

Response ID ANON-2C2Q-5M1F-H

Submitted to **Charging for technology appraisal and highly specialised technology recommendations and miscellaneous amendments to NICE legislation**

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About you

1 What is your name?

First name:

Paul

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2 What is your email address?

Email:

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3 Is it okay for the Department of Health and Social Care to contact you by email about your response?

Yes

4 Are you responding as an individual or on behalf of an organisation?

Organisation

Organisation response

5 What is your organisation's name?

Organisation:

Royal College of Radiologists

6 Which sector does your organisation work in?

Other

If other please specify:

Professional membership body

7 We will be producing a report after the consultation closes. Let us know if what we can include from the options below:

Your response, Your organisation's name

Consultation questions

8 Do you agree or disagree that charging companies for making technology appraisal and highly specialised technology recommendations provides a more sustainable model for this activity in the longer term, given the wider policy landscape, budgetary pressures and the need to be responsive to developments in the life sciences industry?

Agree

Please explain your response, including any alternative proposals if you disagree.:

Charging seems sensible given the likely increased demand for appraisals, austerity in the NHS, and the need to get innovative products to the NHS patient. We understand that the aim is to improve the quality of assessors presumably by using the funding to provide backfill to release expert assessors. Caveat is that there will be no one available to provide backfill - certainly in radiology – even the outsourcing companies cannot currently cover the demand. However, it is important to ensure that NICE processes are not changed by payment and ensure that stakeholders are reassured / convinced of that.

9 Do you agree or disagree that such charges should be calculated on a cost recovery basis?

Disagree

Please explain your response, including any alternative proposals if you disagree. :

The complexities of NHS finances will make calculations based on a cost recovery basis challenging. If whatever NICE charges for appraisal results in the costs being recoverable by the company, this is likely increase cost to the NHS. The proverbial catch 22: to support the cost of NICE appraisals, the downstream cost to the NHS will increase. How are the costs recovered if the technology fails NICE appraisal and is not adopted?

10 Do you agree or disagree that small companies (as defined by the Companies Act) should pay 25% less for technology appraisal and highly specialised technology recommendations than larger companies?

Agree

Please explain your response, including any alternative proposals if you disagree.:

Small companies should have a discount but, given the small impact on overall costing of a 25% reduction and the wish (stated elsewhere) to encourage small entrepreneurs, we wonder if there needs to be scope built in for more than one level of payment e.g. a sliding scale where the smallest/shortest established get a 40% discount? It will need to be a simple formula however, otherwise scrutinising financial company profit levels may be necessary, which adds a new unwanted level of complexity.

One additional caveat is that, even if SMEs pay 25% less, it may still not be affordable at the time they apply as costs may only be recouped once technology has passed NICE assessment. This may well act as a deterrent to some SMEs applying at all.

11 Do you agree or disagree that small companies should be able to pay in installments as proposed in paragraph 2.4 bullet 2?

Agree

Please explain your response, including any alternative proposals if you disagree.:

Paying in installments seems sensible, but the proposed 40/50/10 could still be prohibitive. We can understand that these companies should not be presenting for NICE approval without a robust expectation of a positive outcome, but the three very large payments could act as a disincentive to the smallest companies or those with only one product.

12 Do you agree or disagree with the analysis in the accompanying Impact Assessment on the impacts of the proposed charging?

Disagree

Please explain your response, including any alternative data or assumptions if you disagree.:

The impact assessment suggests all monies saved (that would have otherwise been spent on assessments) will be used to pay for 'NHS expert time'. However, this assumes that backfill/outourcing is available, and that the generated funds will go towards this. This is a big assumption in shortage specialties, especially considering that outsourcing companies are already struggling to cope.

Also, given the preface that this money is not currently in the system and that capacity would be reduced if charging is not implemented, it seems unrealistic to suggest that the money not actually there, will be put back into the NHS in a way where measurable QALYs will be saved.

13 Do you agree or disagree that NICE's appeal panel NHS membership should be drawn from the whole of the UK and not just England?

Agree

Please explain your response:

In order to get access to the best opinions, the option to go UK wide is sensible.

14 Do you have any further comments on the proposals in this consultation document?

Further comments:

1. This covers all devices, but in the supporting literature there is specific mention of pharma only, and that all pharma is large. There needs to be cognisance that the presentation of artificial intelligence (AI) and mechanical devices, (created by a spectrum of niche small life-sciences companies, through to global conglomerates), are likely to vastly increase in the coming years.

2. Often a number of companies develop a similar device at a roughly similar time. There is scope to encourage companies that they should proceed down the Technology Appraisals (MTA) route, especially if all have similar levels of evidence available. Making it explicit that MTA is a preferred option, might encourage companies to enter into trials of comparative outcomes rather than one versus another. Competition could result in consumption of significant resources and, in rare indications, the available population of patients. This could be further incentivised by, for example, a reduction in payment for all technologies who are assessed together.

3. We are slightly concerned that by charging companies, there will be an unspoken expectation that the recommendation will be likely a positive one. This will need to be made explicit from the outset. Not all technology appraisals will/should have positive outcomes. A false expectation of success may result in an increase in appeals which could prove costly, negating benefits accrued from charging in the first place. However, we appreciate that the charging mechanism should encourage companies to have products that are potentially market-ready before they apply.

4. NICE does not think there will be a reduction in the number of assessments - charging might deter smaller companies from applying for NICE approval. Also, will charging change the way NICE approaches assessments?

Feedback on consultation process

15 Help us improve how the department runs consultations by answering the following questions:

Satisfied

Further comments::

Satisfied

Further comments::

16 How did you hear about this consultation?

Direct communication from third sector organisation or regulatory organisation

Other please specify: