Title: *NICE's technology appraisal and highly specialised technology work programmes – charging and Appeals Panels* **IA No:** **RPC Reference No: N/A** **Lead department or agency:** Department of Health **Other departments or agencies: National Institute for Health and Care Excellence**	**Impact Assessment (IA)** **Date:** 05/07/2018 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries:** Jane Newton

Summary: Intervention and Options

RPC Opinion: 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**
£ 374 m	£m	£m	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, the National Institute for Health and Care Excellence (NICE) makes recommendations on whether drugs and other interventions should be funded by the NHS at a given price. NICE's TA and HST programmes are currently funded through the core funding that NICE receives from the Department of Health & Social Care (DHSC). In order to reduce NICE's reliance on government funding, this IA considers alternative options for funding its TA and HST programmes. This is the focus of the present IA. There are parallel proposals to amend regulations concerning membership of appeals panels. These are not considered in this IA since any costs and benefits are not monetisable and likely to be small.

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 the majority of the cost of producing TA and HST recommendations from Government to those life science companies who submit their products for NICE assessment. The exception would be for small companies who would pay 25% less than large 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 SME discount): As per Option 2, with a 25% discount and staggered payment options offered to smaller companies. **This is the preferred option.**

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Month2019/20

Does implementation go beyond minimum EU requirements?		Yes / No / N/A		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	

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 SELECT SIGNATORY: ---------- Date: ----------

Summary: Analysis & Evidence

Policy Option 1

Description: 'Do Nothing'

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:** 0

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. The value of costs and benefits are therefore zero, by definition.

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 NICE's TA and HST programmes current level of activity

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 assessment

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: 365**

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		0.6	**5**

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. The estimated impact on UK society is lower than this, reflecting the fact that the pharmaceutical industry is global, with only around 10% of turnover affecting UK industry. The assumption is that UK production and R&D decisions would be unaffected overall by the proposed system of charging, so that the only expected impacts would be on UK shareholder profits. The discounted value of these impacts over the 10-year appraisal period is costed at just under £5 million (£4.8m).

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	0		40	**370**

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, if 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 their work.

Key assumptions/sensitivities/risks **Discount rate (%)** NHS 1.5% Other 3.5%

The estimates are based on the current volume or mix of assessments, assuming that these would be the same as in to Option 1. Consequently, the costs and benefits refer respectively to the UK societal 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 assessment, 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: 356**

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		0.5	**4**

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

Business: The majority of costs of TA and HST programmes (£10 million per year) would be covered by payments from life sciences companies, with a 25% discount for small companies (defined by the Companies Act 2006) worth around £0.25 million per year. The discounted impact of these costs on UK society over the 10-year appraisal period is just over £4 million (£4.1 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	0		39	**360**

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

The public purse (DHSC) would save the full cost of HTA activity (£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 their work. Providing a discount to small companies could 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.
Additional administrative costs associated with collecting charge revenue are negligible and that work is undertaken by current NICE staff without displacing other activities.

10% of submissions for NICE appraisal are from small, UK-based companies.

BUSINESS ASSESSMENT (Option 3)

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. Through its TA and HST programmes, NICE makes recommendations on whether drugs and other treatments should be routinely funded by the NHS, depending on evidence of their cost-effectiveness. NHS commissioners are legally required to fund treatments recommended in NICE's final guidance.
2. This activity is currently funded from the Grant-in-aid funding that NICE receives from the DHSC. NICE's funding from the DHSC has been reduced in recent years[1] and NICE needs to identify other sources of funding to enable it to continue the full breadth of its work. The scope and impact of this wider programme of work is hard to quantify, and the potential benefits of this wider programme of work have not been costed in the present IA.
3. The policy question is whether the costs of NICE's TA and HST programmes should be transferred from Government to those life sciences companies who submit their products for NICE assessment.

