Classification: Official

Publication approval reference: PAR864

NICE National Institute for Health and Care Excellence

NHS

The Innovative Medicines Fund: engagement on proposals

19 November 2021

Contents

How do I make my views known? 2
Post-engagement 3
Engagement questions 3
1. Background and purpose 4
2. Introduction to the Innovative Medicines Fund and Managed Access 6
3. Guiding principles for the Innovative Medicines Fund 8
4. Key features of the Innovative Medicines Fund 11
(a) NICE guidance 11
(b) Entry into the Innovative Medicines Fund 12
(c) Resolving uncertainty through the Innovative Medicines Fund 12
(d) Commercial Access Agreements 15
(e) Updating NICE guidance when a medicine exits the Innovative Medicines Fund 16
(f) Interim funding for NICE recommended medicines 19
(g) Financial control 20

How do I make my views known?

NHS England and NHS Improvement and the National Institute for Health and Care Excellence (NICE) welcome your comments on our proposals for the Innovative Medicines Fund.

This public engagement is open for 12 weeks, from 19 November 2021 until midnight on 11 February 2022. You can respond by:

(a) completing the online engagement at www.engage.england.nhs.uk

(b) downloading and printing a copy of the consultation response form at www.engage.england.nhs.uk, and sending your completed form to: NHS Commercial Medicines Team, NHS England, 80 London Road, Elephant and Castle, London, SE1 6LH.

Alternatively, you can ask for a copy of the consultation response form to be posted to you. Please contact: england.commercialmedicines@nhs.net.

We would like to hear from anyone with an interest in the subject of the engagement. We are committed to involving patients and potential future patients in the development of the Innovative Medicines Fund, and we are particularly keen to hear from as many patients, carers and patient representatives as possible to inform these proposals.

Your responses will be public documents and all, or any part, of a response may be publicly available. If you wish to refer to confidential information in your response, please provide it in a separate document and clearly mark each page 'confidential'.

NHS England and NHS Improvement and NICE are subject to the Freedom of Information Act. While both organisations respect the confidentiality of any information provided to them, you should be aware that we may be obliged to release even confidential information under that Act. Please do not include sensitive personal data in your response.

Post-engagement

Following this engagement, NHS England and NHS Improvement and NICE will consider all relevant feedback. We are expecting a large number of responses and because of this, we expect to publish feedback on the NHS England website in the form of a report capturing all the material issues raised.

Anyone responding to this engagement should note that engagement responses may be published in full as part of NHS England and NHS Improvement and NICE's commitment to openness and transparency.

Engagement questions

Engagement questions are included in annex A. We look forward to receiving your responses.

1. Background and purpose

1. This document sets out our proposals for establishing an Innovative Medicines Fund, which will operate alongside, and on similar terms to, the Cancer Drugs Fund (CDF). Like the CDF, the Innovative Medicines Fund will have a fixed funding envelope of £340 million per annum, creating a total of £680 million of ringfenced NHS England funding for early access to potentially life-saving new medicines.

2. Since 2016 the CDF has provided earlier, time-limited access to promising new cancer medicines via managed access agreements (MAAs), while further evidence is collected on their clinical and cost-effectiveness . This has benefitted over 73,000 patients who have been able to access 91 CDF funded medicines treating 205 cancers.

3. This managed access approach has played a key role in responding to a long-standing challenge in the evaluation of cancer medicines, where the data available to NICE is not always sufficient to make long-term decisions regarding the clinical effectiveness and value for money of new treatments or indications.

4. In these situations, the CDF and use of MAAs has meant that NICE can recommend treatments for a limited time while further data is collected to clarify any identified clinical uncertainties. NICE then uses this data to recommend whether or not the treatment should be made routinely available on the NHS.

5. A similar challenge faces non-cancer medicine evaluations, particularly those for rare conditions, where limited data, and with that significant clinical uncertainty, would result in negative NICE guidance. While cancer medicines used to dominate NICE's evaluation programme, today there is a more even split between cancer and non-cancer evaluations. In addition there is a growing pipeline of promising treatments for rare conditions, which offer the potential to improve outcomes and transform the quality of life for patients and their carers.

