OMA and NSA. They are complementary offers which operate outside of NICE's formal guidance production process and actively collaborate to triage enquiries to the most appropriate team.

39. OMA helps companies to 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.

40. 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 earlier in the market access and reimbursement process. NHS England is a key participant in OMA engagement meetings.

41. 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.

Step 2: Engagement with NHS England

42. NHS England offer surgeries to discuss a variety of commercial issues facing companies. Depending on the issues to be discussed, NHS England bring together the relevant expertise and skill-mix to discuss the key topics. These meetings often take place closer to the NICE appraisal than OMA meetings/NSA and provide the opportunity for more focused discussion, with NICE as an additional participant. Companies and patient groups are also able to engage with NHS England on clinically related matters through clinical stakeholder surgeries.

43. The NHS England clinical stakeholder surgeries were set up in 2014 as a way for companies and patient groups to interface with the Specialised Commissioning team. Requests for clinical stakeholder surgeries moving forward will be managed via the triage system.

44. Effective horizon scanning is essential to allow the NHS to understand the products which are likely to be coming to the NHS for routine commissioning and give an indication of their likely impact on patients, existing pathways and services, and budgets. It also provides an indication about the future commercial environment, so that the NHS can be ready to respond as markets evolve.

45. Pharmaceutical companies are encouraged to make information available at all stages of product development, which can then be used to inform horizon scanning. This is set out in **Figure 3**.

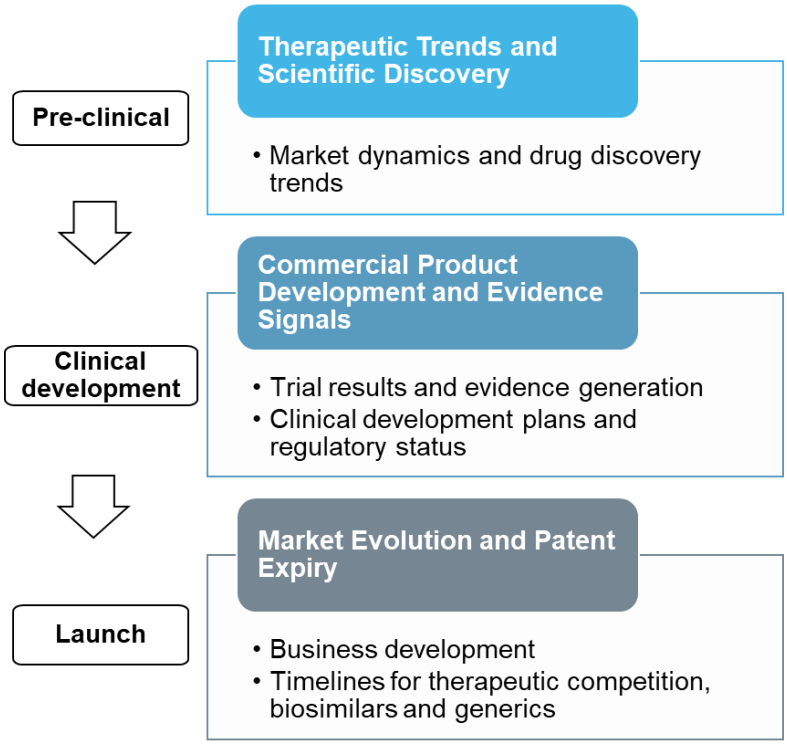
46. UK *PharmaScan* is the single national database repository of information about all new medicines and all significant new indications to be launched in the UK. It is used by NHS England, NICE and devolved nation HTA bodies to inform their horizon scanning activities.

47. 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 the information submitted regularly up-to-date. Information on patent expiry and potential timing of competition entry, such as biosimilars or generics, is also a vital area where the NHS will seek clarity from companies. Companies should ensure they are registered to use the system; have appointed leads within their organisation for keeping the system up-to-date; and respond to requests made about horizon scanning information in a responsive and timely manner.

48. For further information about registering or using UK *PharmaScan* please see https://www.ukpharmascan.org.uk/login or email contactus@ukpharmascan.org.uk.

49. UK *PharmaScan* will be further developed and enhanced over time to meet the evolving horizon scanning requirements of NHS England. This will ensure it will remain the primary source of information for all relevant agencies to drive improved financial, clinical and service planning around the introduction of new medicines.

