NICE National Institute for Health and Care Excellence

NICE health technology evaluations: the manual (PMG36) consultation

September to October 2025

This document provides themed responses to the consultation comments received on proposed updates to NICE health technology evaluations: the manual (PMG36).

1. A public consultation was held between 25th September and 22nd October 2025. Stakeholders were given the opportunity to provide detailed comments and responses on the consultation documents.

2. We received 525 responses from 36 organisations and individuals. More details are provided in table 1.

Table 1 Consultation responses by organisation type

Respondent	Number of organisations (or individuals)	Percentage of comments
Industry/consultancies	19	66%
Trade bodies/associations	3	15%
External Assessment Groups (EAGs) and academic institutions	5	6%
Voluntary and community sector organisations and members of the public	4	7%
NHSE, NHS trusts, NHS network groups, MHRA	3	3%
Royal Colleges	2	3%

Findings from the consultation, implications, and next steps

Section 1 – General comments

Summary of comments received

1. Respondents commented that diagnostics and other HealthTech are foundational to the shifts set out in the 10 year plan, driving the move towards prevention and system efficiency. But that these technologies are not currently valued as highly as they should be, despite being the enablers that make transformation possible. Establishing this route to mandated funding through the technology appraisal process is essential to enable equitable and consistent access. However, for this to be effective, it must be scalable and supported by transformation support and assessment considerations that are at least equivalent to those applied to medicines.

2. Respondents stated that NICE in conjunction with NHS England need to ensure that when HealthTech that is recommended has a significant financial impact on systems, consideration is given to providing adequate additional funding to ensure consistent uptake and reduce health inequalities. Respondents highlighted the potential for HealthTech to introduce significant costs and resource pressures, and the need for these impacts to be adequately assessed with appropriate funding variation and implementation timescales applied.

3. Respondents stated that the changes shift NICE's manual from a broad, catch-all "health technology evaluation" framework to a sharper, dual-track system: one for medicines and one for HealthTech with more flexible, proportionate evidence expectations. This should make processes clearer, reduce burden on non-pharmaceutical innovators, and maintain robust standards for medicines. However, respondents also stated that while medicines retain the current evaluation methods,

the growing separation from HealthTech risks creating less flexible rules and slower processes for medicines in comparison.

4. Alternatively, respondents also stated that the manual still felt focused on medicines, and that the proposed changes did not introduce significant enhancements to the processes or methodological considerations for HealthTech evaluations. The suitability to assess digital technologies was questioned.

5. Respondents stated concern about any differences in the process or methods of evaluation between HealthTech and medicines. This included a statement that whilst there is a need for process differentiation between HealthTech and pharmaceutical evaluation, there were inconsistencies introduced by the proposed changes that were not considered to be appropriate. Respondents stated that integrated care boards are mandated in law to fund technologies with a positive NICE technology appraisal, so HealthTech should be subject to the same rigorous assessment for clinical and cost effectiveness as medicines.

6. Respondents stated that a societal perspective is essential to capture wider impacts such as productivity gains from earlier diagnosis and reduced travel costs for patients and carers from community-based care. They urged NICE to update the guidance to clarify when societal impacts can be included in evaluations and to provide methods for measuring these benefits.

Our response

7. The proposed changes to PMG36 are to facilitate efficient assessment of HealthTech for technology appraisal guidance while retaining predominately the same process as has been, and will be used, for medicines. In this we have drawn on years of experience in assessing HealthTech (in the former medical technologies evaluation programme [MTEP] and diagnostics assessment programme [DAP] and ongoing work in the HealthTech programme). Assessment will be rigorous,

using the standard process of external assessment groups (EAGs) to provide reports for an independent committee to base recommendations on, which are subsequently available for comment during consultation, and potential further update or revision of guidance by committee. The appeal process for technology appraisal and highly specialised technologies guidance (as described in Guide to the technology appraisal and highly specialised technologies appeal process) will be used for technology appraisal guidance produced on HealthTech.

8. Responses to comments received on specific proposed changes to aspect of technology appraisal process for evaluations of HealthTech (such as use of evidence submissions and technical engagement) are provided in following sections.

9. Section 5.10 of PMG36 describes considerations for varying the funding requirement, which includes consideration of whether the health technology can be appropriately administered, and if appropriate health services resources, including staff, are in place.

10. In December 2022, the NICE board reviewed an options appraisal for adopting a wider perspective in NICE assessments. The board concluded that NICE should retain its existing approach to perspective (using a health sector perspective in the reference case) while making use of flexibilities to consider wider effects in exceptional circumstances. NICE's position on perspective is continually under review as the methods and evidence base evolve.

Section 2 – HealthTech guidance and technology appraisal guidance

Summary of comments received

11. Respondents highlighted the need to clearly set out the remit of PMG36 and the HealthTech manual (PMG48) to avoid confusion and

commented that the distinction between the 2 manuals is not entirely clear at present.

12. Respondents stated that the outcomes section of the manual should be revised in line with the recent HealthTech manual (PMG48) update in that, in addition to clinical outcomes, the scope can include outcomes related to NHS and personal social services (PSS), such as resource use and system efficiency. This broader perspective was stated to be particularly important for HealthTech evaluations. In addition, the PMG36 manual should further be revised in line with the recent update to the HealthTech manual update in that if impacts are not fully captured in incremental costs or QALY outputs, the assessment report can present differences in non-cost or non-QALY outcomes, and links to other clinically relevant outcomes can be considered.

13. Respondents stated that the manual needs more recognition that HealthTech can prevent health deterioration and better management of long term conditions through behaviour change. They stated that behaviour-mediated effects develop gradually and are difficult to capture quantitatively within QALY-based frameworks.

14. Respondents stated that committees should consider the reliability and generalisability of the evidence when reviewing cost effectiveness estimates. However, this should be interpreted in the context of the technology being assessed, as a higher degree of uncertainty is often inherent in HealthTech evaluations compared with medicines. They also highlighted the importance of using real-world evidence and non-randomised studies. However, some respondents stated that HealthTech should be subject to the same requirements for evidence of clinical effectiveness and economic evaluation to determine cost effectiveness as medicines.

Our response

15. Further text has been added to the introductory sections of PMG36 and PMG48 to clarify that for HealthTech that is considered for non-

technology appraisal guidance (HealthTech guidance), the NICE HealthTech programme manual describes the methods and processes that NICE follows. The PMG36 manual is also being renamed to clarify that it relates to NICE technology appraisal and highly specialised technologies guidance.

16. Technologies recommended for use in early use HealthTech guidance while further evidence is generated that complete the evidence generation process will be considered for re-evaluation by NICE, and this can be through technology appraisal guidance. Section 1.8 in the NICE HealthTech programme manual (PMG48) has been updated to clarify this.

17. The methods described in PMG36 allow the consideration of uncaptured benefits (that is any impacts that are not captured in cost effectiveness or cost comparison estimates) in decision making; for example, see section 6.3.5. The manual also states that uncertainty should be considered proportionately for the evaluation (including the type of technology being assessed; see section 6.2.34).

Section 3 – Topic selection

Summary of comments received

18. Respondents asked for greater detail on how decisions are made about which HealthTech will be assessed in technology appraisal guidance, rather than HealthTech guidance (which does not have a funding mandate).

19. Respondents also asked for greater detail on how a decision that a HealthTech topic may be reconsidered for assessment through technology appraisal guidance (as described in section 2.1.4). They stated that the decision should have stronger governance and transparency.

Our response

20. As described in NICE-wide topic prioritisation: the manual, the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 require a direction from the Secretary of State before NICE is able to make a technology appraisal or highly specialised technology recommendation on a topic (medicines and health technologies). So, the decision to produce guidance as technology appraisal guidance is ultimately a ministerial decision and is not made by NICE.

21. Existing text in PMG36 states that NICE may pause progression of the evaluation to request that the prioritisation board reconsider the routing decision. The text proposed to be added in this consultation added further explanation as to how this may apply for HealthTech topics, rather than add a new step to the process. Ultimately the decision about whether to re-route a HealthTech topic initially selected for technology appraisal guidance to a different type of guidance will be made by the prioritisation board. Full detail on the NICE prioritisation board can be found in NICE-wide topic prioritisation: the manual.

22. 'Limited evidence' as described in the proposed text to be added as a potential rationale for requesting the NICE prioritisation board reconsider the routing of a HealthTech topic to technology appraisal guidance refers to consideration that a topic may have insufficient evidence for a routine use recommendation, and may be better suited at that time to an evaluation for early use guidance (see section 2.1.28 in the NICE HealthTech programme manual for greater detail on early use guidance suitability considerations). As described in point 16 above, technologies recommended through early use HealthTech guidance that complete the evidence generation process will be re-evaluated by NICE, and this can be for technology appraisal guidance.

23. The statement that routing decisions are not subject to appeal is present in existing PMG36 text and has not been added in this consultation.

Section 4 – Evidence submissions and requests for information

Summary of comments received

24. Respondents stated that companies should be invited to submit evidence for HealthTech if they want to and not only be able to respond to requests for information. They stated that companies should always have the opportunity to provide further information at any stage should information gaps be observed. This includes economic models. Respondents asked that adequate time should be given to provide information and suggested a minimum of 6 weeks.

25. Respondents asked for clarification as to why the approach is different for HealthTech, stating that they could see no justification for this. NICE should not prevent companies from submitting evidence when this option is granted to pharmaceutical companies. They stated that manufacturers are likely to have valuable and important evidence to submit, including trial or real world clinical data and economic models that are highly relevant to the evaluation.

26. Alternatively, some respondents supported the approach for HealthTech evaluations in terms of providing evidence via a response to a request for information. They stated that it should be made clear that companies can provide evidence on any studies know to them as part of responses to requests for information.

Our response

27. Requests for information include the opportunity for companies to provide information on, or cite, studies or economic models they consider relevant to the assessment. As stated in the text proposed for addition to PMG36 in the consultation unpublished evidence and

economic models can be provided with a request for information. However, to further clarify this point in the updated manual we have amended the text to specify that requests for information are made during scoping to obtain information about a technology, and companies are asked to provide responses to evidence requests after a scope publishes (described in section 5.5.30 of PMG36). This can include unpublished evidence and economic models. The timelines for providing responses to evidence requests will be indicated to companies as early as possible, with the time period for providing responses starting after the final scope publishes.