6. The creation of the Innovative Medicines Fund will ensure there is equal potential for cancer and non-cancer patients to benefit from the latest treatments.

7. The Innovative Licensing and Access Pathway (ILAP) will help NICE and NHS England and NHS Improvement identify potential candidates for the Innovative Medicines Fund and provide an opportunity for multi-agency discussions about further data collection requirements.

8. In addition to supporting promising but uncertain medicines, the Innovative Medicines Fund (like the CDF) also presents an opportunity to accelerate the introduction of proven treatments where NICE is able to confidently recommend a medicine for routine use in the NHS.

9. **Section 2** of this document introduces the Innovative Medicines Fund and the key features of managed access. **Section 3** gives the principles underpinning it and **Section 4** outlines the key features of the Innovative Medicines Fund, including detail on how the Innovative Medicines Fund will work in practice.

10. These proposals will amplify the impact of the increased commercial flexibilities that NHS England and NHS Improvement, working in partnership with NICE, can offer to those companies that are willing to price their products realistically and responsibly.

2. Introduction to the Innovative Medicines Fund and Managed Access

11. The fastest way for a medicine to reach NHS patients is for a company to submit evidence of its clinical-and cost-effectiveness through a NICE health technology evaluation (i.e. technology appraisal or highly specialised technologies).

12. Where NICE is unable to recommend a medicine for routine use in the NHS because it needs further data to resolve the outstanding clinical uncertainty, the Innovative Medicines Fund, as a managed access fund, has the potential to significantly benefit patients by opening the opportunity for them to access promising new medicines whilst this data is collected.

13. The Innovative Medicines Fund will provide a consistent and transparent managed access process for companies offering promising non-cancer medicines at a responsible price.

What is managed access?

14. Managed access is an approach that the NHS takes to ensure patients can access promising but still clinically uncertain treatments, while supplementary data is collected (over a time limited period) to allow more informed decision making about patient access and long-term NHS funding.

15. For any medicine NICE recommends for use with managed access, a MAA is put in place between NHS England and NHS Improvement and the company. MAAs consist of two parts:

    - a time-limited Data Collection Agreement (DCA) to collect the data that should resolve the clinical uncertainties (as defined by NICE)

- a Patient Access Scheme and/or a Commercial Access Agreement (CAA) to ensure that the MAA offer value to taxpayers.

16. At the end of the data collection period, the data collected, along with any other available and relevant evidence, is used by NICE to make a decision on whether the treatment should be routinely available on the NHS.

17. The Commercial Framework for New Medicines gives more detail on how NHS England NHS Improvement work in partnership with NICE and companies on commercial medicines activity to deliver patient access to proven, affordable and transformative medicines in a financially sustainable way.

3. Guiding principles for the Innovative Medicines Fund

18. The design of the Innovative Medicines Fund has been informed by NHS England and NHS Improvement and NICE's experience from the CDF and other commercial and data collection arrangements.

19. Our experience, has reinforced the importance and relevance of the principles underpinning the CDF, that should similarly underpin the Innovative Medicines Fund.

20. The principles that will guide the Innovative Medicines Fund are:

Principle 1: The Innovative Medicines Fund should operate as a managed access fund for non-cancer medicines so that any patient, regardless of their condition, has equal potential opportunity to benefit from promising but uncertain medicines. The Innovative Medicines Fund will extend the principles of the CDF so that NICE can recommend any medicine, for a limited time, while further data is collected to resolve clinical uncertainty. The increasingly even split between cancer and non-cancer NICE evaluations reinforces the case for extending managed access beyond cancer to address evidential uncertainty.

Principle 2: Clear and robust criteria should ensure that the Innovative Medicines Fund targets the most promising medicines for which there is significant remaining uncertainty around the level of clinical benefit. Only NICE will be able to recommend a medicine for use via the Innovative Medicines Fund. Any medicine may be recommended for the Innovative Medicines Fund provided it: addresses a high unmet need; provides significant clinical benefits; represents a step-change in treatment for patients and clinicians; and evidential uncertainties can be resolved in a reasonable time.