Rationale for intervention

4. The Cabinet Office triennial review of NICE, published in July 2015[2], recommended that consideration should be given to whether NICE should introduce charges to industry for its appraisals activity. The Accelerated Access Review published in October 2016[3] endorsed the recommendation in the triennial review that NICE should consider recovering the costs of its assessments, given the value to industry of a technology appraisal.
5. Public bodies are increasingly looking to reduce their reliance on Government funding and seek other sources of revenue. The introduction of charges for this activity will bring NICE into line with other public bodies in the health and care sectors that recover the costs of independent regulatory, inspection, licensing and compliance activities directly from the organisations subject to these regimes.
6. 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.
7. An amendment to NICE's regulations is required for NICE to charge for producing TA and HST guidance.

Policy objective

8. The policy objectives are to:
    - reduce NICE's reliance on Government funding while ensuring that NICE is able to continue the full breadth of its work;
    - enable NICE to recover the costs of producing its technology appraisal (TA) and highly specialised technologies guidance (HST) from life science companies whilst maintaining the same level of rigour and independence; and
    - ensure that small companies are not dissuaded from developing and marketing new technologies in the UK.

[1] There was a reduction of £3.3 million (6%) from 2017-18 to 2018-19 in cash terms. NICE Business Plan 2018-19 (https://www.nice.org.uk/Media/Default/About/Who-we-are/Corporate-publications/Corporate-and-business-plans/business-plan-18-19.pdf)

[2] 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)

[3] Accelerated Access Review: Final Report (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/565072/AAR_final.pdf)

Options considered

Option 1: ‘‘Business As Usual’

9. This is the baseline against which other options are assessed. The value of costs and benefits are therefore zero, by definition.
10. In 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 thus does not meet the objective of reduced reliance on Government funding, and against the context of public bodies reducing their reliance on government funding, may not be sustainable in the long run.

Option 2: Introduce Charges

11. NICE is permitted to introduce charges for those companies who submit their products for assessment, against a defined tariff, on an aggregate cost recovery basis.
12. Products will 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.
13. 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.
14. 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 discounted charge for and staggered payment option for small companies.

15. NICE and Government wish to encourage small companies to continue to participate in TA and HST assessments and seeks to minimise barriers to their participation.
16. 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). The effect of this subsidy would be to reduce income from TA and HST charges to NICE by around 2.5%; and

    - 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.

17. NICE will keep the charging model under review to ensure that there is no detrimental impact on the willingness of companies, including small companies, to launch products in the UK.

The cost of NICE's TA and HST programmes

18. NICE undertakes a number of different types of TA and HST assessment, and has derived unit costs for each by attributing total spend (comprising direct, indirect, and overhead costs) of their TA and HST programmes in 2016/17 to their respective volumes.
19. In order to reflect the varying complexity (and so costliness) of different types of assessment, a weighting approach has been taken. Whilst it has not been possible to calculate these weights by considering historical cost data (as NICE has had no need hitherto to capture costs in this way and some types of assessment are new), an estimate has been made based on the length of time each type of assessment takes or is planned to take, the number of committee meetings each type requires, and so on.[4]
20. These derived unit costs directly inform the proposed schedule of charges, with the amount payable by a company submitting a technology for appraisal given in Table 1, below:

Table 1: Estimated cost per appraisal/proposed charges for 2019/20 (£000s), by appraisal type

£ thousands

Appraisal type	Cost
Single Technology Appraisals (STA)	£126
Highly Specialised Technologies guidance (HST)	£126
Fast Track Appraisals (FTA)	£88
Multiple Technology Appraisals (MTA) - Standard	£188
Multiple Technology Appraisals (MTA) - Complex	£251

Source: Updated estimates from NICE, July 2018

21. 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; thus, no assessment of costs associated with VAT is made here.
22. To calculate the total cost of NICE's TA and HST programmes, these costs/ proposed charges must be scaled by expected volumes based on current figures. NICE has provided information on the actual volume of published guidance from 2013/14 to 2017/18, and forecasts of TA/HST activity for 2018/19. These show sustained growth in earlier years before levelling off. These data have been used as the basis for this Impact Assessment, and are shown in Table 2, below.

