

General comments on the proposal

Role	Comments
Chair of UK registered Charity	Life is precious, and every help should be made available to a patient in order for them to have a longer life if they so wish.
NHS Professional	WRT following up recommendations in the form of ongoing audit what if centres do not provide the appropriate data? How will this be set up to ensure timely feedback and will Trusts be funded to do this? 7000 appears to me to be quite a high figure - in our patch (1M pop) that would equate to over 100 patients - if for example lenalidomide was approved via this system AND the incidence was such that 100 pts would receive treatment that would equate to Â£5M per annum - how will this be funded?
other	The Appraisal Committees are working to a formula which is not transparent to healthcare professionals and impossible for patients or carers to understand. The credibility of NICE is at stake here as their system is denying drugs and treatments routinely available in developed countries. This reform is only part of a very necessary package to bring England into line
NHS Professional	We need to mend NICE before it becomes so far out of touch in this area. NICE needs to build credibility with the public so its important message that we should only use medicines which work is not buried in avoidable controversy
NHS Professional	1.1 – refers to effective use of ‘NHS resources’ – should this be cost effective – incorporating notion of clinical effectiveness, operation and allocative efficiency, affordability and opportunity cost. These are all of crucial importance to the funder (ultimately the taxpayer) of health care and probably not well understood by the average taxpayer. A fuller understanding of the implications is important in allowing the public to come to an informed view. 1.5-refers to ‘medicines’. Should this be all health technologies?
NHS Professional	It is inappropriate to apply lower thresholds to some treatments over others. this is inequitable. Implying that the rarity of a condition would also lower the threshold to approval of treatment is also inequitable. Rarity does not confer higher priority , it simply states a lower natural prevalence. The only equitable way forward is to apply the same rules to all treatment modalities.
Biostatistician	Applaud NICE-evaluation plan but note tacit assumption that patients who receive NICE-tx give data access. Same may not apply for patients who elect NOT to accept tx. Suggest prototype design as follows: Baseline 1. diagnosis date 2. date of entering progression state 3. date of tx election. 4. up to 10 covariates 4.1 sex 4.2 year of birth 4.3 NHS region 4.4 Eq-5d state at election 4.5 to 4.10 other key covariates (eg yes/no re prior surgery, radiotherapy, chemotherapy, immunotherapy) 5. start date: NICE tx 6. end date NICE tx 7. costly adverse event/ICU date 8. death date RANDOM 1 in 5 sample to RECORD: 9. serial (3-monthly) EQ-5d states or costs
Patient	I would hope that the appraisal committee would listen to specialists such as the 26 oncologists that wrote in support of Sutent for kidney cancer patients, and also listen to the citizens council, when making decisions, so that compassion and common sense prevail, and we can be proud of our NHS, based on these higher principles than

