

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE and NHS ENGLAND

Proposals for changes to the arrangements for evaluating and funding drugs and other health technologies appraised through NICE's Technology Appraisal and Highly Specialised Technologies programmes

Comments proforma

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Role:	Chair, Scientific Committee
Organisation:	The Royal College of Ophthalmologists
<p><i>Have you or your organisation received any payments, grants or other funding from the pharmaceutical industry in the last three years?</i></p>	<p>Personal DOI: Currently chairman of NICE Cataract Guideline Development Committee</p> <p>Organisational DOI: The Royal College of Ophthalmologists receives funds from government bodies and charitable trusts which is spent in pursuit of our charitable objectives. The only funds received from a pharmaceutical company was £40,000 from Bayer in 2014 which was distributed as part of the awards and scholarship scheme – no money was kept by the RCOphth.</p> <p>We have commercial relationships with a variety of companies – we sell advertising space (College News and Eye- this via a third party publisher) and exhibition space (some seminars and for Congress – this via Optic UK, a trade association). We could find out how much, it would be difficult but this is at market rate.</p> <p>In 2013 and 2014 we had a fundraising drive for the refurbishment of 18 Stephenson Way. Of the c £500,000 only £10,000 was cash from instrument firms, the rest was from charitable trusts and members. We do have gifts in kind for the Skills Centre.</p>

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Consultation Question	Response to consultation questions Please do not paste other tables into this table, as your comments could get lost – type directly into this table.
1. Do you agree that NHS England should set a budget impact threshold to signal the need to develop special arrangements for the sustainable introduction of cost effective new technologies?	Yes In the context of an increasingly financially constrained health budget, this proposal provides a clear framework for industry, healthcare purchasers, clinicians and patients
2. Do you agree that £20 million is an appropriate level? If not, what level do you think the threshold should be set at and why?	Yes Evidence provided in the consultation document suggests that the proposed threshold will affect only around 20% of new technologies. Is there any expectation that the threshold will increase automatically in line with inflation or NHS expenditure?
3. Do you agree that NHS England should enter into a dialogue with companies to develop commercial agreements to help manage the budget impact of new technologies recommended by NICE?	Yes This clearly has the potential to reduce NHS expenditure. Ideally the details of any such agreement should be in the public domain. This may not be possible but, as a minimum, the fact that such an agreement has been made should be known, and the agreement should be uniform across the NHS, rather than being negotiated with individual purchasers.
4. Do you agree that NICE should consider varying the funding requirement for technologies it recommends, for a defined period, in circumstances where NHS England makes a case for doing so, on the grounds that the budget impact of the adoption of a new technology would compromise the allocation of funds across its other statutory responsibilities?	This would be reasonable provided that there is a robust process in place by which NHS expenditure could be increased or reallocated that could be undertaken during the defined period. Ideally, such a process should have been defined as part of the consultation document. There should be a defined maximum amount of time by which NICE can vary a funding requirement.
5. Do you consider that the criteria for the fast track process	The criteria are appropriate, but evidence for both cost per QALY and budget impact may

<p>are appropriate? If not, what other criteria do you suggest?</p>	<p>be limited or of poor quality at the start of the process, and any such evidence is likely to have been generated by the company concerned.</p> <p>As companies may seek to exploit this fast track process, consideration should be given to requiring companies to enter a commercial agreement to address the possibility that the new technology eventually exceeds the budget impact.</p> <p>Presumably, the proposed fast track process will be subject to continuous audit against these criteria.</p>
<p>6. Do you agree that NICE should ‘fast track’ new health technologies with a maximum incremental cost effectiveness ratio of £10,000 per QALY and whose costs are estimated to fall below the budget impact threshold?</p>	<p>There are good cost savings arguments in favour of doing so.</p>
<p>7. Do you agree that NHS England should commit to accelerating funding for technologies approved under the fast track process from 90 days to 30 days?</p>	<p>No</p> <p>The current 90 days is in place in order that appropriate health resources, including staff are in place. There is no evidence to suggest that, just because a new technology meets the criteria for fast tracking, that such resources can be put in place any more quickly.</p>
<p>8. Do you agree that NICE should absorb its proposed ‘abbreviated’ technology appraisal process into the proposed fast track process?</p>	<p>In principle, yes. However, it is my understanding that the current eligibility criteria for the abbreviated technology appraisal process are:</p> <ul style="list-style-type: none"> • they are expected to provide similar or greater health benefits, compared with an established NICE-recommended treatment for the same indication • they are expected to have a similar or lower cost, compared with this comparator • they can be compared with 1 or more technologies already recommended in published NICE guidance for the same indication <p>Will these criteria remain as alternatives to the proposed cost effectiveness and budget impact thresholds in the proposed fast track process?</p>
<p>9. Do you agree that NICE and NHS England should use a cost per QALY below which the funding requirement is applied for Highly Specialised Technologies?</p>	<p>Yes</p>

<p>10. Do you agree that £100,000 per QALY is the right maximum up to which the funding requirement would be applied? If not, what cost per QALY do you suggest, and why?</p>	<p>On balance, this is reasonable, given the potential development costs and small population to treat.</p>	
<p>11. Do you agree that if the cost per QALY level is exceeded, the technology should be considered through NHS England's specialised commissioning prioritisation process?</p>	<p>No</p> <p>It would appear that the reason for switching from a NICE assessment process to an NHS England specialised commissioning prioritisation process is the subsequent funding stream. The consultation document suggests that if the cost per QALY exceeds £100,000, the technology will be evaluated by NHS England, potentially using a different assessment process.</p> <p>I would recommend that NICE determine the cost per QALY for all new technologies. NHS England should not duplicate this evaluation if the £100,000 threshold is exceeded. Its role should be limited to one of negotiating funding. In this way it will be clear that all evaluations of cost per QALY are carried out by one organisation (NICE) using the same process.</p>	
<p>12. Do you agree the proposed new arrangements mean that NICE would not need to take budget impact into account in its highly specialised technologies evaluations?</p>	<p>It is my understanding that the reason NICE will undertake a budget evaluation in future is to</p> <p>"... inform the arrangements, described below, which NHS England will seek to put in place to help manage the impact of technologies, recommended by NICE, which have a very high budget impact."</p> <p>Apart from this procedural issue related to subsequent funding of new technologies, NICE will not take budget impact into account when performing any assessments. It is therefore reasonable for NICE not to take budget impact into account in its highly specialised technologies evaluations as the subsequent stream is different.</p>	
<p>13. Do you consider that any proposals in this consultation would result in NICE or NHS England failing to comply with their responsibilities under the relevant equalities legislation?</p>	<p>No</p>	
<p>Section number primarily related to your</p>	<p>Other</p>	<p>General comments</p>

<p>comment (please enter only one)</p> <p>Indicate 'general' if your comment relates to the whole document</p>	<p>section numbers related to your comment</p>	<p>Please insert each new comment in a new row.</p>

To submit your comments, please email this form to: TAandHSTconsultation2016@nice.org.uk

Closing date: Friday 13 January 2017

PLEASE NOTE: NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of the Institute, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.