28. Evidence requests ensure an equal playing field for companies regardless of their size and maturity. It still allows companies to submit all relevant evidence but is less of a burden for small and medium sized enterprises, and who are less familiar with health technology assessment (HTA), that is without imposing the requirement to produce, or commission, a literature review or economic model.

29. As noted in NICE-wide topic prioritisation: the manual (in section 7.1.3), new medicines that meet the criteria stated in the 2024 voluntary scheme for branded medicines, pricing, access and growth will be selected for assessment by the technology appraisal programme, except when there is a clear rationale not to do so (further detail provided in the document). There is therefore greater certainty about which medicines will be assessed in technology appraisal guidance, allowing planning for this, including activities related to an evidence submission. In contrast, not all HealthTech will be assessed in technology appraisal guidance, or by NICE at all. In addition, intended uses for HealthTech can be broad, covering many potential use cases. The scoping process for guidance typically involves determining which use case(s) will be assessed in guidance, which may only be finally determined for the final scope. These factors mean that there is likely to be much less certainty in advance for HealthTech companies to prepare for any information provision to NICE. So, companies would

not be able to develop a de novo economic model until the final scope is published. Providing time for this would require a substantial delay to guidance production. Evidence requests post-scoping are intended to help companies provide information that meets the decision problem for guidance to NICE in a timely manner. This approach was successfully used in the former diagnostics assessment programme for over 10 years. As described in PMG36 (section 5.8.48), consultation on the draft guidance is an opportunity for companies and other stakeholders to comment on whether all the evidence available to the committee has been appropriately taken into account, the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence, and if the draft recommendations are sound and constitute a suitable basis for guidance to the NHS.

30. While NICE tries to be as amenable as possible to receiving information from companies, to ensure that NICE, external assessment groups and committees can properly consider any information provided to factor into decision making, we cannot accept information at any point in the guidance process. Response to evidence requests should be the primary means to provide information considered relevant at the outset of the assessment period for guidance produced on HealthTech. As stated in PMG36 (section 5.8.52), after draft guidance has been produced a stakeholder can requests that NICE considers additional evidence.

Section 5 – Evaluation of a single HealthTech

Summary of comments received

31. Respondents asked for detail and clarification of process when only a single HealthTech is included in the evaluation. They requested that where only a single technology is available this should be assessed, as prioritising multiple technology appraisals could delay patient access to technologies. They further stated that it was not appropriate to omit a single transformative HealthTech product from evaluation on the

grounds that there are no similar products on the market at that point in time.

Our response

32. When multiple technologies that can be used for the use case, or use cases, being evaluated in technology appraisal guidance are available to the NHS, they will be assessed in 1 piece of guidance. When only 1 technology is available, guidance will be produced for a single technology. It is expected that most HealthTech technology appraisal assessments will be for multiple technologies.

33. Text has been added to the introduction section of PMG36 to clarify that “While it is expected that most evaluations of HealthTech will evaluate multiple technologies, when only 1 technology is available, guidance will be produced for a single technology. The process for evaluation of HealthTech will be the same regardless of how many technologies are being evaluated.”

34. Decisions about which technologies to be included in an evaluation are made during scoping, and with consideration of input from stakeholders and experts. The assessment of multiple technologies was routinely done in NICE diagnostics assessment programme guidance for over 10 years. Examples of past guidance from this programme, including scopes where technologies to be include are set out, can be found here.

Section 6 – Approach to cost comparisons for HealthTech

Summary of comments received

35. The consultation proposed adding text to section 2.6 of PMG36 to state that in the context of consultation on the draft scope, determining cost-comparison suitability would be for medicines only. Respondents asked for clarification as to why this would be for medicines only, stating that a cost comparison approach may be well suited to some HealthTech assessments.

Our response

36. The proposed amendment to make this approach for medicines only has not been made to the updated PMG36 document. As stated in table 4.1 in PMG36, cost comparison (as well as cost utility) is a reference case analysis so can be used for assessment of HealthTech.

Section 7 – Appeals and resolution

Summary of comments received

37. Respondents asked for clarification on whether the appeals process will apply to non-technology appraisal guidance on HealthTech produced by NICE, that is, produced according to the HealthTech Programme Manual PMG48. Respondents stated a preference that all HealthTech guidance should follow the appeals process.

38. Respondents asked why reference to resolution was proposed to be removed from PMG36.

Our response

39. As stated in the pre-existing NICE HealthTech programme manual (PMG48), in section 1.5.17, the resolution process is used for HealthTech guidance. Changing this to the appeal process has not been considered as part of this consultation. But any technology appraisal guidance produced on HealthTech will follow the appeals process (as established for technology appraisals) following PMG36.

40. Reference to resolution, and sections describing this, have been removed from PMG36 because this manual now exclusively describes process for technology appraisal and highly specialist technology guidance (which does not include resolution). Detail on resolution has instead been moved to NICE HealthTech programme manual (PMG48; see section 1.5.17 onwards).