Principle 3: Innovate Medicines Fund recommendations should be reserved for medicines that (a) demonstrate plausible potential to be

cost-effective; and (b) are priced responsibly during the period of managed access, reflecting their uncertain clinical benefit. To be recommended for use via the Innovative Medicines Fund, medicines will both need to demonstrate their potential to be cost-effective and deliver value for money by being priced responsibly. The price should reflect both the uncertainty as well as the overall burden imposed on the NHS by any data collection arrangements. Those medicines that show greatest certainty of clinical benefit should be valued most highly.

Principle 4: Managed access should be for the shortest time necessary to collect the data required to resolve any uncertainties identified by NICE. The purpose of 'managed access' is to resolve significant remaining clinical uncertainty associated with a medicine so that NICE can make a recommendation on routine commissioning in the NHS. Managed access does not displace or replace the need for good quality clinical trials. Any data collection arrangement should generate timely, high-quality data and should be proportionate to the research question, recognising that managing these arrangements is highly resource intensive for all parties. The timeframe should be as short as possible to provide certainty to patients and the NHS and to minimise the burden on all parties. The appropriate timeframe will be considered on a case-by-case basis and will not exceed five years.

Principle 5: The entire eligible patient population, as determined by NICE, should have the opportunity to access medicines recommended for the Innovative Medicines Fund in the managed access period.[1] There will be no cap on the number of eligible patients who can access a treatment during the period of managed access.

Principle 6: All medicines that enter the Innovative Medicines Fund must be re-evaluated by NICE, who will make final recommendations on whether the treatment should be routinely available on the NHS. New data collected as part of the MAA, along with any other available and relevant evidence, is submitted for the NICE re-evaluation (a NICE guidance update) and could support price adjustments upwards or downwards in the context of NICE making a final routine commissioning decision.

[1] The duration of a managed access agreement, including both the data collection period and the time required for the NICE re-evaluation.

Principle 7: Any patient who starts treatment with an Innovative Medicines Fund recommended medicine during the period of managed access should have the option of continuing treatment in the event that NICE is unable to recommend its routine use in the NHS at the point of re-evaluation. If an Innovative Medicines Fund recommended medicine is not recommended for routine commissioning at re-evaluation, patients will continue to receive the treatment until such time that the patient and the treating clinician determines it is no longer clinically appropriate. No further funding will be available for medicines that NICE does not recommended for routine commissioning in the NHS. Any patients who were prescribed the medicine when it was in the Innovative Medicines Fund will continue to receive it at the company's cost.

Principle 8: The Innovative Medicines Fund should never have to close to potential new entrants. The Innovative Medicines Fund will operate within a fixed budget of £340 million with an expenditure control mechanism (ECM) to ensure that any spend above this, is paid back on a proportional basis by all companies receiving funding from the Innovative Medicines Fund. Agreeing to the ECM will be a condition for all companies receiving funding from the Innovative Medicines Fund and will ensure that the Innovative Medicines Fund does not have to close to new entrants.

21. The above principles underpin the primary role of the Innovative Medicines Fund: operating as a managed access fund. In addition to this, the **Innovative Medicines Fund could provide a potential source of funding to support earlier access to certain medicines that NICE is able to recommend for routine use in the NHS**. For further details, including how this mirrors arrangements in place for cancer drugs through established CDF 'interim funding' agreements, see paragraphs 58-63.

4. Key features of the Innovative Medicines Fund

22. Since April 2020, NICE has evaluated all new active substances licensed for their first indication and significant new indications, except where there is a clear rationale not to do so. These evaluations follow the standard process described in the draft NICE Manual (as updated). This document should be read in conjunction with the draft NICE Manual.

(a) NICE guidance

23. The NICE Manual will outline the recommendations NICE can make:

- recommended for use – 'yes'
- recommended for use with managed access – 'time limited' access (via the Innovative Medicines Fund or CDF with a MAA) - 'maybe'
- case for adoption not supported – 'no'.

