

<b>Title:</b> NICE's technology appraisal and highly specialised technology work programmes – charging and Appeals Panels <b>IA No:</b> <b>RPC Reference No:</b> N/A <b>Lead department or agency:</b> Department of Health and Social Care <b>Other departments or agencies:</b> National Institute for Health and Care Excellence (NICE)	<b>Impact Assessment (IA)</b>			
	<b>Date:</b> 05/11/2018			
	<b>Stage:</b> Final			
	<b>Source of intervention:</b> Domestic			
	<b>Type of measure:</b> Secondary legislation			
<b>Contact for enquiries:</b> Jane Newton				
<b>Summary: Intervention and Options</b>				<b>RPC Opinion:</b> Not applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANDCB in 2014 prices)	One-In, Three-Out	Business Impact Target Status
£332	N/A	N/A	Not in scope	Non-qualifying provision

**What is the problem under consideration? Why is government intervention necessary?**

Through its technology appraisal (TA) and highly specialised technologies (HST) programmes, NICE makes recommendations on whether drugs and other medical technologies should be routinely funded by the NHS, depending on their cost-effectiveness. These programmes are currently funded through the core funding that NICE receives from the Department of Health & Social Care. To reduce NICE's reliance on Government funding, this IA considers alternative options for funding these programmes. Parallel proposals to amend regulations concerning membership of appeals panels that are not considered in this IA since costs and benefits are likely to be small and are not easily monetisable.

**What are the policy objectives and the intended effects?**

The policy objective is to enable NICE to continue the full breadth of its functions while reducing its reliance on Government funding. The effect would be to transfer most of the cost of producing TA and HST recommendations from Government to those life science companies who submit their products for NICE appraisal. The exception would be for small companies who would pay 75% less than large and medium companies.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

**Option 1 (“Business as usual”):** NICE do not introduce charges. NICE's TA and HST programmes continue to be funded through core Government funding from the DHSC.

**Option 2 (Introduce charges):** Transfer the cost of NICE TA and HST programmes to the life sciences sector by amending the NICE regulations that underpin those programmes, allowing NICE to charge life science companies that submit a product for assessment.

**Option 3 (Introduce charges with small company discount):** As per Option 2, with a 25% discount and staggered payment options offered to small companies.

**Option 4 (Introduce charges with small company discount):** As per Option 2, with a 75% discount and staggered payment options offered to small companies. **This is the preferred option.**

<b>Will the policy be reviewed?</b> It will be reviewed. <b>If applicable, set review date:</b> 2020					
Does implementation go beyond minimum EU requirements?			Yes / No / N/A		
Are any of these organisations in scope?		<b>Micro Yes</b>	<b>Small Yes</b>	<b>Medium Yes</b>	<b>Large Yes</b>
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)			<b>Traded:</b>		<b>Non-traded:</b>

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible MINISTER: \_\_\_\_\_ Lord O'Shaughnessy \_\_\_\_\_ Date: \_\_\_\_\_ 6 December 2018 \_\_\_\_\_

# Summary: Analysis & Evidence

# Policy Option 1

Description: "Business as usual"

## FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate:

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate		0	0

### Description and scale of key monetised costs by 'main affected groups'

Option 1 ("Business as usual"), with NICE's TA and HST programmes supported through grant-in-aid funding received from the DHSC, is the baseline against which the other options are assessed.

### Other key non-monetised costs by 'main affected groups'

This is the baseline against which other options are assessed.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate		0	0

### Description and scale of key monetised benefits by 'main affected groups'

This is the baseline against which other options are assessed.

### Other key non-monetised benefits by 'main affected groups'

This is the baseline against which other options are assessed.

Key assumptions/sensitivities/risks (%)

Discount rate

NHS 1.5 Other 3.5

The proposal to introduce charges was developed as part of a wider consideration of NICE funding, and in the context of reducing NICE's reliance on grant-in-aid funding. The estimates in the present IA are based on current volume and mix of appraisals undertaken as part of NICE's TA and HST programmes.

## BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

# Summary: Analysis & Evidence

# Policy Option 2

**Description:** Introduce charges that permit NICE to recover the costs of its TA and HST programmes from life science companies that submit a product for appraisal

## FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2019	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 354

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate			£16m

### Description and scale of key monetised costs by 'main affected groups'

Business: The full cost of TA and HST programmes (£10 million per year) would be covered by payments from life sciences companies submitting their products for appraisal. The estimated impact on UK society is lower than this, reflecting the fact that the pharmaceutical industry is global. The discounted value of these impacts over the 10-year appraisal period is approximately £16 million (£15.8m).

### Other key non-monetised costs by 'main affected groups'

The proposed charges could affect production and R&D decisions of small companies, but there is a lack of evidence on the extent of the barrier.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate			£370m

### Description and scale of key monetised benefits by 'main affected groups'

Transferring the full cost of TA and HST programmes (£10 million per year) to industry would result in financial savings to DHSC. These savings, when reinvested in other NHS services, are assumed to generate health benefits equivalent to 6,700 Quality Adjusted Life Years (QALYs) over the appraisal period, which are valued at £60,000 each. When monetised and discounted, these health benefits are valued at £370 million (£369.7m) over the 10-year appraisal period.