Section 8 – Technical engagement

Summary of comments received

41. Respondents asked for clarification on why technical engagement was proposed not to be an option for HealthTech assessments. They stated that this should be an option if appropriate and highlighted the importance of being able to resolve issues before committee.

42. Respondents commented that not including technical engagement differs to the EUNetHTA approach, might cause confusion and disadvantage highly innovative medical devices or diagnostics.

Our response

43. Technical engagement as described in the pre-existing PMG36 text is for use in the context of assessment of single technologies (as described in section 5.7 'Topic progression – single technology appraisal'). We anticipate that the majority of evaluations of HealthTech will involve multiple technologies. In addition, as stated in existing text in the manual, technical engagement is not a mandatory stage of the evaluation process and will only be included if NICE considers that it is appropriate, helpful and proportionate, taking into account whether the technical engagement process is likely to resolve key issues before the committee meeting. Therefore, of the expected small proportion of evaluations of HealthTech that are expected to involve single technologies, technical engagement would not be used for all such topics. For simplicity and to make the process as clear as possible for HealthTech companies, we have therefore retained the text stating that technical engagement will be considered for evaluations of medicines only. In addition, during scoping for topics involving HealthTech scoping workshop will be routinely held, as well as a consultation on the scope, to allow greater engagement with companies and other stakeholders.

Section 9 – Managed access

Summary of comments received

44. Respondents stated that managed access opportunities should be possible for HealthTech as well as medicines and asked for clarification as to why this is not the case. They stated that this not being an option undervalued HealthTech and recommended that NICE amend the process to allow HealthTech to have the opportunity to enter managed access schemes where appropriate.

45. Respondents also stated that currently early use guidance (previously early value assessment [EVA]) is the only route for recommending HealthTech for use with evidence generation, and that this comes with no guarantee of adoption.

46. Respondents also stated that the manual text appeared to rule out technologies that have been previously recommended through early use guidance being subsequently assessed as part of technology appraisal guidance.

47. Respondents stated that do not think it is appropriate for NICE to recommend HealthTech where there is uncertainty in the evidence for mandated use in the NHS for the generation of evidence, and that this is against a long established principle that unfunded research should not be carried out in the NHS. They stated that additional central funding should be made available to support use of these technologies and the generation of data to inform the evidence base.

Our response

48. As stated in PMG36 (sections 5.5.19 and 5.5.20), managed access is only for medicines evaluated through technology appraisals and highly specialised technologies, and proposals for managed access can be made for any medicines that may be considered eligible through the Cancer Drugs Fund or the Innovative Medicines Fund. To ensure that the option of a recommendation for use while further evidence is

generated is available for HealthTech, a further recommendation option (for HealthTech only) for use during the evidence generation period has been added to PMG36 (section 6.4.12 and 6.4.13). This will follow the approach set out for this type of recommendation in the NICE HealthTech manual, which includes consideration of the available evidence to support use of the technology. However, there is no available equivalent fund as for medicines.

49. HealthTech that has previously been assessed through early use assessment and recommended for use while further evidence is generated will be re-evaluated by NICE at the end of the evidence generation period or potentially earlier (as described in the NICE HealthTech programme manual [PMG48]). This assessment could be for routine use HealthTech guidance or through technology appraisal guidance. Section 1.8.1 in NICE HealthTech programme manual has been amended to better clarify this.

Section 10 – Commercial opportunities for HealthTech

Summary of comments received

50. Respondents stated that the proposed description of the NICE Commercial Liaison Team's (CLT's) role and the approach to pricing appears to draw heavily from processes designed for pharmaceuticals, which may not be appropriate for HealthTech evaluations. They asked for greater detail on how the CLT will engage with the distinct commercial realities of HealthTech, to ensure that NICE's commercial processes for HealthTech are fit for purpose and proportionate to the realities of this sector.

51. Respondents stated that it did not make sense to limit the opportunity for companies to make commercial opportunities for medicines only and not allow this for HealthTech. They also stated that that commercial opportunities after the first committee meeting should not only be available for medicines.

52. Respondents stated that commercial opportunities should not be limited to medicines. They stated that companies should be able to make a patient access scheme (PAS) proposal for HealthTech.

53. Respondents, in response to the proposed additional text on commercial opportunities for HealthTech, stated that this was a positive step, but that more clarity is needed. They also stated that they welcomed the ability for both medicines and HealthTech to negotiate confidential prices but noted that in practice robust mechanisms to keep prices confidential do not exist due to the differing management of budgets compared to pharmaceuticals. They recommended NICE collaborate with commissioning stakeholders to ensure confidential pricing arrangements are kept truly confidential.

54. Respondents stated that the manual does not go as far as it could in giving greater parity to HealthTech, and the lack of a clear route for commercial negotiation was stated to likely to be a major barrier.

55. Respondents objected to HealthTech being restricted in when they can provide updated price agreements during the consultation and request that this is changed to be more flexible.

56. Respondents highlighted that the smaller scale of production and greater heterogeneity of HealthTech products mean that cost of goods, production costs, and supply chain factors can fluctuate significantly, affecting achievable sale prices. Fixed or standardised prices may therefore be unrealistic, and scenario-based or conservative pricing models, where future price changes are considered, may be more appropriate.