	cost alone.
Local government professional	I would like to think that the wording and proposals above, will not exclude those already paying privately for their treatments, even if they fall outside of the time frame limits!
NHS Professional	I feel strongly that the title of this consultation document is misleading. May I suggest that something like Appraising disease modifying medicines at the end of life would be more appropriate.
NHS Professional	there are other illnessess - such as alzheimers disease and other dementias, that although the disease itself is not terminal, the patients life in quality terms is very short. the QALY cost for these patients has not been adjusted accordingly - but perhaps it ought to be?
Patient	Many of my patient group need Sutent NOW! Â Please deliver your final decision asap.
Patient	We need to make these drugs available to all who need them, not just for humanitarian reasons. Â A larger data base of use will surely clarify future decisions and might in some cases, by prolonging survival rates, even save lives which would otherwise definitely be lost. Â There is always a potential cure around the corner with the amazing advances being made by our superb medical researchers - not all of these will necessarily be exorbitantly priced drugs. (For example, the HIFU treatment being researched in Oxford and supported by the charity UCARE.) All patients deserve the right to life, and quality of life if they are terminal, and at least the hope of surviving to benefit from future advances.
Consultant	I believe that all claimants on NHS resources should be treated the same, regardless of the nature and cause of their health problem (though very minor problems might deserve fewer resources). For the first ten years of its life, this was the Institutes position. It is difficult to fathom why the position has changed, unless the Institute has been placed under political pressure. There was little point spending so much effort establishing your reputation for independence and robustness, only to roll over now. The claim that those terminally ill value life highly is correct, but do not those with deteriorating sight value their continuing ability to see, those with mental health problems value their ability to maintain their mental functioning, those with pain from chronic disease value a pain-free state, just as highly? Others who depend on the NHS will pay the opportunity costs of extra funding for cancer drugs, and the equity of the service will be damaged.
Patient	I have been refused these drugs due to cost effectiveness and this is totally unfair, I have a right to life and if there is a drug to help me in this fight to live then I deserve to be given it. You pay for people to give up smoking they are a burden on the health costs as they choose to smoke I DID NOT CHOOSE TO GET CANCER, I DO NOT SMOKE OR DRINK I EAT A BALANCED AND VARIED DIET AND TRY TO BE AS HEALTHY AS I CAN, I should not have been condemed to a life on death row as IVE COMMITTED NO CRIME TO FIT THE PUNISHMENT YOU ARE PLACING ON ME AND OTHER PATIENTS WHO NEED THESE DRUGS. THE STRESS AND WORRY YOU CAUSE US BY DELAYING THIS DECISION AND THE PAIN YOU PLACE OUR FAMILY MEMBERS UNDER IS TOTALLY UNACCEPTABLE! Why research life saving/extending drugs then dangle them like a carrot to patients but refuse to let them have them on cost what price can be put on a life?
Patient	Perhaps a more personal approach needs consideration. Â How would individual members of the NICE panel feel if

	it was themselves or their loved ones that were faced with the situation of knowing there was a drug which could help to extend their lives, but was only for the rich. Â As for "free" NHS treatment. Â I have paid National Insurance contributions all my life, so is this not my right to receive NHS treatment?
Public	It should also be noted that some people do not want to accept life-extending treatment and the availability of these treatments on the NHS should not affect the way they are cared for.
Public	It would help if this page explained what the normal allowance per QALY used by NICE. This should be public and in no way hidden. While the page is an attempt at plain English. Why not something like NICE currently will only approve treatments that achieve a QALY for Â£20000 (or what ever) but proposes to increase this to Â£100,000 for a maximum 7000 people per annum who have a rare terminal condition. Im sure it needs adjusting but Im sure you get the idea.
Patient	Please support this cause as the this drug is far superior to any existing archaic treatment with far fewer side effects & in some cases allows patients to wok towards a possible cure.
Patient	I have tried Interferon Alpha, and last month it stopped working for me. Apparently I did very well on it, as it held my tumours for 6 months. If my Oncologist were to accept the situation as is then I would have been sent home to die. Instead I have hope, and so I have returned to work and am looking forward to going on with my life, paying taxes and contributing to society. I feel confident that if I were to appear before my PCT they would agree that I am someone who has a lot to offer, but why should I get preference above someone else. What a decision a PCT is being asked to make. Spend the money please, it isnt yours its mine, and the government has it in its coffers. and stop asking these loaded questions.
other	Being from another country I really believe that your NHS system works, and will continue to work as long as people see people and not money. Â Money does not make who we are.
Patient	Whilst we all welcome a further appraisal of these drugs any further delay could be fatal for many sufferers. So please do not put any delay on the final process as people need these drugs NOW. Please instruct all PCTs to make these drugs available to all patients immediately before the final decision rather than the unsatisfactory present guideline which has led to the current post code lottery. The amount of money spent on Cancer drugs was reduced last year, that make us one of the lowest in the western world. WHY??
Carer	THESE KNEW DRUGS MUST BE MADE AVAILABLE TO CANCER PATIENTS.IT IS EVERYONES HUMAN RIGHT TO ACCESS THESE DRUGS. THE QUALY FOR THESE DRUGS ARE NOT AS EXPENSIVE AS YOU MAKE THEM OUT TO BE.LOTS OF THINGS NEED TO BE TAKEN INTO CONSIDERATION,EG.SUNITIB, MOST PATINTS TAKE A REDUCED DOSE (37.5mL)WHICH IS CONSIDERABLY CHEEPER THAN THE HIGH DOSE OF 50ML.MOST PATIENTS ARE ON 37.5ML.THIS MUST BE LOOKED AT. IF A LOVED ONE CAN HAVE 6/12 MONTHS EXTRA LIFE IT SHOULD NOT BE WITHHELD FROM THEM.IT IS INHUMAN NOT TO PASS THESE DRUGS YOU MUST RECONSIDER YOUR DECISION.
NHS Professional	Speed needed of assessment, also abolishment of exceptional funding and associated post code prescribing
other	It was our understanding that the spirit of the Richards Report, published last week, was to ensure that more end of