Figure 3: Horizon Scanning Across the Product Lifecycle



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

51. A cross-functional Horizon Scanning Steering Group (HSSG) has been set up and is working to enhance and optimise the NHS' horizon scanning ability, reaffirming the commitment set out in the 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 and aligned to AAC goals.

Getting in contact

52. Companies can contact both NICE and NHS England directly.

53. At NHS England, a triage function has been developed to enable a faster and more consistent engagement between the NHS and companies. It provides a single point of engagement for all commercial queries. It offers advice, and signposting for companies. We anticipate this will help support patients having faster access to the most innovative or best value new treatments. The triage system is able to respond to specific enquires and requests with helpful and relevant advice for companies.

54. The triage function aims to:

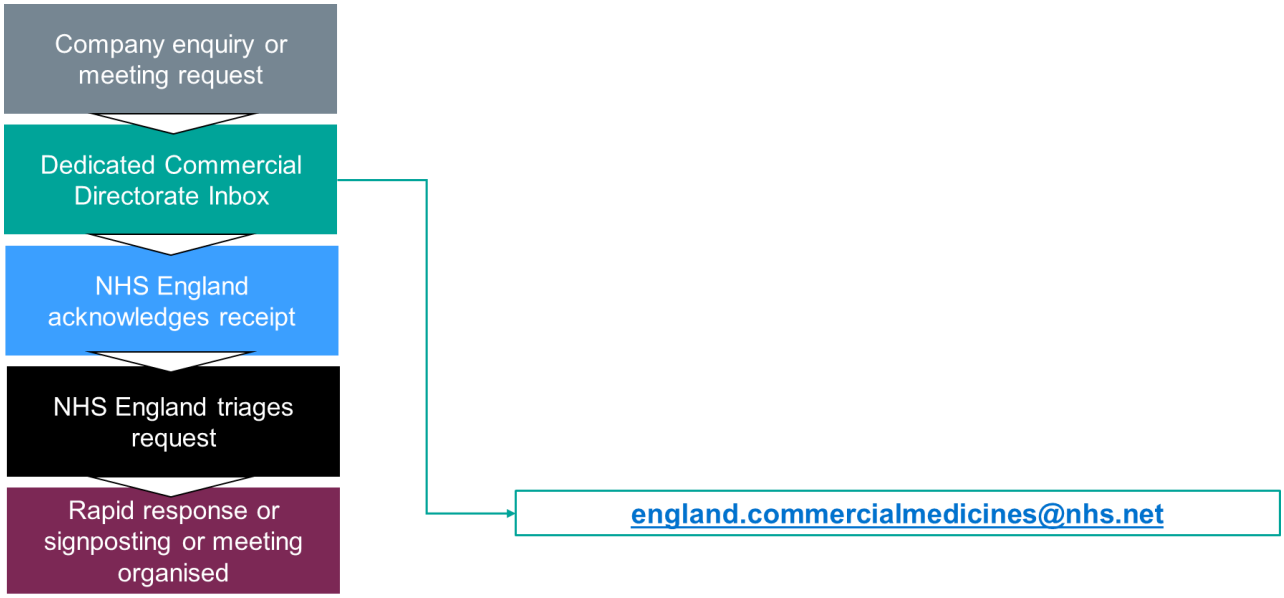
- Resolve enquires in a timely fashion.
- Arrange a meeting or teleconference where appropriate.
- Signpost and redirect enquiries outside the commercial medicines directorate when necessary.

Going forward, the triage function will also manage requests for clinical stakeholder surgeries and continue to evolve to meet future demands.

Typical outcomes for companies engaging with NHS England through the triage function is a resolution to their query, advice on who to engage with or a tailored commercial surgery being arranged.