57. Respondents requested clarification as to what "existing price" would be used for HealthTech where volume or contract duration commitments are often in place.

58. Respondents stated that the CLT's remit should explicitly include non-price commercial solutions such as value-based procurement, service redesign, or risk-sharing mechanisms.

Our response

59. Further detail has been added to the section on 'Commercial opportunities for HealthTech' (section 5.13 in the updated PMG36 manual) in response to comments received. Whilst we acknowledge the differences between HealthTech and pharmaceutical evaluations, it is important that NICE and the CLT has a standardised way of working across technology evaluations.

60. The CLT facilitates commercial engagement within the NICE process – it does not negotiate or procure products or services on behalf of the NHS. We have updated the text to make this clear.

61. The disparity in terms of detail between the medicines and HealthTech commercial opportunities sections is reflective of the limited number of technologies which have been appraised via the NICE technology appraisal route. It is worth noting that the medicines section also refers to the voluntary scheme and the commercial framework for new medicines – two policy approaches which do not exist for HealthTech. As more HealthTech products are appraised via the technology appraisals route, and experience is gained, we would anticipate that this section will be updated accordingly.

62. We agree that PAS principles for branded medicines may be able to be applied to some HealthTech products. However, we are also aware that the NHS also has established procurement approaches for HealthTech which are based on the often higher levels of competition seen with HealthTech compared with branded medicines.

63. Section 5.4.1 in PMG36 describes how confidential pricing information is handled.

64. Commercial opportunities are not restricted to medicines only. The proposed text consulted on for on ‘Commercial opportunities for HealthTech’ (section 5.13 in the updated PMG36 manual) states that “…after the committee meeting, the NICE CLT provides further information to the company(s) and relevant NHS bodies, to support further commercial activity if required. Additional time may be granted at this stage of the process to allow further commercial activity.” We have updated the manual to clarify this point.

65. NICE’s CLT will contact companies to submit a price in advance of the technology appraisal. This price should be a non-confidential “public price” and then further details of any confidential discounts/commercial arrangements so that correct confidential and non-confidential prices can be utilised for the purpose of the appraisal. Where complex arrangements are in place, it is the responsibility of the submitting company to clearly set out the details to the NICE CLT so that they can be checked to be used in the evaluation.

Section 11 - Scoping

Summary of comments received

66. Respondents requested that greater detail should be added to clarify that HealthTech can have multiple use cases, and that this needs to be reflected in the scope for the assessment.

67. Respondents stated that the criteria for including multiple technologies in a technology appraisal guidance on HealthTech should include consideration of strength and credibility of supporting evidence. Including technologies with little or no evidence in assessments was suggested to discourage companies to invest appropriately in evidence generation.

68. Respondents also asked for greater detail on decisions that are made about which HealthTech are included in the scope for assessment. This included whether multiple technologies included in guidance will

be considered a class or if brand-specific assessments (and recommendations) will be used.

69. Respondents asked to what extent companies and other stakeholders can discuss what technologies are included in the scope and other aspects of the decision problem.

70. Respondents asked for greater clarification on the regulatory requirements for HealthTech to be included in a scope.

Our response

71. Further text has been added to section 2.2.3 in PMG36 to highlight that "Health technologies can often be used in multiple different ways or for various purposes (use cases). For example, in different populations or at different points in a care pathway. The scoping stage refines and clarifies the use, or used, of the technology in the clinical pathway that will be included in the assessment after input from clinicians, patients and other stakeholders."

72. Further detail has been added to section 2.2.4 in PMG36 to provide more detail on considerations about which HealthTech to include in an assessment, and better align with considerations in the NICE HealthTech programme manual. This includes consideration for setting out criteria that technologies need to meet to be included in an assessment, and that interventions may be defined as a class or group of technologies. This is expected to occur infrequently but is a provision that already exists in PMG36 (see, for example, section 4.4.18 "When a group of related technologies is being evaluated as part of a 'class'…"). Considerations of what interventions to include in an assessment and whether to consider them as a group or class can be commented on during the scoping process (see next point).

73. There are opportunities for stakeholders to provide information and input on the scope and decision problem during scoping in response to

a scope consultation (see section 2.5 in PMG36) and, if held, a scoping workshop (see section 2.7 in PMG36).

74. Further text has been added to section 2.2.5 to clarify that scopes for technology appraisals on HealthTech can include for evaluation HealthTech that does not have regulatory approval. But inclusion in the scope does not mean that the HealthTech will be included in the final recommendations if regulatory approval has not been received at that stage. As stated in section 6.1.11 of PMG36: "The committee does not normally make recommendations on using a technology outside the terms of its regulatory approval. Exceptionally, the Department of Health and Social Care may direct NICE to develop guidance on a technology outside of its regulatory approval."