	<p>life new therapies would be available through the NHS, reducing the distressing need for patients to pay for them by private means. In restricting this advice to patient populations of less than 7000 new cases pa, common yet devastatingly poor prognosis diseases (such as lung cancer) will be disadvantaged. We urge NICE to reconsider this unfair restriction.</p>
NHS Professional	<p>NICE should seek to maximise health gain to the population and take account of reducing inequalities. This is an ethical endeavour and promotes justice in the use of resources. Discriminating in favour of a particular group therefore discriminates against every one else and will result in NICE making recommendations that when implemented achieve a net harm to the population by diverting resources away from interventions with great cost-effectiveness. It is appealing to discriminate in favour of people with less common terminal illnesses, but then the same argument can be made for children, for conditions that are painful, where dignity is at stake (e.g. continence), for people with dependent children, for people who who might lose independence (e.g through blindness). I may be out of date, but no mention is made anywhere that the threshold is £20,000 and up to £30,000. Surely this approach could be used. That is the threshold is £20,000 per QALY but interventions extending life may be considered as justification to go to £30,000.</p>
Carer	<p>"There but for the grace of God, go I" One day we might be in the same place - would we happy with this situation then?</p>
NHS Professional	<p>i would only refer back to my first response - i am dismayed at this unethical suggestion which can only have arisen due to political or industrial influence</p>
NHS Professional	<p>Comment on NICE guidelines on appraising end of life medicines 10th Nov 2008 The current guideline on appraisal of end of life medicines by NICE has brought up further controversy regarding its allocation on these drugs. Whilst an attempt to help fund drugs in these situations, the policy of funding a particular drug for 7000 new patients per year would create confusion and inequality. Firstly, it is difficult to estimate the figures as they are not based on incidence of disease. Local audit and pharmacy databases will have to be accessed, and huge variation in practice may lead to errors in estimation. Underestimation may result from constantly emerging data, patient load and unexpected referrals and would lead to problems with subsequent applications and may even leave patients undergoing treatment stranded or suitable ones left out in the cold. Overestimation would preclude appropriate patients from benefiting. Use of targeted treatments may be identified more easily from molecular markers, but identifying patients for generic drugs is less specific. Therefore identifying and estimating patients in different subsites will vary. Would the rationale of funding a particular drug then be based on the arbitrary cut off figure suggested by NICE then be a fair way of helping patients who need a particular drug most? Not so for patients with common cancers including oesophageal, gastric and most colorectal tumours, but potentially more in favour of patients with for example- RCC, HCC and pancreatic cancer. How a particular licensed drug is classified for use in subtypes of lymphoma (e.g. MALT, Mantle cell and T-cell) is not clarified. Even if the drug is funded in a small subpopulation from the onset, it will create a sense of inequality with larger populations requiring life prolonging treatment. Surely it must be derived that the majority would not be prejudiced against the minority certainly not</p>

