

## 6 Consultation questions

6.1 The Institute would like to receive comments on the proposal to issue supplemental advice to its Appraisal Committees, in the form of an amendment to its *Guide to the Methods of Technology Appraisal*.

6.2 The particular matters on which the Institute is seeking a response are as follows:

6.2.1 Your view on the proposition that the Committee should be asked to place additional weight on proven survival benefits in patients with terminal illness and short life expectancy;

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- FPM welcomes the proposal for broader access to treatments for patients approaching the end of their life. FPM is concerned about the weight given to survival benefits, and recommends considering added therapeutic value, including health-related quality of life in addition to life extension, as a more appropriate basis for the supplemental advice proposal.*

6.2.2 Whether the wording in section 2, in particular, is appropriate and will help the Appraisal Committees achieve the objective set out in section 1;

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**2.1 The Institute will amend the advice it gives to its Appraisal Committees to ask them to consider recommending the use of medicines, with an ICER in excess of £ 30,000, where all the following criteria are met:**

- FPM supports the proposed withdrawal of an upper ICER threshold for recommending the use of medicines in patients approaching the end of their life.*
- FPM is of the opinion that the eligibility criteria should be based on added therapeutic value considerations in terms of not only length of life, but also the patient's health-related quality of life.*

**2.1.1 The medicine is indicated, in its licence, for a patient population normally not exceeding 7000 new patients per annum, and;**

- FPM is concerned with the proposed limit of 7000 for this favours patients with uncommon forms of cancer over others. FPM would like NICE to enter into dialogue on the consequences of such a limit for terminal patients with for example, other cancers.*

**2.1.2 The medicine is indicated for the treatment of patients with a diagnosis of a terminal illness and who are not, on average, expected to live for more than 24 months, and;**

- FPM accepts that 24 months is, on average, is a wide ranging, working hypothesis and we understand that predicting remaining life expectancy is very difficult and we suggest that NICE may wish to adopt a flexible approach, to ensure that the maximum number of patients have the opportunity to receive such therapies.*

**2.1.3 There is sufficient evidence to indicate that the medicine offers a substantial extension to life, compared to current NHS treatment.**

- ***FPM would like to see either survival benefits or health-related quality of life benefit or both of these as eligibility criteria.***

**2.2.1 The estimates of the extension to life are robust and can be shown or reasonably inferred from either progression free survival or overall survival (in trials in which cross-over has occurred and been accounted for in the effectiveness review). Life-extension inferred from modelled mortality gains, where the effects of the intervention are only on morbidity will not be sufficient, and;**

- **O.K.**

**2.2.2 The assumptions used in the economic modelling should be plausible objective and robust, and;**

- ***FPM welcomes that NICE modelling will now be transparent.***

**2.2.3 No alternative treatment with comparable benefits is available through the NHS**

- **O.K.**

**2.3 Higher ICERs will need to be justified by demonstrable increases in extension to life, and a sound case for the impact of innovating for a small patient population. *Either survival benefits or health-related quality of life benefit or both of these.***

6.2.3 Whether there are valid alternative methods which might be used to achieve the same ends, in the short or the long term.

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- ***FPM understands that risk sharing agreements are happening and would recommend consideration of conditional approval whilst awaiting further data, including health-related quality of life. Indeed, where evidence of lack of benefit or increasing harm arise, consideration should be given to early termination of therapy.***

6.2.4 Other comments

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6.3 Responses to consultation should be made by 5.00 pm on Wednesday 10 December 2008.