Section 12 – Timelines for NICE actions

Summary of comments received

75. Respondents requested that all relevant papers be provided at least 2 weeks in advance of the first committee meeting, as previously stated, rather than 1 to 2 weeks as proposed in the consultation

76. Respondents stated that proposed text to add to section 5.8.21 stating that when the outcome of a committee meeting cannot be shared within 7 days, that "…stakeholders will be informed of this within 7 days of the committee meeting, and the outcome will be shared when available" would allow NICE to put a break into its own process without clear rules for why. They suggested that NICE is held accountable for sharing the reason for any delay, committing to releasing the committee decision within the minimal period and committing to updating stakeholders (at 7 day intervals).

Our response

77. Committee papers are shared with attendees as soon as it is practicably possible. We aim to balance the need to provide attendees with sufficient time to prepare for committee meetings, with producing

guidance efficiently and avoiding unnecessary delays. Companies will have access to some committee papers more than 2 weeks in advance of committee: such as the assessment report in advance of the first committee meeting (a copy is shared with the company for fact checking) and the consultation document is available for over a month before a second committee meeting.

78. Further text has been added to section 5.8.21 as suggested to state that, where it is not possible to share the outcome of a committee meeting with stakeholders within 7 days, stakeholders will be informed of this with an explanation, further updates will be provided at 7 days intervals and the outcome will be shared when available.

Section 13 – Assessment of HealthTech and medicines in the same evaluation

Summary of comments received

79. Respondents asked for clarification of how assessments would be done for medicinal products labelled together with an in vitro diagnostic.

80. Respondents also asked for clarification of how any future hybrid technologies combining a medicine with a device or diagnostic would be handled and approaches if medicines and HealthTech are evaluated together (for example, for the same indication).

Our response

81. Section 4.8 in PMG36 describes approaches for the assessment of treatment alongside a companion diagnostic. This includes if a diagnostic test to identify patients or establish the presence or absence of a particular biomarker is not routinely used in the NHS but is introduced to support the treatment decision for the specific technology.

82. Initial consideration of new technologies by NICE is done by the NICE Prioritisation Board, as described in NICE-wide topic prioritisation: the manual. As stated in section 7.1.3, new medicines that meet the criteria stated in the 2024 voluntary scheme for branded medicines, pricing, access and growth will be selected for assessment by the technology appraisal programme, except when there is a clear rationale not to do so. New medicines are generally assessed as a single technology appraisal.

Section 14 – Varying the funding requirement

Summary of comments received

83. Respondents commented that the threshold for budget impact stated in the manual (£40 million per year in any of the first 3 financial years of its use in the NHS) should also be used for HealthTech when deciding if a longer time to implement the statutory funding requirements for technologies can be requested.

Our response

84. We are not proposing to change this because the budget impact threshold and test has been set in the context of the voluntary scheme for branded medicines pricing, access and growth (VPAG) and the NHS Commercial Framework for New Medicines. Additionally, funding is not always the main factor when considering the length of time needed for implementation of HealthTech. For example, some tests may require logistics and specific requirements for transporting samples; training may be required to use new devices; new protocols, contract changes to service delivery or recruitment of staff may be needed for a technology that enables care to be delivered in the community rather than in a hospital. For these reasons, requests for longer implementation time will be considered on a case by case basis.

Section 15 – Severity modifier

Summary of comments received

85. Respondents stated that the severity modifier should also be applied in guidance for HealthTech, as it is for medicines, to ensure fairness. Also, that not accounting for severity undervalues HealthTech.

86. Respondents also stated that the idea of a severity modifier for HealthTech should be explored fully. They also welcomed NICE's exploration of how the severity modifier could be applied for technology appraisals of HealthTech. They recommended that any future approach explicitly considers technologies that reduce acute events and long-term complications in chronic conditions, where the severity of disease and future health impact are not fully reflected in baseline QALY estimates.

Our response

87. As stated in the text proposed to be added to section 6.2.12 in this consultation, the severity of a condition should be considered deliberatively within decision making. We are currently exploring approaches on how the severity modifier could be applied for technology appraisals of HealthTech. NICE Listens is our programme of deliberative public engagement. It is used to give us an understanding of public opinion on moral, ethical and social value issues. The NICE Listens web page includes details of a current project about valuing health gains in severe disease. The aim of this public dialogue is to investigate how the public thinks NICE should account for disease severity in its health technology evaluations. We're also working on a stated preference study that will generate quantitative data from a large, representative sample. The research is being designed in a way that is technology-agnostic, so the findings could be applied to HealthTech and other non-drug interventions.

Section 16 – Experts

Summary of comments received

88. Respondents stated that the requirements for clinical experts should be strengthened to require an expertise in the technology modality as well as the subject area of evaluation. These skills and knowledge were stated to now be sufficiently prevalent in the clinical community such that this requirement should not be a barrier to identifying suitable experts.

89. Respondents commented that the experts should not just be ‘clinical experts’ but also that expertise required for a HealthTech evaluation may need a broader range of experts such as porters, those with experience of infection prevention and control or electrical and biomedical engineering and healthcare scientists.

90. Respondents also stated that the experts identified should be a diverse group with representative experience of the care pathway and be selected based on their experience with the relevant technologies, ensuring a balanced range of perspectives to avoid bias for or against any particular technology. Respondents stated that experts should have direct experience of all of the technologies in question or at least a fair representation where there are a very high number of technologies involved.

91. Respondents stated that companies should be allowed to nominate experts, in line with approach taken for technology appraisals of medicines.

92. Respondents commented on existing text in section 1.3.6 of PMG36 that states that “Usually, a maximum of 2 clinical experts or 2 patient experts are selected for each evaluation”. They stated that there should always be both clinical and patient experts, and that this should rather be ‘2 clinical experts and 2 patient experts’. Respondents also stated

that the involvement of 2 patients in an assessment may not be sufficient to capture the diversity of patient experience and needs.

93. Respondents asked in what circumstances experts can make a presentation to committee.

94. Respondents stated that experts should always be invited to provide written evidence, clarify issues about the evidence base and participate in committee meetings. They asked for clarification on conditions when a written submission would be asked for and stated that written submissions from experts are a valuable part of the process.

Our response

95. Further text has been added to section 1.3.16 of PMG36 to note that "Experts selected for evaluations of HealthTech may also include, as well as clinical experts, non-health and social care professionals (such as scientists, software specialists, data analysts, engineers or people with procurement or other technical experience) as needed."

96. While section 1.3.16 states that usually a maximum of 2 clinical or patient experts are suggested, this is not an absolute limit. Text proposed to be added in this consultation to this section stated that "For evaluations that focus on HealthTech a greater number of clinical experts will typically be needed to ensure that knowledge of the care pathway and user experience is fully captured."

97. The process for identifying potential experts for evaluations for technology appraisal of HealthTech is as described for medicines, in section 1.3.8, which states that "Stakeholder organisations are invited to nominate clinical experts, patient experts and commissioning experts, which are then selected by NICE to contribute to the evaluation."

98. A decision about who will present to committee will be made by NICE and the relevant committee chair.

99. Text proposed to be added to sections 1.2.10 and 1.3.17 as part of this consultation that changed process that NICE may, rather than will, ask experts to provide written evidence has not made to the update of PMG36.

Section 17 – Critical appraisal

Summary of comments received

100. Respondents commented on the proposal to add text to section 3.4.6 that "The quality of a study's overall design, its execution, and the validity of its results determines its relevance to the decision problem. Critically appraise each study that meets the criteria for inclusion. But, when there are large numbers of studies, critical appraisal may be prioritised for studies considered key for decision making, particularly those providing data used for economic models…" (added text underlined). They stated that guidance for this prioritisation was not given and that this could lead to important evidence being disregarded. Also, that if there are a large number of studies that meet the inclusion criteria, these should all be included (for example in a systematic review or meta-analysis) otherwise important evidence may be missed. Respondents suggested that one way to address this could be to develop a structured framework for prioritisation, which would make the process more transparent, consistent, and easier to justify.

Our response

101. The included text does not suggest that studies should be excluded from consideration (if they meet inclusion criteria for the review) but that critical appraisal of identified studies may in some cases need to be restricted to those the external assessment group (EAG) consider most relevant. This is considered a pragmatic step to help manage reviews where a very large number of studies are identified, for example because multiple HealthTech products are being considered. Criteria for this step are likely to be very topic specific, and

can be set out in the protocol for the assessment (see section 5.6.1 of PMG36).

Section 18 – Charging for technology appraisals

Summary of comments received

102. Respondents asked for detail on NICE charging companies for technology appraisal evaluations for HealthTech. They asked whether, if there is less involvement opportunities for assessments of HealthTech (compared to medicines) because of the removal of a company submission requirement, if HealthTech topics will be exempt from fees, or if a separate fee schedule will be created.

103. Respondents also asked for detail on financial exposure for companies for a terminated evaluation, particularly for multiple technologies, including what happens if not all companies complete a request for information. And on how NICE would proceed in circumstances where sufficient evidence is available for some, but not all, of the technologies included in the assessment.

Our response

104. Technology appraisals of HealthTech are being delivered in the context of the Rules-based Pathway, an NHS cross-partner initiative to support the implementation of clinically effective technologies that address priority needs in the NHS are represent value for money for the taxpayer. Because this is initiative is new starting with a small number of topics, we will not be charging for technology appraisals of HealthTech currently.

105. Text proposed to be added to PMG36 as part of this consultation clarified that HealthTech will not automatically be withdrawn from a scope or guidance because a response to a request for information or evidence request has not been received. But not providing information needed by NICE may affect the assessment of a technology or procedure and consequently the recommendation.

Section 19 – Requests for clarifications

Summary of comments received

106. Respondents asked for clarification on several points in the consultation and manual:

- How NICE considers new versions of technologies and how this triggers a review of guidance
- How NICE assess and factor in relevant information from the Risk Management File and Post Market Surveillance plans. Also, how recommendations for research relate to Post Market Surveillance plans
- Expectations about distributional cost effectiveness analysis, including sources of evidence considered acceptable
- NICE's approach to confidential information
- How companies are engaged in the process.

107. Respondents also asked about the experience of the NICE technical team, and if they will have sufficient experience and training in HealthTech. They also asked for confirmation that HealthTech will be reviewed by committees with appropriate experience of HealthTech and that relevant stakeholders will be engaged.

108. Respondents also for more clarity about the role of external assessment groups (EAGs) in technology appraisals done on HealthTech.