24. When recommending for use via managed access (either in the Innovative Medicines Fund or CDF), NICE will consider whether:

- the medicine has the plausible potential to satisfy the case for adoption, at the price offered by the company
- the only reason that the medicine cannot be recommended for use is significant clinical uncertainty
- the data required to resolve the uncertainty can be collected and analysed within a reasonable time, without undue burden (clinical, financial and for patients and their carers)
- additional data collection could sufficiently resolve the clinical uncertainties identified.

25. Medicines that are recommended for managed access through the Innovative Medicines Fund will be made available to all eligible patients under the terms of the MAA. As they are not, at this stage, being recommended for routine use in the NHS patient access is not provided under Section 7 or 8 of the National

Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

(b) Entry into the Innovative Medicines Fund

26. It is essential that companies engage early so that NICE and the NHS can identify potential candidates for managed access and consider data collection needs and service preparedness as well as opportunities for further evidence generation to be developed. Early engagement activities between NICE, NHS England and NHS Improvement and companies aim to address potential barriers to patient access and identify, develop and assess the feasibility of opportunities for new prospective data collections, ahead of the NICE evaluation. For the medicine being evaluated, they also provide a chance to identify relevant future comparators in the pipeline.

27. Companies interested in managed access must engage early with NICE and demonstrate that their technology has the potential to meet the following eligibility criteria:

- the technology has the potential to address an unmet need
- the technology has the potential to provide clinically significant benefits to patients
- the technology will demonstrate the potential to be plausibly cost-effective at the price being offered
- the new evidence to be generated is considered meaningful and could sufficiently reduce uncertainty.

(c) Resolving uncertainty through the Innovative Medicines Fund

28. When considering whether a medicine is a suitable candidate for the Innovative Medicines Fund, NICE will define and describe the specific area(s) of clinical uncertainty that are preventing it from recommending the medicine for routine commissioning in the NHS, and the data that could feasibly be collected within a reasonable time to sufficiently resolve these uncertainties. Proportionate and practical data collection considerations will be at the heart of any MAA. Further data collection must have the potential to resolve remaining evidential uncertainties, particularly as these relate to health outcomes

29. Data collection will depend on the uncertainties identified. NICE will seek advice from clinicians, patient groups, academics and data custodians to ensure each DCA takes account of the complexities in relevant treatment pathways, patient access, ongoing or planned clinical trials, existing studies, routine population-based datasets and real world data collections, in light of the identified clinical uncertainties. Depending on the nature of the data collection and required analyses, NICE will work with the company to facilitate the development of an appropriate framework for data collection, which will be outlined in the DCA.

30. Advice from NICE will inform the duration of the DCA. The duration will:

- be considered on a case-by-case basis
- be as short as necessary to address the identified uncertainties
- include review points to check progress
- cover the data collection period[2] (up to a maximum of five years) plus the time NICE requires to evaluate the new evidence.

31. NICE will be responsible for:

- facilitating the development of the DCA, with reference to relevant considerations from the committee
- supporting all stakeholders to understand and to fulfil their roles according to the DCA
- co-ordinating all stakeholders' review of DCA activities to ensure they are proceeding as planned to generate the additional evidence for the NICE guidance update
- providing information to all stakeholders about the guidance update process, following a period of managed access in the Innovative Medicines Fund
- updating the guidance following a period of managed access in the Innovative Medicines Fund.

32. Companies will be responsible for:

[2] The time specified in the data collection agreement for data collection and analytical outputs to be developed.

- paying a proportionate share of the costs of data collection, validation and analysis;
- producing a data/statistical analysis plan to ensure methods and analytical outputs are clearly outlined and agreed within six months of the start of the MAA
- submitting new evidence to NICE at the end of the data collection period
- covering the cost for any patients who were prescribed the medicine when it was in Innovative Medicines Fund if NICE is unable to recommend its routine use in the NHS at the point of re-evaluation.

33. Ongoing clinical trials may be the primary source of data, where they are collecting data that could address the uncertainties identified. Real world evidence may be also be collected to address gaps in the existing evidence and meet all DCA requirements.

34. The DCA will be reviewed and incorporated into the MAA once approved.

35. While a medicine is in the Innovative Medicines Fund, data will be collected as per the DCA.

36. The DCA will include a requirement for the company to make a new evidence submission to NICE at the end of the data collection period. The duration of the MAA will give NICE sufficient time to complete a guidance update using the new data and any other evidence that is available. The evidence submission will use the NICE process and methods in place when NICE invites the company to participate in the guidance update.

37. NICE will co-ordinate arrangements, through an MAA Oversight Group, to maintain a regular overview of each DCA. The MAA Oversight Group will have representation from NHS England and NHS Improvement, data custodians, the company, clinicians and patient groups (as required). Arrangements may include an interim review of a DCA at a prescribed time point to confirm that the data collection is on track and delivering the analytical outputs required for the NICE guidance update. Several systems in the NHS will support this process, e.g. electronic prescribing and NHS England's High Cost and Cancer Drug Prior Approval System (Blueteq™). These processes are described more fully in the draft NICE Manual.

38. Key to the success of a managed access approach is effective data collection and subsequent analysis to address identified clinical uncertainties. Therefore, NHS England and NHS Improvement will ensure that all NHS providers responsible for submitting data are able to do so.

(d) Commercial Access Agreements

39. A recommendation for use of a medicine via the Innovative Medicines Fund will trigger the need for a commercial conversation with NHS England and NHS Improvement to agree a Commercial Access Agreement (CAA) (although, ideally, commercial conversations will have already begun). The CAA will form part of the MAA and determine the level of reimbursement to manage the cost of a medicine to the NHS in a sustainable and financially sound way during the managed access period. This will be a confidential agreement between NHS England and NHS Improvement and the company.

40. The Innovative Medicines Fund Commercial Agreement will determine the level of reimbursement during the managed access period. This will be a confidential agreement between NHS England and the company, with input from NICE, and will be considered on a case-by-case basis. However, the level of reimbursement should reflect the decision uncertainty, and, as a minimum, the company will need to present an offer that brings the range of potentially plausible cost effectiveness estimates as determined by NICE to below the relevant cost effectiveness threshold (i.e. £20k-£30k per QALY, taking account of any applicable QALY weightings). Greater flexibilities will be reserved for products that offer greater value and potential health gain to the health service.

41. Each CAA will be considered on a case-by-case basis, to support the inclusion of medicines in the Innovative Medicines Fund and facilitate patient access.

42. A NICE recommendation for managed access use in the Innovative Medicines Fund is a conditional recommendation, and patient access to treatment is therefore funded by the Innovative Medicines Fund. The NICE guidance update will provide a final recommendation concerning the future use of the medicine in the NHS, and this may not be routine use. Each MAA will include safeguards to ensure any eligible patients who have started an Innovative

Medicines Fund recommended treatment have the option to continue that treatment in the event that NICE does not recommend it for routine use in the NHS.

43. All eligible patients will have access to treatments NICE recommends for managed access use in the Innovative Medicines Fund.

44. If the company does not propose an acceptable CAA, the medicine will not enter the Innovative Medicines Fund and not be available to patients. In that situation, NICE will consider making a recommendation that the medicine should not be routinely commissioned in the NHS because the case for adoption is not supported. If the company offers a new reimbursement proposal after the Final Appraisal Determination (FAD) is published, NICE may reconsider the medicine as part of a new evaluation, subject to NICE charging associated with a new evaluation.

45. To be approved any CAA must be operationally manageable for the NHS, without unduly complex monitoring, disproportionate additional costs and bureaucracy, and it must allow the ECM to be applied fairly. Any burden for the NHS should be proportionate to the benefits of the managed access approach taken in the Innovative Medicines Fund for the NHS and patients.

46. A Budget Impact Test (BIT) assessment will not apply to any part of a patient population for a medicine recommended for managed access use in the Innovative Medicines Fund but will be applied at the point of NICE re-evaluation.

(e) Updating NICE guidance when a medicine exits the Innovative Medicines Fund

47. All medicines recommended for managed access use in the Innovative Medicines Fund will be subject to a NICE guidance update at the end of the data collection period. This update will be undertaken according to the NICE process and methods in place at the time the company is invited to participate in this, and will be subject to NICE charging associated with a new evaluation.

48. The company must provide a further evidence submission, including an updated proposed price, to support a NICE guidance update following a

period of managed access. If a company fails to do this, NICE will withdraw the guidance.

49. A medicine will begin the process of exiting the Innovative Medicines Fund at the end of the data collection period specified in the DCA (or the time limit of a maximum of five years is reached), whichever is sooner. NICE will schedule the start of the re-evaluation to coincide with the end of the data collection period. Patients will continue to have access to the treatment and new patients may start on this while the NICE guidance update is ongoing.

50. NICE and NHS England and NHS Improvement will have a single process for MAA exits, one which will take account of changes in clinical pathways, new evidence and commercial options following a period of managed access. All guidance updates will be re-scoped to reflect these changes. The NICE guidance update will look at all the available evidence afresh: it will not continue the original evaluation, rather reconsider the case for adoption. The NICE guidance update will consider all relevant evidence – including any evidence submitted during the original evaluation, new evidence that has become available and the new data collected, along with a new price proposal from the company.

51. If, following a NICE guidance update, NICE recommends a medicine for routine use in the NHS, the treatment may benefit from Innovative Medicines Fund funding from the time the positive draft recommendation (which is subject to the ECM) is published, at the price that generated the recommendation (see paragraphs 59-64).

52. If, following a NICE guidance update, an Innovative Medicines Fund medicine is:

    a. **Recommended for routine use:** it will transfer to routine commissioning within 90 days of final guidance publication (or within 30 days for medicines with an Early Access to Medicines Scheme [EAMS] designation or low incremental cost-effectiveness ratio (ICER) appraisal).

    b. **Optimised:** it will transfer to routine use for the eligible patient population, within 90 days of final guidance publication (or within 30 days for medicines with EAMS designation).

c. **Not recommended for use:** no further funding will be available for new patients to be prescribed the medicine from the date of final guidance publication, because it has not been recommended as a clinical and cost-effective medicine for the NHS to use. Any patients who have been prescribed the medicine during the time the medicine was in the Innovative Medicines Fund will continue to receive the medicine at the company's cost until the patient and the treating clinician deems it appropriate to discontinue treatment and/or they meet a treatment stopping criteria (in line with NHS treatment continuation policies or company-sponsored free of charge schemes).

53. The MAA will clearly define the exit strategy, balance risks and take account of NHS treatment continuation policies, to give clarity to clinicians, patients and their carers, commissioners and the company should NICE not recommend any medicine for routine use following re-evaluation.

54. It is possible, when exiting the Innovative Medicines Fund, for the cost of the product to increase or decrease, depending on the NICE evaluation of cost-effectiveness at the point of guidance update.

55. A medicine that NICE recommends for routine use in the NHS, following a period of managed access, will be subject to a BIT assessment as per the NICE Manual and before it can be routinely used in the NHS.

56. A condition of entry into a MAA is that the company will be required to provide all new evidence generated to NICE as part of its submission for the guidance update. Even if a company withdraws from the MAA or decides not to proceed with the NICE guidance update, it will be required to make the new evidence available and present this at an engagement event with stakeholders, so that the implications for patient access to their medicine can be understood. The outcome of this process will be published on the NICE website.

57. In signing up to a MAA, all companies are accepting that at the end of the DCA, NICE will re-evaluate their medicine, using the methods and process that are in place at the time they were invited to participate in the guidance update. NICE will be able to make a recommendation for routine use in the NHS, or not. There will be no further opportunity to recommend continued use in the Innovative Medicines Fund.

(f) Interim funding for NICE recommended medicines

58. The primary function of the Innovative Medicines Fund is to operate as a managed access fund while evidential uncertainty is resolved in medicines that otherwise show significant clinical promise. In addition, it is proposed that the Innovative Medicines Fund should provide a discretionary source of early funding for certain medicines that NICE can recommend for routine commissioning in the NHS from the point of marketing authorisation. Legislation requires the funding of NICE approved medicines within 90 days of final guidance being published. However, under these arrangements, funding could be brought forward by up to five months, starting at the point NICE issues a draft positive final guidance.