	based on the restriction of the ability of NICE to fund a particular drug. For example, from our database of patients in 2005, incidence of oesophageal patients was 7823, gastric cancer 7981, colorectal cancers 36766, pancreatic cancer 7632 and hepatocellular cancer 3120. Our 2004 database on lymphomas show an incidence of 1564 Hodgkin and 10310 Non-Hodgkin Lymphoma patients. The perpetual question of co-payment and top-up fees will still exist for most. Would the fact that prolonging life by X amount, however statistically insignificant- convince patients and relatives not to use it? Whilst some patients may benefit from the proposed guidelines, many will still be left confused and ostracized. Professor David Cunningham Specialist in Gastrointestinal cancer and Lymphoma Head of GI/Lymphoma unit Royal Marsden Hospital Sutton SM2 5PT
NHS Professional	This is a positive step in the right direction
Patient	These are referred to as "end of life medicines", but the benefit may last for years. Unless patients are able to try these drug treatments they will not know how they will respond. If a patient may gain several years of good quality life, and some do, it cannot be right to refuse on cost grounds. For an average response, cost to the NHS will be small because although the drugs are expensive, they will only be needed for a few months. The side effects may make the patient stop taking them or reduce the dose. Only the few patients who respond well and for some time, will be costly for the NHS. The emotional effect for newly diagnosed patients of not knowing whether a potentially life-prolonging drug will be available, is huge. When this consultation was announced there was huge relief among patients, and doctors felt that fighting for drugs would soon be over, saving the costs of the consultants' time spent writing letters to PCTs, etc. The £30,000 ceiling for a QALY is a figure, which has not increased with inflation. For the very rare diseases the actual cost to the NHS is relatively small. Please let common sense and humanity prevail.
other	The actions of NICE need to be made more speedily and efficient, involving the correct people at the right times - unfortunately in my investigations of the actions and processes of this QUANGO, I have found incompetency, double standards and a waste of public resources. Now is the time to begin to put that right, to address the important issues and to make humane decisions that might help the NHS claw up that standard of Cancer care table.
Public	Whilst we welcome further appraisal of these drugs, any further delay will be unwelcome. So please do not unnecessarily lengthen the final process as people need these drugs NOW.
Public	Please do not unnecessarily lengthen the final process as people need these drugs NOW. How many people are you willing to let die while you decide whether their worth it
Carer	We need the drugs now!!! not after a lengthy delay when more people will die while you procrastinate!
Patient	Whilst we welcome further appraisal of these drugs, any further delay will be unwelcome as time is of the essence if we are going to get active treatment for my husband's kidney cancer. So please do speed up the final process as we need these drugs NOW. Also could you please ask the PCTs to immediately make these drugs available before the final decision rather than the unsatisfactory present "guideline" which has exacerbated the present "post code lottery". This could make a real difference to my husband whose condition is deteriorating as we speak, he had an

	operation two weeks ago to remove a mass from his neck! Which is costly and could have been prevented if he had excess to sutent 7 months ago.
NHS Professional	I do not think that patients are being properly counselled when they enter their "end of life care". I see many patients being given chemotherapy when they are dying making their life and those of their partners/families a misery. These are educational issues not only for the patients/etc but also for their specialists who seem unwilling to discuss end of life care and so actually are treating themselves and not the patient.
Public	It seems ridiculous that while this deliberation is taking place, people in urgent need of medicines are becoming more ill by the day. A policy should at least be in place that allows patients to receive these drugs while decisions are being made.
Healthcare Other	I appreciate the political pressure to introduce this kind of advice but I feel it fudges the issue and dilutes NICEs effectiveness. It also paves the way for a whole raft of other special circumstances that call for a QALY to not equal a QALY.
NHS Professional	Will previous decisions be revisited in the light of any changes in approval criteria made?
NHS Professional	what do patients value, ? time all of it? time to get adjusted to outcome? time to do things? pursuit of cure at whatever sacrifice? if we know it would help to preface the work with that body of opinion.
Pharmaceutical Industry	The sooner the better
other	I am the wife of a rare cancer patient who has seen the beneficial effects of one of the newer drugs. I very much wish that all people who may benefit will be able to receive such treatments. If they are available within other European social health systems, they should be provided automatically by the NHS.
NHS Professional	relatively impossible dilemma but we should err on the public generosity in support of hope
other	We welcome the initiative, but it will have little impact unless the funding and NICE analysis criteria of a treatment trials acknowledge the unique problems of rare conditions with rapid disease trajectories.
NHS Professional	Drugs for these minority terminal illnesses will never be cheap. It costs huge amounts to develop these drugs and unless we change the way we fund pharmaceutical research we will have to accept a high cost for these drugs when they are licensed. However it is true that pharmaceutical companies do make not money out of a drug that is so over priced and is not considered cost effective. They are therefore open to negotiation to improve take up of new drugs as exemplified by beta interferon in MS and agreement to fund after 14 injections of Lucentis for macular degeneration. Many of the end of life drugs proposed are only effective in a few individuals. It would be very reasonable to negotiate to pay only for drugs where they were found to be effective in an individual. It would therefore be reasonable only to use patients in which the drug was effective to calculate a QALY. This may put many drugs below the ICER £30,000 per QALY budget, which has been arbitrarily imposed by NICE.
NHS Professional	A very reasonable approach to the current disquiet. <i>Review</i> is important and description of how that will be done may require development in the light of experience with the proposed system.