### Other key non-monetised benefits by 'main affected groups'

Allowing NICE to recover costs to fund their TA and HST programmes would reduce their reliance on grant-in-aid funding and provide financial stability to support the full breadth of its activities.

Key assumptions/sensitivities/risks	Discount rate (%)	NHS 1.5% Other 3.5%
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The estimates are based on the current volume and mix of appraisals; the same as in Option 1. Consequently, the costs and benefits refer respectively to the UK impact of industry paying for these programmes, and the monetised health benefits of NHS spending on alternative services. It is assumed that administrative costs associated with collecting charge revenue are negligible and that work is undertaken by current NICE staff without displacing other activities.

## BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

# Summary: Analysis & Evidence

# Policy Option 3

**Description:** Introduce charges that permit NICE to recover the costs of its TA and HST programmes from life science companies that submit a product for appraisal, with a 25% discount and staggered payment for small companies

## FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2019	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: 347

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate				£14m

### Description and scale of key monetised costs by 'main affected groups'

Business: Most of costs of TA and HST programmes (£10 million per year) would be covered by payments from life sciences companies, except for a 25% discount for small companies (defined by the Companies Act 2006) worth around £0.25 million per year. The discounted UK impact of these costs over the 10-year appraisal period is just over £14 million (£13.7 million).

### Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	Optional
High	Optional		Optional	Optional
Best Estimate				£360m

### Description and scale of key monetised benefits by 'main affected groups'

The public purse (DHSC) would save the full cost of the TA and HST programmes (£10m per year), net of a 25% discount for smaller companies (£0.25m per year). These savings, reinvested in other NHS services, are assumed to generate around 6,500 QALYs over the appraisal period, valued at £60,000 each. When monetised and discounted, these benefits are valued at £360 million (£360.5m) over the appraisal period.

### Other key non-monetised benefits by 'main affected groups'

Allowing NICE to recover costs to fund their TA and HST programmes would reduce their reliance on grant-in-aid funding and provide financial stability to support the full breadth of its activities.

Providing a discount to small companies is in line with the Government's commitment to provide the right support to small companies as stated in the Industrial Strategy.<sup>1</sup> It is designed to reduce specific impacts of charges on R&D and production in this part of the life sciences industry.

Key assumptions/sensitivities/risks	<b>Discount rate (%)</b>	NHS 1.5 Other 3.5
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There is no change in the volume or mix of assessments relative to Option 1. Administrative costs associated with collecting charge revenue are negligible as above.

Currently, around 10% of submissions for NICE appraisal are from small, UK-based companies, but this may fluctuate from year to year. It is assumed that the £0.25m cost of providing a 25% small-company discount would be covered by an adjustment to NICE's grant-in-aid or to their wider programme of work.

## BUSINESS ASSESSMENT (Option 3)

<b>Direct impact on business (Equivalent Annual) £m:</b>			<b>Score for Business Impact Target (qualifying provisions only) £m:</b>
<b>Costs:</b>	<b>Benefits:</b>	<b>Net:</b>	

<sup>1</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/664563/industrial-strategy-white-paper-web-ready-version.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/664563/industrial-strategy-white-paper-web-ready-version.pdf)

# Summary: Analysis & Evidence

# Policy Option 4

**Description:** Introduce charges that permit NICE to recover the costs of its TA and HST programmes from life science companies that submit a product for appraisal, with a 75% discount and staggered payment for small companies

## FULL ECONOMIC ASSESSMENT

Price Base Year 2018	PV Base Year 2019	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: £332m

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate			£10m

### Description and scale of key monetised costs by 'main affected groups'

Business: Most of costs of TA and HST programmes (£10 million per year) would be covered by payments from life sciences companies, except for a 75% discount for small companies (defined by the Companies Act 2006) worth around £0.75m per year. The discounted impact of these costs on UK society over the 10-year appraisal period is just under £10 million (£9.6 million).

### Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	Optional	Optional
High	Optional	Optional	Optional
Best Estimate			£342m

### Description and scale of key monetised benefits by 'main affected groups'

The public purse (DHSC) would save the full cost of the TA and HST programmes (£10m per year), net of a 75% discount for small companies (£0.75m per year). These savings, reinvested in other NHS services, are assumed to generate around 6,000 QALYs over the appraisal period, valued at £60,000 each. When monetised and discounted, these benefits are valued at £342 million (£341.9m) over the appraisal period.

### Other key non-monetised benefits by 'main affected groups'

Allowing NICE to recover costs to fund their TA and HST programmes would reduce their reliance on Government funding and provide financial stability to support the full breadth of its activities.

Providing a discount to small companies is in line with the Government's commitment to provide the right support to small companies as stated in the Industrial Strategy. It is designed to reduce specific impacts of charges on R&D and production in this part of the life sciences industry.

Key assumptions/sensitivities/risks

Discount rate (%)

NHS 1.5 Other 3.5

There is no change in the volume or mix of assessments relative to Option 1. Administrative costs associated with collecting charge revenue are negligible as above.

Currently, around 10% of submissions for NICE appraisal are from small, UK-based companies, but this may fluctuate from year to year. It is assumed that the £0.75m cost of providing a 75% small-company discount would be covered by an adjustment to NICE's grant-in-aid or to their wider programme of work.

## BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

## Evidence Base (for summary sheets)

### Problem under consideration

1. The National Institute for Health and Care Excellence (NICE) is the independent, expert body responsible for providing authoritative, evidence-based guidance, advice and recommendations for the health and care system. NICE operates a range of work programmes, including: the development of guidelines providing guidance on the diagnosis, management and care of defined groups of patients; recommendations on the clinical and cost effectiveness of individual treatments; and recommendations on the safety and efficacy of interventional procedures.
2. Through its technology appraisal (TA) and highly specialised technologies (HST) programmes, NICE makes recommendations on whether drugs and other medical technologies should be routinely used in the NHS, based on evidence of their cost-effectiveness. The NHS is legally obliged to fund medicines and medical technologies recommended by NICE's TA or HST programmes.
3. NICE's TA and HST programmes are currently funded from the grant-in-aid funding that NICE receives from the Department of Health and Social Care (DHSC). In common with other non-departmental public bodies, NICE's grant-in-aid funding has been reduced in recent years, falling from £66.4 million in 2013/14 to £51.2 million in 2018/19.<sup>1</sup> NICE needs to identify other sources of funding to enable it to continue with its full programme of work.
4. This Impact Assessment evaluates options for transferring the costs of NICE's TA and HST programmes from Government to life sciences companies who submit their products for appraisal.

### Rationale for intervention

5. The Cabinet Office triennial review of NICE, published in July 2015<sup>2</sup>, recommended that the Government should consider introducing charges to industry to cover the cost of NICE's TA and HST programmes. The Accelerated Access Review published in October 2016<sup>3</sup> endorsed this recommendation, noting the value to industry of a technology appraisal.
6. Non-departmental public bodies are increasingly seeking to reduce their reliance on Government funding and find other sources of revenue. The introduction of charges for their appraisal activity would bring NICE into line with other public bodies in the health sector that recover costs of independent regulatory, inspection, licensing and compliance activities from organisations subject to these regimes. For example, MHRA charges for its licensing and regulatory work.<sup>4</sup>
7. The Government and the health and care sector values the important role that NICE plays in supporting patient access to clinical and cost-effective new treatments and in driving quality improvement, and are exploring how other sources of funding can support this valuable work.
8. An amendment to NICE's regulations is required for NICE to charge for producing its TA and HST guidance.

### Policy objective

The policy objectives are to:

- reduce NICE's reliance on Government funding while ensuring that NICE can continue the full breadth of its activities.
- enable NICE to recover the costs of producing TA and HST guidance from life science companies that submit their products for appraisal, making this part of their activity self-sufficient and allowing NICE to develop the programme in response to a changing environment.

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<sup>1</sup> <https://www.gov.uk/government/consultations/nice-recommendations-charging-and-appeal-panels>.

<sup>2</sup> Department of Health, Report of the triennial review of the National Institute for Health and Care Excellence, July 2015  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/447317/NICE\\_Triennial\\_Review\\_Report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/447317/NICE_Triennial_Review_Report.pdf)

<sup>3</sup> Accelerated Access Review: Final Report.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/565072/AAR\\_final.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/565072/AAR_final.pdf)

<sup>4</sup> <https://www.gov.uk/government/publications/mhra-fees/current-mhra-fees>

- ensure that small companies are not dissuaded from developing and marketing new technologies in the UK.

## Summary of comments from public consultation

9. This IA has been updated following the DHSC consultation “NICE recommendations: charging and appeal panels.”<sup>5</sup> Out of 78 respondents to the consultation, 41 respondents represented views from the life sciences industry, including pharmaceutical companies, industry representatives, consultancies and medtech companies. The next largest group of respondents represented patient groups (12), with other responses from NHS organisations and individuals.
10. Respondents expressed their support of the important work carried out by NICE in undertaking appraisals of new medicines. Industry respondents agreed that a financial contribution from companies was justified, but stated their view that the proposed model of charging could reduce the attractiveness of the UK as a market in which to develop and sell new medicines. Several respondents expressed their view that uncertainty about regulatory and market conditions following the UK’s exit from the EU made charging a riskier policy in this respect.
11. The specific impact of charging for HST guidance on incentives to launch medicines for rare conditions was raised as a concern by industry respondents, since expected returns from sales of orphan drugs are lower than for medicines with larger patient populations. Similar concerns were raised in relation to medical devices, diagnostics and transformational products. Patient groups also expressed concern about access to new medicines, especially for rare conditions.
12. Financial barriers for small companies to launching their products was identified as another area of concern. Not all respondents agreed that the proposed 25% discount would remove the barrier to market entry. Some respondents thought financial barriers could apply to a wider group of SMEs, not just to small companies as defined by the Companies Act 2006.
13. The impact of charging on the relationship between NICE and industry was a second area of concern. The potential for conflicts of interest and the public perception of such conflicts were identified as risks. Several respondents suggested that industry finance could damage the international reputation of NICE. Several companies stated that they would want greater formal involvement in the appraisal process, such as the choice of appraisal route and timing of submissions, as well as performance monitoring, in return for industry funding.
14. Finally, several respondents requested further information on how public savings from charging companies for NICE’s TA and HST programmes would be reinvested in the NHS. There was industry support for the view from their representative, ABPI, that DHSC’s standard approach to valuing these savings lacked a strong evidence base, specifically the assumption that the NHS generates health benefits at a rate of £15,000 per Quality Adjusted Life Year (QALY).<sup>6</sup>

## Revisions to the policy and Impact Assessment following public consultation

15. Following the consultation, the proposed policy has been amended to create greater flexibility for NICE to adjust its charges in future, should this be required. In addition, a larger discount of 75% for small companies has been evaluated, and is now the Government’s preferred option.
16. The IA has been revised in the following ways:
  1. The value of a NICE appraisal to companies is described more fully.
  2. Financial barriers faced by small companies are assessed by comparing the proposed fee levels with the estimated UK turnover of companies that have submitted their products to NICE for appraisal over the last five years.