109. Respondents asked for clarification on the proposed text to be added to section 5.4.12 related to EAG analysis and confidential appendices to the assessment report.

Our response

110. For information on the processes and methods for checking that published guidance is current and how decisions are made on whether updates are needed, see the processes and methods guide for NICE-wide guidance surveillance.

111. In producing the assessment report the EAG will broadly consider the available evidence and can consider unpublished evidence provided by companies. Section 3 in PMG36 describes approach to evidence considerations used in assessments. The focus of research recommendations is to identify evidence that would be needed for a potential future assessment of clinical and cost effectiveness done as part of a NICE assessment. In some cases, this may differ from what is required in Post Market Surveillance plans.

112. Section 4.12 in PMG36 describes approaches for distributional cost effectiveness analysis (DCEA). This includes a link to a support document (the technology evaluation methods support document on health inequalities) that provides further information on approaches and methods.

113. Section 5.4 in PMG36 describes the approaches taken by NICE in handling confidential information.

114. Section 1.3 in PMG36 describes how participants, including companies, are involved in the process. Detail on the stakeholders that NICE invite to take part in an evaluation can be found in section 1.2.16 of PMG36.

115. NICE technical staff working on evaluations done for technology appraisals of HealthTech will include those working in the HealthTech Directorate, that is, with experience of routinely assessing HealthTech products for NICE guidance. The advisory committees used for this guidance will also include those who produce HealthTech guidance.

116. Detail on EAGs can be found in sections 1.2.11, 1.3.24, 1.3.25 and 1.3.26 in PMG36.

117. Section 5.4.12 in PMG36 has been amended to better clarify that the detail related to production of analyses with confidential price discounts include situations where the EAG has produced the economic model for the assessment (as for HealthTech) as well as when reproducing any company analyses.

Section 20 – Condition or technology specific requests

Summary of comments received

118. Respondents asked for greater detail to be added to PMG36 for specific considerations related to assessment of light based technologies, including requirements for planned assessments to use a recognised skin-tone classification, ensure representative recruitment across skin-tone groups, and report subgroup performance. They also highlighted the importance of economic models considering specific subgroups and the need to consider device specific performance.

Our response

119. Including condition or technology specific considerations is beyond the scope of the PMG36 text. But these considerations are included in deliberations about drafting the scope for assessment. For example, the importance of highlighting potential subgroups in the population included in the scope for the assessment when the clinical effectiveness or value for money of the technology might differ from the overall population, or groups who need special consideration is described in section 2.2.9 of PMG36. The manual also includes a section on analysis of data for patient subgroups (section 4.9) and how committee will consider which individuals benefit most from the technology and whether there are subgroups of individuals for whom the effectiveness evidence suggests differential cost effectiveness or cost savings (section 6.2.28).

Section 21 – Informed Consent for procedures requiring evidence generation or managed access

Summary of comments received

120. Respondents recommended the inclusion of an 'Enhanced Informed Consent' section in NICE's manual for procedures requiring evidence generation or managed access. This was in reference to new procedures recommended within the 'special arrangements' framework (now 'evidence generation'), which is a type of recommendation specified in the NICE interventional procedures manual. The comment provided suggested text that is planned to go on the NICE website related to enhanced informed consent.

Our response

121. New interventional procedures are typically assessed through the interventional procedures programme, see section 7.1.2 ('Topics that involve use of new interventional procedures'), or through NICE Clinical guidelines which have manuals (Interventional procedures programme manual and Developing NICE guidelines: the manual), that are not being updated as part of this consultation. However NICE programmes work together closely, and the referenced update to the NICE website to include specific text could be utilised if relevant to any technology appraisal or highly specialised technology guidance.

Section 22 – Disease area portfolio reviews

Summary of comments received

122. Respondents stated that the draft does not provide a process for NICE to revisit, in a single coordinated exercise, multiple technology appraisals within the same disease area when evidence, pathways, safety, or costs (including biosimilars) have materially changed over time. This was stated to be particularly an issue for ophthalmology, as over the past 15 years NICE has issued multiple, separate technology

appraisals each undertaken at a different time, using different comparators, evidence bases, and cost assumptions.

123. Respondents suggested to introduce an explicit, disease-area "portfolio review" mechanism within the manual for medicines, enabling NICE to review and, where needed, harmonise all relevant technology appraisals in a therapeutic class or disease area.

124. Respondents asked to NICE to confirm whether the final manual will include (or, if not, to commit to developing) a formal disease-area portfolio review mechanism so that NICE can re-review all anti-VEGF recommendations across retinal diseases when the evidence base, care pathway, safety, and biosimilar costs have significantly changed. This was stated as necessary to ensure consistency, equity of access, and maximum NHS value in ophthalmology, and provide a model applicable to other therapeutic classes facing similar cumulative changes.

Our response

125. The updates made to PMG36 will only be within the scope of what was described in the consultation documents. The proposed changes here are therefore out of scope for any updates at this time. As described on the NICE Modular updates webpage, a modular update is a review of the methods and/or processes that inform our guidance, that may result in an update to our manuals. This webpage also provide detail on how you can suggest a modular update, and how this will be considered by NICE.