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

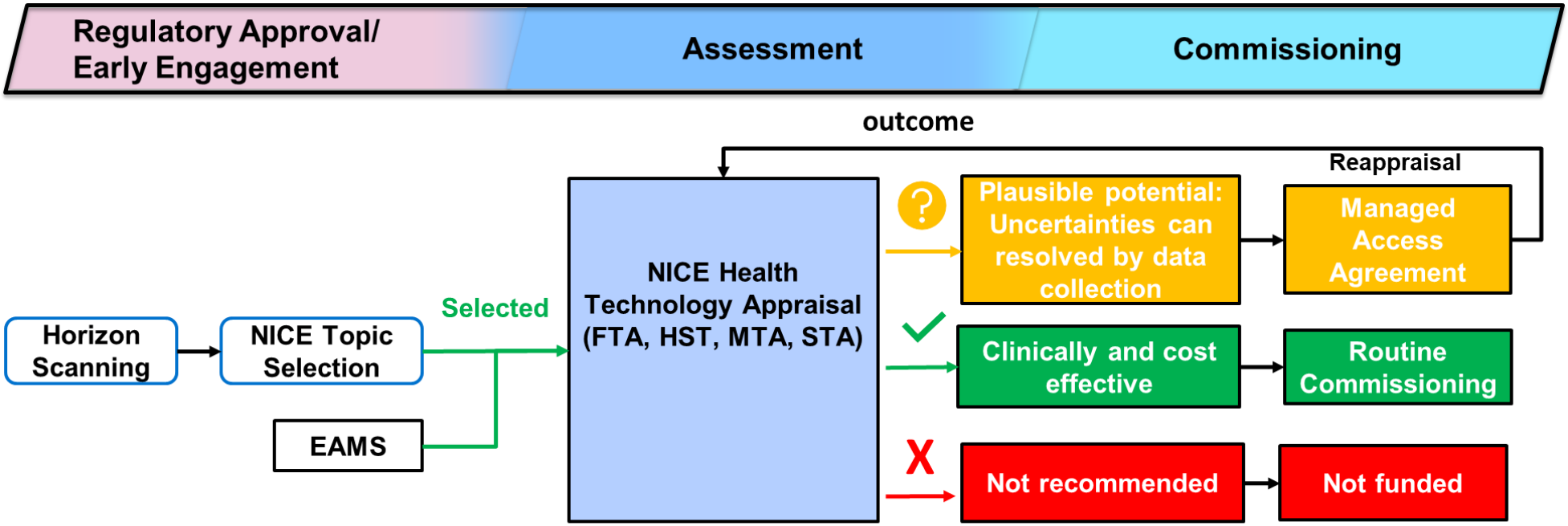
Figure 4: NHS England – Triage System



Section 4: Routes to Commissioning

56. 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 circumstance, there are other routes which medicines may go through to become routinely commissioned in the NHS. A summary of these routes is set out in **Figure 5**:

Figure 5: A simplified and stylised schematic of routes to commissioning in the NHS in England for new medicines



*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. NICE expects to achieve this by April 2020.

Key: EAMS – Early Access to Medicines; FTA - Fast-track Technology Appraisal; HST - Highly Specialised Technology; MTA - Multi-Technology Appraisal; STA - Single Technology Appraisal.

57. For products that go through NICE's topic selection into a technology appraisal, there are opportunities for commercial discussions if the product under consideration is not deemed to be clinically and cost-effective.

Regulatory Approval and Early Engagement

58. As set out in the previous section, the route to commissioning begins with companies providing horizon scanning information through UK *PharmaScan*. Companies then have the opportunity for early engagement with NICE and NHS England as set out in the previous section.

59. Topic selection is the process for deciding which topics NICE will produce technology appraisal guidance on. NICE manages this process on behalf of the Department of Health and Social Care. NICE can only begin to appraise a technology when it has been formally referred by the Secretary of State for Health and Social Care. Further information on topic section can be found here.

60. 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 a marketing authorisation when there is a clear unmet clinical need. EAMS operates within the current regulatory structure and is voluntary and non-statutory. Once licensed, medicines which have been developed through the EAMS will be appraised for routine use by NICE (and equivalent bodies in the devolved administrations). Companies will be able to use the evidence collected in the earlier stages of the scheme to support the appraisal.