<sup>5</sup> <https://www.gov.uk/government/consultations/nice-recommendations-charging-and-appeal-panels>

<sup>6</sup> The QALY is a standard unit used to measure health gains that combines impacts on longevity and health-related quality-of-life. The DHSC estimate of the cost at which an additional QALY is gained or lost in the NHS is £15,000. This figure is based on a published estimate of the cost per QALY at the margin in the NHS, <https://www.york.ac.uk/che/research/teehta/thresholds/>.

3. Additional information is given on how NICE's processes are designed to mitigate any conflicts of interest that could arise from industry funding of its programmes, and on how the structure of fees for different types of appraisal was calculated.
4. Assumptions about the way that financial costs to industry would impact on UK industry have been revised.

## Options considered

### Option 1: "Business as usual"

17. Under the "business as usual" scenario, the production of NICE's TA and HST guidance would continue to be funded through the grant-in-aid funding that NICE receives from DHSC. This option does not meet the objective of reduced reliance on Government funding, and may not be sustainable in the long run in the context of public bodies reducing their reliance on Government funding.

### Option 2: Introduce Charges

18. NICE would be permitted to introduce charges for those companies who submit their products for assessment, against a defined tariff, on a cost recovery basis. This follows the Government's standard approach to charging for public services, with the same charge applied to all users of a defined category of service, so recovering full costs for that category of service.<sup>7</sup>
19. Products would continue to be selected for referral to NICE's TA and HST programmes through the established topic selection process and criteria and NICE will continue to develop guidance through its standard methods and processes.
20. The Government is legally responsible for referring individual topics to NICE for TA and HST assessment and will therefore retain overall control of which topics are referred to NICE for assessment.
21. As now, assessment by NICE will not be a requirement for drugs to be funded by the NHS, and companies will not be mandated to participate in the assessment process. Where NICE does not assess a technology, or is unable to make a recommendation because the company does not participate in the assessment, NHS commissioners will continue to be required to make funding decisions based on an assessment of the evidence.

### Option 3: Introduce charges as per Option 2, whilst offering a 25% discount and staggered payment option for small companies.

22. NICE and Government wish to encourage small companies to continue to participate in the TA and HST programme and seek to minimise barriers to their participation.
23. NICE intends to implement two measures to reduce the burden on small companies (as defined by the Companies Act 2006) and to reduce the risk of lower levels of activity:
  - To provide a subsidy of 25% to small companies, in effect by funding 25% of the cost of appraisals for small companies from NICE's grant-in-aid funding. The remaining appraisals and HSTs would still be charged at the calculated full cost. This would not be a form of cross-subsidisation from medium or large companies to small companies. The effect of this subsidy would be to reduce annual income from TA and HST charges to NICE by around 2.5%.
  - To allow small companies to pay by instalments with 40% payable at the outset, 50% when the committee first meets (typically around half way through the process) and 10% just prior to the final decision being published. For licensing fees charged by MHRA, small companies can delay their payments, although there is no discount for small companies.<sup>8</sup>

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[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/742188/Managing\\_Public\\_Money\\_\\_MPM\\_\\_2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/742188/Managing_Public_Money__MPM__2018.pdf)

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[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/474152/Payment\\_Easements\\_for\\_Small\\_Companies.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/474152/Payment_Easements_for_Small_Companies.pdf)



#### **Option 4: Introduce Charges as per Option 2, with a 75% discount and staggered payment options for small companies**

24. Following the public consultation on the proposals, the Government is considering a further option where small companies would be offered larger discount of 75%, with the effect of reducing annual income from charging by around 7.5%.

#### **Evidence used to inform analysis**

##### **The cost of NICE's TA and HST programmes**

25. NICE undertakes five different types of TA and HST assessment, and derived an average cost per appraisal for each by dividing total spend on their TA and HST programmes in 2016/17 by the number of appraisals conducted. This includes direct costs, indirect costs and overheads.
26. To reflect the varying complexity and cost of different types of assessment, a weighting approach was taken. NICE has not previously had a need to document individual costs of activities involved in each assessment. Instead, weights were based on an estimate of the length of time involved in contributing activities, e.g. the number of committee meetings.
27. The weightings used are as follows: Single Technology Appraisals (STAs) are taken as the base unit and are given a weighting of 1; Highly Specialised Technology evaluations (HSTs) required a similar level of resource and are also allocated a weighting of 1; Fast Track Appraisals (FTAs) were developed to require around 70% of the resource of a standard STA and so are given a weighting of 0.7; standard and complex Multiple Technology Appraisals (MTAs) are given weightings of 1.5 and 2 respectively.
28. HSTs were observed to have taken as much staff and committee time as an average STA, so a weighting of 1 was applied. Given the small number of HSTs undertaken to date, this estimate could be revised in future.
29. The proposed schedule of charges is based on these unit costs. A full cost recovery basis has been used as is permitted under rules set out in 'Managing Public Money' (see paragraph 18 above). The amount payable by a company submitting a technology for appraisal is listed below in Table 1.