[4] The weightings used are as follows: Single Technology Appraisals (STAs) are taken as the base unit (that is, they are given a weighting of 1); Highly Specialised Technology evaluations (HSTs) are observed to require similar resource and 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 are given a weighting of 1.5 and 2 respectively.

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

Appraisal type	2013/14	2014/15	2015/16	2016/17	2017/18	2018/19
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
Total	**32**	**32**	**49**	**55**	**73**	**78**

Source: Updated estimates from NICE, July 2018

23. It should be noted that the increase in output for 2017/18 is the result of a change in demand and planned increase in capacity to NICE's TA programme[5], rather than reflecting an underlying trend. The amount of activity undertaken as part of NICE's TA and HST programmes may be volatile, varying over time in line with the medicines pipeline. For the purpose of this Impact Assessment, we have used the 2018/19 activity levels.

24. Note that these numbers refer to the volume of published guidance, but charges will be payable at the beginning of a TA/HST, not at its conclusion, with the exception of small companies who can pay in instalments. Taking the forecast number and composition of appraisals in 2018/19 (Table 2) and the proposed charges for 2019/20 (Table 1), it is estimated purely on the basis of these figures that the total cost of TA and HST programmes will be £10 million per year over the next ten years from 2019/20 to 2028/29. These figures take no account of any changes to activity levels that might occur.

25. The impact of transferring these costs from the public purse to those companies who wish to submit their technology for appraisal, through the introduction of charges (Option Two), and through charges with a discounted rate for small companies (Option Three), are considered below.

[5] https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/technology-appraisals/increasing-ta-capacity-consultation.pdf

The Costs and Benefits of Each Option

Option 2: Introduce Charges

Costs

26. It is anticipated that the full cost of NICE's TA and HST programmes will be transferred to companies wishing to submit their technologies for appraisal and based on current figures this has a *financial* cost to companies of **£10m per year**, paid through charges described above.

27. The introduction of charges will bring about a reduction in company revenues commensurate with the increase in savings for the public purse, and in turn resulting in a reduction in the profits gained by shareholders in pharmaceutical companies. This reduction reflects the UK societal impact.

28. In line with HMT Green Book guidance, a number of adjustments are made to the financial cost in order to estimate the impact on UK society, by reflecting: (a) the proportion of revenue taken as profit; and (b) the proportion of revenue that is earned in the UK.

29. Empirical estimates of the proportion of the reduction in gross profits that will translate into loss of profits for shareholders are not available. However the Department for Business, Energy and Industrial Strategy (BEIS) has provided an estimate that 30% of pharmaceutical revenue is ordinarily taken as profits.

30. The pharmaceutical industry as a whole is global so, overall, the majority of NHS drug spending will accrue to overseas interests. BEIS estimate, based on analysis of trade information, that around 10% of drug spend is on domestic production – that is, output generated by UK factors of production (UK-owned capital or UK labour). Assuming that returns to capital are shared between the UK and overseas in the same proportion as total returns, this implies that a corresponding proportion of the reduction in profits will accrue to UK shareholders.

31. It is assumed that one in ten submissions are from small companies. For the purpose of this Impact Assessment those 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.

32. The net result of these adjustments suggests that the true cost of this option is **£ 0.5m per year**, and that it has a present value (cost) of **£4.8m** over the appraisal period. Table 3 below summarises these assumptions.

Table 3: Summary of assumptions used to estimate UK impact of costs to industry

Input	Value	Source
Gross profits as a proportion of pharmaceutical revenue	30%	BEIS
Ratio of UK to global industry (including through share ownership)	10%	BEIS

33. Though charges are designed to fully recover costs, any additional administrative effort associated with the collection of charging could not be considered a saving (as it represents additional expenditure, offset by charges, relative to the 'Business As Usual' scenario). However, NICE has indicated that additional administrative effort is expected to be negligible and can be wholly absorbed by existing staff and budgets, thus no estimate is made here.