Assessment

61. 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 from April 2020. For medicines that have been selected for NICE appraisal, there are four potential processes that products can be routed down:

    a. **Single Technology Appraisal (STA)** - this is a technology appraisal that assesses a single drug or treatment

    b. **Multiple Technology Appraisal (MTA)** – this is a technology appraisal that assesses several drugs or treatments used for one condition

    c. **Fast Track Appraisal (FTA)** – this is a fast-track technology appraisal for technologies that offer exceptional value for money

    d. **Highly Specialised Technologies (HST)** – this is a technology appraisal process for a single drug or treatment for very rare conditions

    Further information on the NICE appraisal processes can be found here.

62. From April 2020, there may still be a relatively small number of instances where topics are not selected for a NICE appraisal or are off-label indications. In such circumstances, it will be for the relevant commissioning body (NHS England or

individual Clinical Commissioning Groups) to reach a policy position on whether the treatment will be routinely commissioned or not. In the case of NHS England for specialised services, the existing and published service development policy and methods will be followed (click here for further details).

Commissioning of Services

63. NHS England and Clinical Commissioning Groups (depending on whom the responsible commissioner is) are under a legal duty to fund all medicines receiving a positive recommendation from NICE (the statutory funding requirement). This legal requirement is reaffirmed in the NHS Constitution which states that patients have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if their doctor believes they are clinically appropriate.

64. 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.

65. In certain circumstances, when there is outstanding clinical or financial uncertainty, and these can be plausibly addressed by data collection, a Managed Access Agreement (MAA) may be appropriate. However, because any MAA must formally be agreed between NICE, NHS England and the relevant company, if and when agreement is reached, commissioning in line with the terms of the MAA will commence. The timing of introduction will be considered on a case by case basis but usually not beyond 90 days post final guidance. Further details on this and other commercial options are set out in **Section 5.**

66. Although the NHS commissions the majority of treatments available to it, some treatments will not be available routinely as they have not been recommended by NICE as clinically and cost-effective and therefore are not an appropriate use of NHS resources. However, there may be situations where a clinician believes that their patient's clinical situation is so different to 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 or CCGs), on behalf of a patient, to fund a treatment which would not usually be provided by NHS for that patient. This request is called an Individual Funding Request (IFR) and more details about NHS England's policy can be found here.

Section 5: Commercial Options

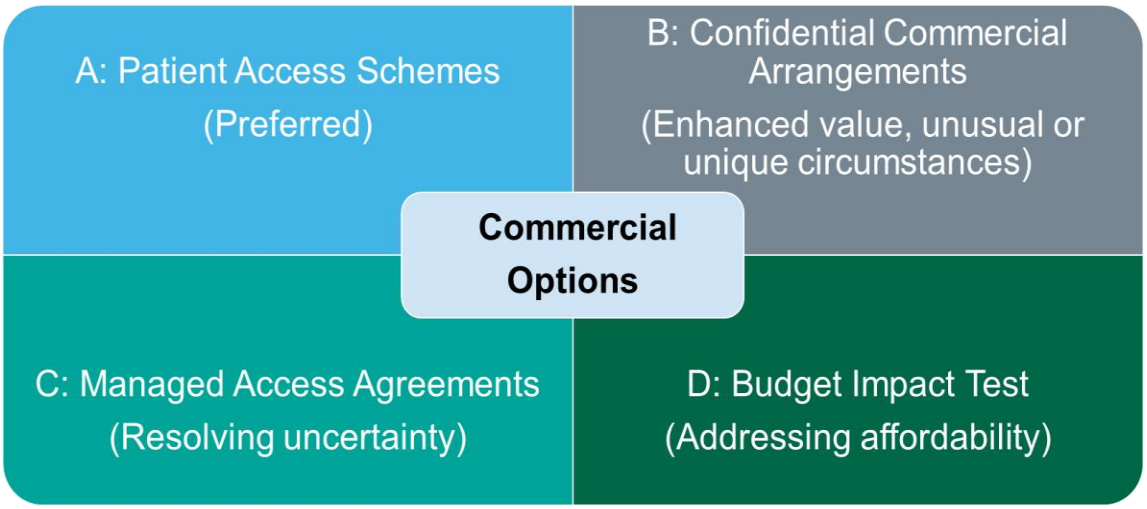
67. This section sets out the commercial options that may be available to companies and/or that may be pursued by NHS England and NICE in particular circumstances.