**Table 1:** Estimated cost per appraisal/proposed charges for 2019/20 (£), by appraisal type

<b>Appraisal type</b>	<b>Cost per appraisal</b>
Single Technology Appraisals (STA)	£126,000
Highly Specialised Technologies guidance (HST)	£126,000
Fast Track Appraisals (FTA)	£88,000
Multiple Technology Appraisals (MTA) - Standard	£188,000
Multiple Technology Appraisals (MTA) - Complex	£251,000

**Source:** Updated estimates from NICE, July 2018

30. Average costs have been used to create a proposed set of charges, rather than the marginal cost per appraisal. The charges would be kept under review to ensure that the charges were in line with the principle of cost recovery.
31. The recommended prices are shown exclusive of VAT. The supply of these appraisals is expected to be in scope for VAT which will need to be added at the prevailing rate, and be recoverable by the companies involved. It is assumed that VAT will be fully recovered and that additional administrative effort associated with that process is negligible. In line with the Green Book, VAT would be treated as an economic transfer.
32. To calculate the total cost of NICE's TA and HST programmes, these costs/ proposed charges must be scaled by expected future volumes of activity. NICE has provided information on the number of different types of appraisal undertaken each year from 2013/14 to 2017/18, alongside forecasts of TA/HST activity for 2018/19. These show sustained growth in earlier years before

levelling off. These volumes have been used as the basis for this Impact Assessment, and are shown in Table 2, below.

**Table 2:** Number of technology appraisals, 2013/14 - 2018/19

<b>Appraisal type</b>	<b>2013/14</b>	<b>2014/15</b>	<b>2015/16</b>	<b>2016/17</b>	<b>2017/18</b>	<b>2018/19</b>
STA	26	26	43	49	57	61
Rapid review	2	0	1	2	0	0
FTA (Introduced 17/18)	-	-	-	-	2	8
HST	0	1	1	3	3	3
MTA (standard)	1	3	1	3	8	4
MTA (complex)	3	2	3	1	3	2
<b>Total</b>	<b>32</b>	<b>32</b>	<b>49</b>	<b>55</b>	<b>73</b>	<b>78</b>

Source: Updated estimates from NICE, July 2018

33. The increase in the number of appraisals in 2017/18 was the result of a change in demand and planned increase in capacity to NICE's TA programme,<sup>9</sup> rather than reflecting an underlying trend. The number of appraisals undertaken as part of NICE's TA and HST programmes could vary over time in line with the medicines pipeline. For this Impact Assessment, we have used the 2018/19 activity levels.
34. Charges will be payable at the beginning of a TA/HST, not at its conclusion, except for small companies who will be given the option to pay in instalments. Based on the proposed fee levels (Table 1) and the number of appraisals carried out in 2018/19 (Table 2), it is estimated that the total cost of TA and HST programmes will be approximately £10 million per year over the next ten years from 2019/20 to 2028/29.

### The value to companies of a NICE TA recommendation

35. In response to the public consultation on the proposed charges, companies expressed their support of the important work carried out by NICE in undertaking evaluations of new medicines and recognised the importance of NICE being placed on a more sustainable financial footing.
36. NHS commissioners are legally required to make funding available for drugs and treatments recommended in NICE TA and HST recommendations, normally within three months of the publication of final guidance. This is reflected in the NHS Constitution as a right to NICE approved drugs. NICE's recommendations therefore play an important role in ensuring that patients will benefit from clinically and cost-effective treatments shortly after licensing, and in providing assurance to companies with a positive NICE recommendation that there will be NHS uptake of their products.

### Evaluation of incentives to submit products for treatment of rare diseases

37. We have considered whether the introduction of charges would affect the availability of orphan products for the treatment of rare diseases, a concern that was raised by several consultation respondents. There is insufficient evidence to conclude that such products would be disproportionately impacted by the introduction of charges. NHS spending on orphan drugs with a positive NICE recommendation can be very large; for example, the NHS spent around £67.5m on the orphan drug ibrutinib in 2016/17.<sup>10</sup>

<sup>9</sup> <https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/technology-appraisals/increasing-ta-capacity-consultation.pdf>

<sup>10</sup> NHS Digital. Prescribing costs in hospital and the community, England 2016/17. <https://digital.nhs.uk/data-and-information/publications/statistical/prescribing-costs-in-hospitals-and-the-community/2016-17>

## Evaluation of financial barriers to participation for small and medium-sized companies

38. Following the consultation, the scale of financial barriers facing small and medium-sized companies was considered further.
39. NICE provided a list of 120 companies that had submitted 413 products for appraisal between April 2013 and September 2018. Of these, 75% of companies (90 out of 120), covering 92% of appraisals (378 out of 413), were matched to data on company's annual UK turnover in 2016/17 from the Life Sciences database held by the Office for Life Sciences in the Department for Business, Energy and Industrial Strategy. A match was not possible when companies submitting products to NICE had been recently incorporated or did not have a UK subsidiary.
40. Of the 90 companies matched, 22 were small based on the Companies Act 2006 definition (turnover less than £10.2 million and fewer than 50 employees). These accounted for 7.7% of appraisals (29 out of 378) There were 17 medium-sized companies (turnover between £10.2 million and £36 million, fewer than 250 employees), accounting for 12.2% of appraisals (46 out of 378).
41. The 2016/17 average annual turnover of these small, medium and large companies was £2.1 million, £19.9 million and £347.1 million respectively. These figures could overstate the turnover of these companies at the point in time when they submitted their products for appraisal.
42. Nearly half (9 out of 21) of small companies, and a fifth (3 out of 17) of medium-sized companies were subsidiaries of larger overseas companies (listed Global Ultimate Owners - GUOs) with higher listed UK turnover. For one of the small companies, the GUO was not listed.