Benefits

34. It is anticipated that the full cost of NICE's TA and HST programmes would be transferred to companies wishing to submit their technologies for assessment and this represents a straightforward financial saving to the DHSC of **£10m per year.**

35. 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.[6] 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 a Present Value of **£370m** over the appraisal period.

36. The Net Present Value of this option is estimated at **£366m**.

[6] The DH 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/

Assumptions, Risks, and Mitigations

37. A number of risks and mitigations are identified below.

38. This Impact Assessment considers the costs and benefits of charging companies whose technologies are due to be assessed by NICE, on an aggregate cost recovery basis, and based on current levels of activity (relative to the 'Business As Usual' scenario). The introduction of charges is not designed to increase or reduce the number of assessments undertaken. However, the change in NICE's funding model could increase its ability to respond to changes in demand.

39. First: the introduction of charges on a cost recovery basis could remove a capacity constraint on NICE's TA and HST programmes, and might increase activity. 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.

40. Given that new technologies may have an incremental cost effectiveness ratio (ICER) that is higher than the marginal productivity of NHS spending (£20,000-£30,000 per QALY vs £15,000 per QALY), and that the funding requirement that follows a recommendation by NICE is generally associated with an increase in uptake, any additional activity in NICE's TA/HST programmes could have the effect of displacing other health and care services and treatments to the potential detriment of overall cost-effectiveness.

41. 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.[7] These data have been used as the basis for this Impact Assessment.

42. Second: There is a risk that charging on a cost recovery basis 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.

43. 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.

44. 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.

[7] It should be noted that the increase in output for 2017/18 is the result of discrete efficiency savings that NICE's 'Strategic Technology Appraisal Review' (STAR) is expected to make, and is more likely to present a change in the level than in the trend. The amount of activity undertaken as part of NICE's TA and HST programmes may demonstrate some volatility, varying over time in line with the medicines pipeline.

45. 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.

46. Sixth: Respondents to NICE's own consultation suggested that the introduction of charges may present some risk to the level of innovation. Given that (a) the proposed charges are 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, Option 3 considers 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.

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

47. NICE wishes to encourage small companies to continue to participate in assessments and seeks to minimise barriers to their participation.

48. Two measures have been designed 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 assessments for small companies from NICE's Grant-in-aid funding. The remaining assessments 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); and
    - 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.

49. 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. Whilst there is a potential for the proportion to vary over time, the pharmaceutical market is dominated by large companies which reduces the risk of a significant increase in assessments undertaken for small companies.

50. **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.**

51. The cost and benefit profiles of Option 3 are given in Tables 8 and 9, below. This option suggests a cost of **£0.5m** per year, with a present value (cost) over the appraisal period of just under **£4m.** Option 3 suggests benefits of **£39m per year,**

with a present value of just over **£360m. The Net Present Value of costs and benefits is £356m.**[8]

52. Option 3 is judged to have additional benefits, not quantified, associated with minimising 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.

53. 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.

Preferred Option

54. The Net Present Value of Option 3 is **£ 365m**; nearly **£9m (£8.6m)** 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 3 may be considered to be the preferred option on the basis that it better fulfils the final policy objective of minimising barriers to the participation of small companies.**

Sensitivity/Scenario Analyses

55. The charging regime will operate on an aggregate cost recovery basis, with charges reviewed regularly. The primary sensitivity of this Impact Assessment – that observed costs differ from the proposed schedule of charges – is thus easily correctable, obviating the need for additional sensitivity analyses. Although the assumptions used to estimate the UK societal impact of charging industry are uncertain, changes to these inputs would not be expected to alter the ranking of the options or the discrepancy between costs and benefits.

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

56. Potential impacts on small and micro businesses have been considered throughout, with Option 3 developed specifically to consider available mitigations.

Equalities and Health Inequalities

57. The consultation document details the consideration of equalities and health inequalities.

[8] Note that the financial impact again differs from the estimated impact on UK society: the proposed discount would correspond to a financial saving of £0.25m per year for small companies.