68. The framework of potential commercial options has been designed to:

- **Support companies in presenting a value proposition to NICE** that is considered clinically and cost-effective at the relevant threshold.
- **Offer 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.
- **Offer companies the opportunity to discuss the potential for a confidential commercial solution where there may be unusual or unique circumstances** that makes launching a product particularly challenging or commercially unviable.
- **Provide companies with a confidential commercial mechanism where NICE believe there is significant uncertainty** surrounding the clinical and / or cost-effectiveness of a treatment and there is plausible potential for that treatment to be clinically and cost-effective.
- **Support companies and NHS England in working together to identify confidential commercial solutions for addressing NHS affordability challenges** that may arise from otherwise clinically and cost-effective treatments.

69. 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 categories:

Figure 6: Commercial options



A. Patient Access Schemes (Simple and Complex)

70. Patient Access Schemes (PAS) are the starting point or default option for companies to consider when developing their value proposition for appraisal by NICE. Their purpose is to provide a mechanism for companies to improve the cost-effectiveness of a treatment under appraisal beyond that driven by its list price.

71. Unless a treatment is to be considered by NICE at list price, then companies should always include a PAS when making their initial evidence submission to NICE to ensure sufficient time for full consideration in advance of the Appraisal Committee meeting.

72. There are two types of PAS;

- Simple PAS (confidential).
- Complex PAS (transparent).

Simple Patient Access Scheme

73. Simple PAS are confidential and involve the provision of a simple percentage discount on the list price that is applied at source. These are always the preferred option as, in line with the principles set out in **Section 2**, they require less monitoring for 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.

74. 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 i.e. where the technology being appraised for a particular indication is already routinely commissioned for a different indication.

75. NHS England took over responsibility for agreeing PASs from the Department of Health and Social Care in April 2018.

76. NICE Commercial Liaison (Patient Access Scheme Liaison Unit [PASLU]) advise NHS England on the feasibility of a PAS. As a simple PAS involves a more rapid review than a complex PAS, both the NICE Commercial Liaison Team's (PASLU) advice and NHS England's approval is faster. It is important to note though that agreement by NHS England to a PAS should not be seen as a willingness to pay at the proposed level of discount. The advice from the NICE Commercial Liaison Team (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

77. 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.

78. 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 the company and NHS England. VAT consequences associated with the proposed scheme must also be accounted for within the proposal.

79. As with a simple PAS, the NICE Commercial Liaison Team (PASLU) will advise NHS England 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.

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

B. Confidential Commercial Agreements

81. Unlike complex PAS, which are transparent, Confidential Commercial Agreements are, by definition, confidential. In line with the principles set out in **Section 2,** such agreements are at the discretion of NHS England with the default arrangement of offering a PAS (simple or complex) always being available to companies.

82. There are currently two circumstances when NHS England may be prepared to enter into a Confidential Commercial Agreement with a company:

- Where the company wants to propose an enhanced value offer; and/or

- Where there are unusual or unique circumstances that mean launching a product is considered particularly challenging or commercially unviable.

Enhanced Value Offers

83. The Voluntary Scheme sets out the following:

84. *'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*** below sets out some example formats for confidential commercial arrangements with consideration given on a case by case basis.

Table 1: Example formats for 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 staged reductions based on additional patient numbers or company pays back the full amount (similar to budget cap).
Cost-Sharing	The company will fund 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.