## Protections against conflicts of interest arising from industry funding

43. Some respondents to the public consultation were concerned that reliance on industry funding could mean that NICE's TA and HST processes would be inappropriately influenced by companies that stand to benefit from a positive recommendation.
44. NICE has well-developed published policies and procedures that govern the way that it selects topics and appraises medicines,<sup>11</sup> including policies to manage and mitigate individual conflicts of interest.<sup>12</sup> For each individual appraisal, the process is fully documented and published, including minutes of committee meetings. This level of transparency offers the main protection against conflicts of interest.
45. External independent organisations and individuals, not funded by NICE or industry, are involved in the process throughout, from the identification and filtering of topics to the review and synthesis of evidence and the final assessment of the evidence.
46. Other than for small companies, fees would be paid upfront, which would mean that neither NICE as an organisation, nor its staff, would have a financial incentive to provide a positive recommendation in an appraisal.
47. MHRA has a long history of charging for its regulatory work, and has taken steps through its internal organisation to avoid conflicts of interest.<sup>13</sup>
48. Agencies in Canada and Australia that fulfil a similar function to NICE charge for their work and have procedures in place to avoid conflicts of interest.<sup>14</sup>

## The Costs and Benefits of Each Option

### Option 2: Introduce Charges

#### Option 2 Costs

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<sup>11</sup> <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance>

<sup>12</sup> <https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/policy-on-declaring-managing-interests-advisory-committees.pdf>

<sup>13</sup> National Audit Office. Safety, Quality, Efficacy: Regulating Medicines in the UK. 2003 <https://www.nao.org.uk/report/safety-quality-efficacy-regulating-medicines-in-the-uk/>.

<sup>14</sup> See <https://www.cadth.ca/scientific-advice/conflict-of-interest>

49. It is anticipated that the full cost of NICE's TA and HST programmes will be transferred from Government to companies who submit their technologies for appraisal. Based on current figures, this has a financial cost to companies of approximately £10m per year, paid through charges described above.
50. In line with HMT Green Book guidance,<sup>15</sup> the relevant costs and benefits are those for UK society. Adjustments are made to the financial cost to estimate the impact on UK society reflecting the fact that the pharmaceutical industry is global (Chapter 6 Green Book). In this IA, we present the first-order effects on shareholder income, in contrast to the draft IA.
51. The pharmaceutical industry is global and the majority of NHS drug spending will accrue to overseas interests. Based on analysis of trade information, the Department for Business, Energy and Industrial Strategy (BEIS) estimate that approximately 10% of drug spend is on UK based production, including R&D, manufacturing and marketing. It is assumed that returns to capital are shared between the UK and overseas in the same proportion.
52. NICE estimate that one in ten submissions are from small companies. For this IA, small companies are assumed to be wholly UK-based, and so the adjustment described above is not made to the 10% of activity associated with those firms.
53. The net result of these adjustments suggests that the UK societal cost of this option is £1.9m per year, and that it has a present value (cost) of £15.8m over the appraisal period.
54. NICE has indicated that additional administrative effort is expected to be negligible and can be wholly absorbed by existing staff and budgets.

## Option 2 Benefits

55. The full cost of NICE's TA and HST programmes would be transferred to companies wishing to submit their technologies for appraisal. This represents a financial saving to the DHSC of £10m per year.
56. Any savings will release funds, ultimately for use in providing additional treatments and services in the NHS. DHSC estimates that the NHS provides an additional Quality Adjusted Life Year (QALY, the standard unit of health) for every £15,000 of additional spending.<sup>16</sup> The savings of £10m therefore correspond to a gain of nearly 7,000 (6,700) QALYs per year. When valued at £60,000 per QALY, this health gain has a monetary value of £40m per year, or an undiscounted present value of £370m over the appraisal period.
57. **The present value of net benefits is £354m.**

## Option 2 Assumptions, Risks, and Mitigations

58. This IA considers the costs and benefits of charging companies who submit their technologies for appraisal by NICE, on a cost recovery basis, based on current levels of activity. The introduction of charges is not designed to increase or reduce the number of appraisals undertaken. However, the change in NICE's funding model could increase its ability to respond to changes in demand.
59. Independent of the current proposals, the Department of Health & Social Care (DHSC) is considering the potential for broadening the scope of referrals to NICE which, if agreed between DHSC, NHS England, NICE and industry, could result in up to 20 additional technology appraisals per year.
60. The introduction of charges on a cost recovery basis could remove a capacity constraint on NICE's TA and HST programmes. NHS commissioners are legally required to fund treatments recommended in NICE's final guidance. Therefore, any change in the number, mix, or decision criteria of NICE's TA and HST programmes could potentially have substantial financial implications for the NHS.
61. Industry respondents to the public consultation on these proposals stated their view that the charging, in combination with additional regulatory and market costs that may arise following the UK's exit from the EU, could reduce the attractiveness of the UK as a market in which to develop

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<sup>15</sup> <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>

<sup>16</sup> The DHSC estimate of the cost at which an additional QALY is gained or lost in the NHS is £15,000. This figure is based on a published estimate of the cost per QALY at the margin in the NHS. For further explanation see <https://www.york.ac.uk/che/research/teehta/thresholds/>

and sell new medicines. This could lead to reductions in the number of products coming through the medicines pipeline that would be submitted for appraisal by NICE.