59. To benefit from 'interim funding' companies will need to have priced their products responsibly to obtain a routine commissioning recommendation from NICE, received a marketing authorisation and provided complete, accurate and timely information to support service planning.

60. For some medicines the NHS will need more time to support pathway change from a clinical, financial and logistical perspective. Therefore, agreed interim funding may provide a path to full implementation of the NICE recommendation.

61. Given operational and other policy considerations, we envisage that the offer of 'interim funding' will only be made for medicines recommended by NICE that would be commissioned in the context of a prescribed specialised service.

62. In the same way that the CDF operates, any company that wishes to take up the offer of Innovative Medicines Fund interim funding will need to agree to the Innovative Medicines Fund ECM described in the next section. If a company does not, such funding will not be made available.

63. 90 days after NICE issues final guidance (or within 30 days for medicines with EAMS designation or low incremental cost-effectiveness ratio (ICER) appraisal), funding will switch permanently from the Innovative Medicines Fund to routine commissioning budgets, at which point companies will no longer be bound by the ECM.

(g) Financial control

64. To ensure the financial sustainability of the Innovative Medicines Fund, an Expenditure Control Mechanism (ECM) will be in place to enable the Innovative Medicines Fund to operate within a fixed budget. The ECM encourages companies to develop the most competitive CAA and incentivises relevant data generation and publication in as short a time as possible. The ECM aims to ensure that the NHS can secure maximum benefit for patients from its expenditure on these medicines, while more data is obtained on their effectiveness.

65. The ECM will ensure that, in the event the Innovative Medicines Fund budget is overcommitted at the end of a financial year, those companies that have had medicines funded through the Innovative Medicines Fund pay a proportional rebate to NHS England and NHS Improvement. The proportions will be a pro-rata calculation of the spending on each company's medicines as claimed by NHS trusts.

66. The Innovative Medicines Fund is a managed access fund; NHS trusts are reimbursed for the cost of the medicine only. These reimbursements may vary from the amounts paid to companies for medicines purchased because of, for example, VAT, the weight of the patient and wastage charges, as appropriate.

67. Up to 2% of the Innovative Medicines Fund budget may be used to support the administration of the Innovative Medicines Fund (capped at a maximum of 2% of the fixed Innovative Medicines Fund budget).

68. Costs associated with MAAs in place outside of the Innovative Medicines Fund before the establishment of the Innovative Medicines Fund will continue to be funded separately and the medicines they relate to will not enter the Innovative Medicines Fund. Expenditure under these historic MAAs will not be subject to any ECM.

Annex A: Engagement Questions

Section 1: Background and Purpose and **Section 2:** Introduction	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
a. Do you agree with purpose of the Innovative Medicines Fund?	❑	❑	❑	❑	❑	❑
b. Do you agree that the Innovative Medicines Fund should operate alongside, and on similar terms to the Cancer Drugs Fund?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					

Section 3: Guiding principles for the Innovative Medicines Fund	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
a. Do you agree with the objectives and guiding principles underpinning the Innovative Medicines Fund?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					

Section 4: Key Features of the Innovative Medicines Fund	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Don't know / NA
To what extent to you agree with the following key features of the Innovative Medicines Fund?						
a. NICE recommending a medicine in the Innovative Medicines Fund?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					
b. Criteria for entry into the Innovative Medicines Fund?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					

c. Resolving uncertainty through the Innovative Medicines Fund?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					
d. Commercial Access Agreements (CAA)	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					
e. Updating NICE guidance following a period of managed access and exiting the Innovative Medicines Fund?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					
f. Interim Funding for NICE recommended medicines?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					
g. Financial control?	❑	❑	❑	❑	❑	❑
Comments:	*Please provide any further comments you have here.*					

Section 5: Conflict of interest disclosures: have you or the organisation you represent received any payments, grants or other funding from the pharmaceutical and life science industry in the last three years?

☐ Yes ☐ No

If yes, please specify the source of funding and sums involved in each of the last three years:

Section 6: Please tell us which organisation you work for/are responding on behalf of:

NHS England and NHS Improvement
Skipton House
80 London Road
London
SE1 6LH

This publication can be made available in a number of other formats on request.

Publishing approval reference: PAR864