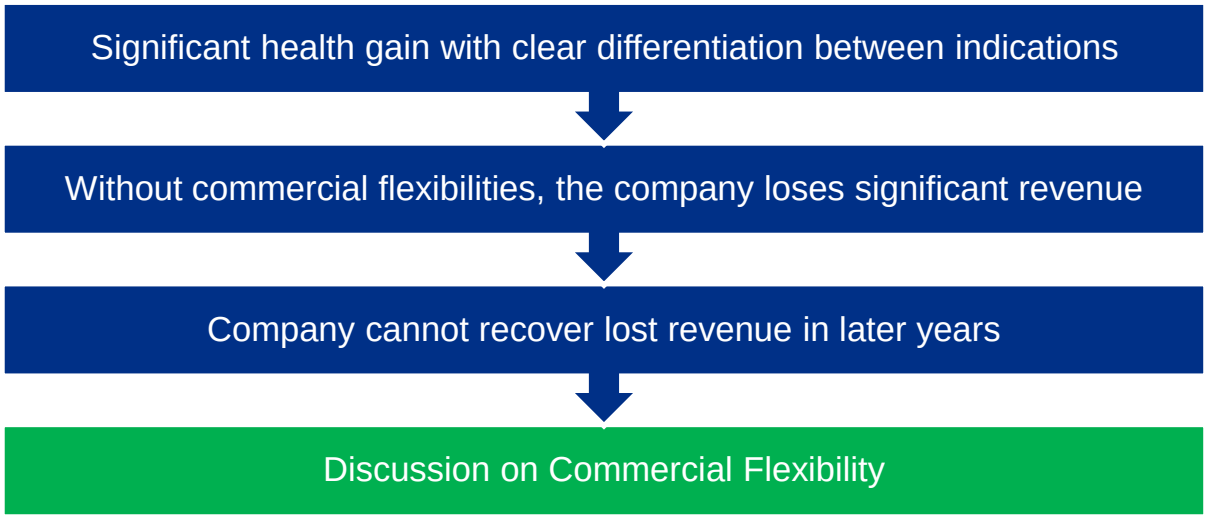
*NB: list is not exhaustive, and a combination of schemes can be applied

Unusual or Unique Circumstances

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

86. For example, the Voluntary Scheme acknowledged that there may be instances where uniform pricing would lead to a reduction in total revenues for a medicine overall from the introduction of additional indications. In such a circumstance, and where medicines have a strong value proposition and the level of clinical effectiveness is highly differentiated and substantial in all indications under consideration, commercial flexibility can be considered (see **Figure 7**). It should be noted that all criteria in **Figure 7** need to be met before a potential discussion on commercial flexibility can be considered. These 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.

Figure 7: Considerations for non-uniform pricing flexibilities



87. 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 and may, therefore, require bespoke commercial solutions.

88. In this respect, NHS England and NICE will continue to:

    a. 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.

    b. 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 appraisal, at the standard NICE threshold, in line with competition law.

89. 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.

90. 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

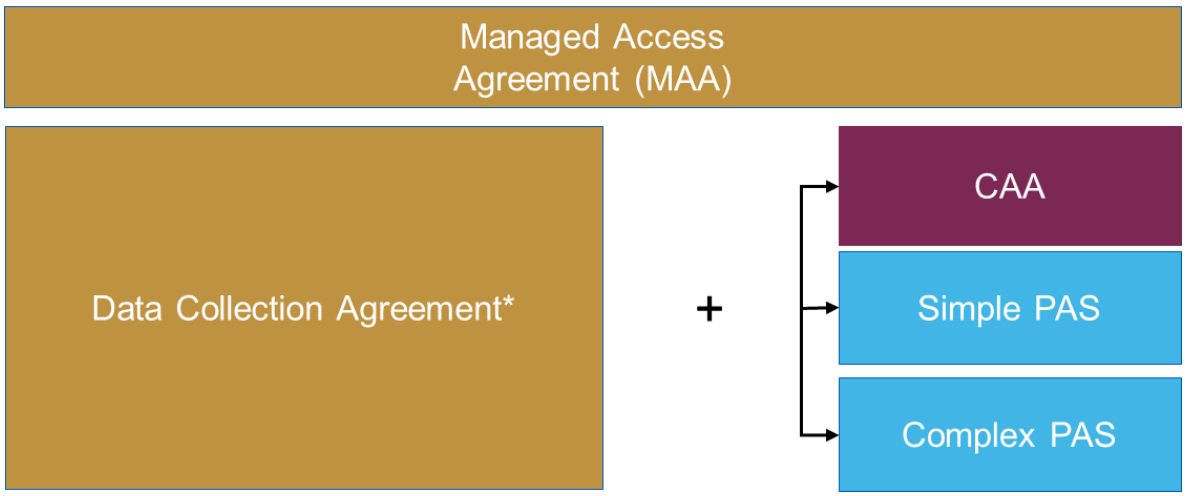
91. There are situations where uncertainty exacerbates the challenge in health technology appraisal. In general, there are two main sources of outstanding uncertainty at the time of appraisal:

- clinical uncertainty; and,
- financial uncertainty.