62. Given the uncertainty around whether numbers of applications are likely to increase or decrease, and how charging would influence this, we have assumed that the number of appraisals will remain constant over time. NICE have provided information on the actual volume of published guidance from 2013/14 to 2016/17, and forecasts of TA/HST activity from 2017/18-2019/20. These show sustained growth in earlier years before levelling off. These volumes have been used as the basis for this IA.
63. Second, there is a risk that charging industry removes the incentive for NICE's Centre for Health Technology Evaluation (CHTE) division to seek to control the cost of undertaking appraisals. This risk is mitigated by charging against a defined tariff, set prospectively. This should ensure costs are controlled, as NICE bear the risk of any overspend.
64. Third, there is a risk that reduced Government funding will have a detrimental effect on the quality and rigour of NICE appraisals. This risk is mitigated by setting charges at a level that permits full cost recovery in aggregate, ensuring that NICE's TA and HST programmes are properly resourced, and thus may continue to offer appropriate scrutiny and world-renowned scientific and economic recommendations to the NHS.
65. Fourth, there is a risk that some TAs and HSTs, such as those in new therapeutic areas or that utilise new surrogate indicators or methodologies, may be more costly than typical appraisals. These additional costs are unlikely to be systematically related to the cost and benefit profile of the technology being assessed, and charging on a cost-recovery basis may disadvantage such innovations. This risk is mitigated by charging against a tariff that reflects average costs and permits full cost recovery in aggregate, thus ensuring that novel innovations are not penalised.
66. Fifth, NICE's reputation is founded on the rigour and independence it applies in the development of its guidance. There is a risk that NICE's independence is perceived as reduced by receiving its funding from the companies whose products are undergoing assessment. This risk is mitigated as NICE will continue to develop its guidance through its established methods and processes which entail consideration by independent academic experts and engagement with the full range of stakeholders. Other Government agencies also charge the cost of their activities to the private sector without compromising their independence. This is described in more detail above.
67. Sixth, respondents to the public consultation on these proposals suggested that the introduction of charges may present some risk to the level of innovation. Given that (a) the proposed charges are typically of a different (lower) order of magnitude to the benefits of a positive NICE recommendation, and (b) that the NHS in England represents only a small fraction of the global pharmaceutical market, the introduction of charges is not expected to have any material impact on global R&D investment decision-making. However, Options 3 and 4 consider the costs and benefits of a proposed discount scheme for small companies, designed to mitigate the risk that there may be a non-negligible and detrimental impact on R&D investment by small companies.
68. The proposed policy of charging has also been amended to allow NICE to recover less than their full costs in future should this be required. This would allow NICE to respond flexibly to developments in the life sciences industry, such as including devices and digital products.

**Option 3: Introduce Charges as per Option 2, whilst offering a discounted charge for and staggered payment option for small companies.**

69. NICE wishes to encourage small companies to continue to participate in appraisals and seeks to minimise barriers to their participation. Option 3 would provide a subsidy of 25% to small companies, in effect by funding 25% of the cost of assessments for small companies from NICE's grant-in-aid funding. The remaining assessments would still be charged at the calculated full cost.
70. Historically the number of assessments carried out on small company products amounts to around 10% of the total activity. This has been assessed by examining work done over the past two years.
71. The cost and benefit profiles of Option 3 are given in the Annex tables, summarised in Table 3 below. This option would involve a UK economic cost of approximately £1.7m per year, with a present value (cost) over the appraisal period of just under £14m. Option 3 suggests monetised

health benefits of £39m per year, with a present value of just over £360m. **Over the appraisal period, the net benefits are valued at £347m.**

72. Option 3 was developed specifically to mitigate the risk (highlighted through NICE’s own engagement with industry) that the introduction of charges may have a detrimental impact on the level of innovation by small companies. NICE engaged with Industry on a proposal for the introduction of charges in 2016. NICE’s original proposal did not differentiate on price for multinational or small enterprises.
73. Option 3 is judged to have additional benefits, not quantified, associated with reducing barriers to the participation of small companies. It has not been possible to quantify these benefits, given a lack of evidence on the extent of the barriers faced by small companies.
74. The quantified costs and benefits, risks, and mitigations for Option 3 will be as per Option 2, except for a 25% discount applied to the 10% of activity that it is assumed is associated with small companies.
75. There is a potential for the proportion of submissions from small companies to vary over time. We have assumed there would be no behavioural response in terms of demand to the higher level of discount. The pharmaceutical market is dominated by large companies which reduces the risk of a significant increase in assessments undertaken for small companies. If the proportion of products submitted by small companies rose from 10% to 20%, the financial cost to companies, and revenue to NICE, would fall from just under £9.8m per year to approximately £9.5m per year.