92. Where such uncertainty exists, NICE is able to recommend that a MAA is explored between the company and NHS England. This would only happen when there is plausible potential for a drug to satisfy the criteria for routine commissioning, and there is uncertainty surrounding the clinical data and consequently the cost effectiveness estimates to make such a recommendation.

93. MAAs consist of two key components (**Figure 8**) - a Data Collection Agreement to mitigate clinical uncertainty (as defined by the NICE Appraisal Committee) and either (a) Commercial Access Agreement or (b) a PAS discount.

Figure 8: Managed Access Agreements explained



The time-limited clinical element of the MAA, i.e. not a commercial agreement which needs to be incorporated into the MAA

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

95. MAAs require the agreement of the company 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.

96. To date, MAAs have been most frequently used in the context of cancer drug appraisal and within the NICE HST appraisal process, where very small patient numbers can lead to significant uncertainty in the clinical evidence being presented.

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

98. Although MAAs have most commonly been seen within cancer and HST appraisals, this is not an exclusive position and it is possible that NICE may recommend that MAAs are explored in a broader set of circumstances in the future. However, one of the key constraints to overcome when considering the possibility of a MAA is the practical data collection considerations and their link to health outcomes that will be critical to resolving any outstanding uncertainties.

D. Budget Impact Schemes

99. NHS England has a responsibility to ensure that any new technologies commissioned do not present an affordability challenge for the wider NHS.

100. If the potential net budget impact is expected to exceed £20 million per year in any of the first 3 years of a technology's use in the NHS, NHS England will engage in commercial discussions, with companies whose technologies are being appraised by NICE, as an alternative to requesting a variation to the statutory funding requirement. The purpose of these commercial discussions is to mitigate the affordability challenge that immediately funding the technology would have on other NHS services. If an agreement between NHS England and the company is not reached, NHS England may then request a variation to the statutory funding requirement.

101. The degree of additional value expected from application of the Budget Impact Test (BIT) will take into account two main dimensions:

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

102. As an illustration, a new treatment expected to have a budget impact of £100m in any of the first 3 years with no or limited competitors, will require to provide more value than a technology with a budget impact of £21m in any of the first three years with multiple competitors entering the marketplace.

Annex A: Summary of Engagement Questions

1. Are the objectives and principles underpinning the Commercial Framework for Medicines clear? Is anything missing? (**Section 2**)

2. Are the respective roles and responsibilities and the processes for engaging with NICE and NHS England clear? Where would further clarity be helpful? (**Section 3**)

3. Are the routes to commissioning and funding new treatments within the NHS clear? (**Section 4**)

4. Is the framework of commercial options available clear? Where might further clarity be helpful? (**Section 5**)

5. What is missing from the Commercial Framework?

6. What additional information could be included?

7. Are you aware of any impact this framework might have on health equalities?

Glossary

AAC: Accelerated Access Collaborative	**MAA:** Managed Access Agreement
BIT: Budget Impact Test	**NICE:** National Institute for Health and Care Excellence
CAA: Commercial Access Agreement	**NSA**: NICE Scientific Advice
CCG: Clinical Commissioning Group	**OMA:** Office for Market Access
CDF: Cancer Drugs Fund	**PAS:** Patient Access Scheme
EAMS: Early Access to Medicines Scheme	**PASLU:** Patient Access Scheme Liaison Unit
HST: Highly Specialised Technology	**QALY:** Quality-Adjusted Life Year

Further Information

Accelerated Access Collaborative	**https://www.gov.uk/government/news/nhs-patients-to-get-faster-access-to-pioneering-treatments**
Early Access to Medicines Scheme	**https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams**
Office for Market Access (NICE)	**https://www.nice.org.uk/about/what-we-do/life-sciences/office-for-market-access**
PASLU (NICE)	**https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit**
Scientific Advice Service (NICE)	**https://www.nice.org.uk/about/what-we-do/life-sciences/scientific-advice**
Technology Appraisal Process (NICE)	**https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance**
Voluntary scheme for branded medicines pricing and access	**https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-pricing-and-access**
Cancer Drugs Fund (CDF)	**https://www.england.nhs.uk/cancer/cdf/**

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