**Option 4: Introduce Charges as per Option 2, with a 75% discount for small companies.**

76. The quantified costs and benefits, risks, and mitigations for Option 4 the same as Option 2, except for a 75% discount applied to the 10% of activity that it is assumed is associated with small companies.
77. Option 4 was developed following DHSC’s public consultation on the proposed charges.
78. The cost and benefit profiles of Option 4 are given in Table 3, below. This option suggests a cost of £1.1m per year, with a present value (cost) over the appraisal period of just under £10m. Option 4 suggests benefits of £37m per year, with a present value of just over £342m. **The present value of net benefits is £332m.**
79. If the proportion of products submitted by small companies rose from 10% to 20%, the financial cost to companies, and revenue to NICE, would fall from just under £9.3m per year to approximately £8.5m per year.

**Table 3** Estimated costs and benefits of each policy option relative to option 1 (no change to regulations, “business as usual” option) over 10-year appraisal period

*£ millions, QALYs*

<b>Costs and benefits of policy</b>	<b>Option 2 - introduce charges on cost-recovery basis</b>	<b>Option 3 - as Option 2, but with 25% discount for small companies</b>	<b>Option 4 - as Option 2, but with 75% discount for small companies</b>
<b>Net benefits of policy (present value)</b>	<b>£353.9</b>	<b>£346.7</b>	<b>£332.4</b>
<b>NHS:</b> financial savings from reduced grant-in-aid to NICE (undiscounted), providing:	£100.2	£97.7	£92.7
- health benefits to NHS patients (QALYs)	6,680	6,510	6,180
- discounted monetised health benefits	£369.7	£360.5	£342.0
<b>Companies:</b> total financial costs of charges to companies submitting appraisals to NICE (undiscounted), of which:	£100.2	£97.7	£92.7
- costs assumed to fall on UK industry (discounted)	£15.8	£13.7	£9.6

Financial savings to the NHS are assumed to produce health benefits at a rate of £15,000 per Quality Adjusted Life Year (QALY). In turn, QALYs are assumed to have a societal value of £60,000 per QALY. Monetised health benefits are discounted at a health discount rate of 1.5% per year, and costs to industry are discounted at a private discount rate of 3.5% per year.

### **Preferred Option**

80. The net benefit (present value) of Option 4 is **£332m**; nearly **£22m (£21.5m)** less than Option 2. However, as noted above, it has not been possible to quantify those additional benefits associated with reducing barriers for small companies. **Option 4 is the preferred option on the basis that it better fulfils the final policy objective of supporting small companies. A 75% discount for small companies is intended to minimise barriers to the participation of small companies and is in line with the Industrial Strategy which states the Government's determination to have the right support for small businesses**

### **Specific Impact Tests: Small and Micro Business Assessment ('SaMBA')**

81. Potential impacts on small and micro businesses have been considered throughout, with Option 4 developed specifically to consider available mitigations.

### **Equalities and Health Inequalities**

82. The Government's response to the consultation details the consideration of equalities and health inequalities.

## Annex – Additional Tables

**Table A1** Benefits from charging companies for NICE TA and HST programmes, compared to option 1 (“business as usual” option)

	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29
<b>Option 2 - introduce charges on cost-recovery basis</b>										
NHS: savings from reducing grant-in-aid to NICE	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022
- health benefits generated (no. of QALYs)	668	668	668	668	668	668	668	668	668	668
- monetised value of health benefits	£40,088	£40,088	£40,088	£40,088	£40,088	£40,088	£40,088	£40,088	£40,088	£40,088
<b>Option 3 - as Option 2, but with 25% discount for small companies</b>										
NHS: savings from reducing grant-in-aid to NICE	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771
- health benefits generated (no. of QALYs)	651	651	651	651	651	651	651	651	651	651
- monetised value of health benefits	£39,086	£39,086	£39,086	£39,086	£39,086	£39,086	£39,086	£39,086	£39,086	£39,086
<b>Option 4 - as Option 2, but with 75% discount for small companies</b>										
NHS: savings from reducing grant-in-aid to NICE	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270
- health benefits generated (no. of QALYs)	618	618	618	618	618	618	618	618	618	618
- monetised value of health benefits	£37,081	£37,081	£37,081	£37,081	£37,081	£37,081	£37,081	£37,081	£37,081	£37,081

**Table A2** Costs of charging companies for NICE TA and HST programmes, compared to option 1 (“business as usual” option)

	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29
<b>Option 2 – introduce charges on cost-recovery basis</b>										
Companies: financial cost of charges	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022	£10,022
- costs assumed to fall on UK industry	£1,904	£1,904	£1,904	£1,904	£1,904	£1,904	£1,904	£1,904	£1,904	£1,904
<b>Option 3 - as Option 2, but with 25% discount for small companies</b>										
Companies: financial cost of charges	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771	£9,771
- costs assumed to fall on UK industry	£1,654	£1,654	£1,654	£1,654	£1,654	£1,654	£1,654	£1,654	£1,654	£1,654
<b>Option 4 - as Option 2, but with 75% discount for small companies</b>										
Companies: financial cost of charges	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270	£9,270
- costs assumed to fall on UK industry	£1,153	£1,153	£1,153	£1,153	£1,153	£1,153	£1,153	£1,153	£1,153	£1,153