Public	This is an opportunity for NICE to redeem itself and show a human face. The public is supportive of the needs of people whose life expectancy is likely to be short. A few months is a precious gift that most people would not begrudge, any more than they resent the cost of rescuing individuals in danger or providing comfort and care for the dying. NICE should recognise and reflect that.
Patient	Given the poor survival prospects of those of us diagnosed with stage 3 & 4 disease I think that as far as NICE is concerned ovarian cancer should probably be considered a terminal disease when diagnosed at these stages. Â The higher IECR should be applied from diagnosis. In the 3CCN all of us completing first line treatment for all ovarian malignancies stages 3 & 4 are told that the likelihood is that the disease will relapse. I don't know of any cases locally where relapse has not happened, usually within 2 years. A few of us may have survival in excess of 5 years but only with ongoing chemotherapies. Given the lack of knowledge of the natural history of the disease and the current disputes over the correct classifications of the "type 2" disease then I think that ovarian cancer diagnoses should be given the benefit of the doubt and the higher IECR should apply. It is impossible to predict response. I had every prognostic factor saying that I should die fairly rapidly but no-one could predict that my tumour would be so sensitive to platinum and that I would survive 6+ years. NICE has made ovarian cancer an exception in the past and could do so again. This should give encouragement to future pharmaceutical research.
Local government professional	Whilst I welcome a more detailed appraisal of these drugs, any further delay will be fatal for people who need drugs such as Sutent today. Please, please consider instructing PCTs to immediately make these drugs available before the final decision is made by NICE. At the moment some PCTs are hiding behind the present draft guidelines which has led to the so called "postcode health lottery" in the UK. For a person of average intelligence trying to understand exactly how NICE come to their conclusions is difficult. As a publicly funded organisation NICE needs to be more transparent.
Public	Whilst we welcome further appraisal of these drugs, any further delay will be unwelcome. Â So please do not unnecessary lengthen the final process as people need these drugs NOW. - Please instruct PCTs to immediately make these drugs available before the final decision rather than the unsatisfactory present "guideline" which has led to the present "post code lottery". - Alan Johnson has said in August 2007 that savings of Â£500 million could be made by better drug procurement. Â This money has therefore been wasted and urgent changes need to be made to ensure the right drugs are purchased centrally to obtain economies of scale.
Patient	see my letter to the Chairman referred to above
other	Your proposals may appear an easy and pragmatic way out of a political problem, but may store up greater problems for the future and damage the supposed independence of NICE. But if you persist, at least make it temporary and subject to monitoring and evaluation so it can be reversed later
Public	My wonderful brother is being kept alive by the Kidney Cancer drug Sutent, he has been lucky in as much as he was given this drug as soon as it was needed, his post code lottery came good! Â Everyone, who is in need of such life extending drugs, should not be denied the chance to a longer life because they live in the wrong post code or can't afford them. Â I totally support and agree with the re-examining of the guidelines on funding for end of life

	medicines.
other	i think this points to the need for a broader debate about the opportunity costs of end of life care. Many of the therapies that would be captured by these guidelines offer only marginal prolongation of life and at the risk of adverse effects. IS this what the community really wants?
Public	I have a friend who has been taking Sutent for 9months. It is effectively holding his kidney cancer in a stable condition. This is not merely life prolonging for the terminally ill but is effectively the difference between life and death for someone who has a chance of recovering.
Public	NICE should remember what it stands for Clinical Excellence not the cheapest treatment available withno consideration for survival and outcomes. It should set its standards so English and Welsh patients and their families have health outcomes and survival on a par with the best in the world. My concern - as NICE has alreday published their proposals on this is will anyone actually listen to ideas put forward on this consultation, or is it just being carried out as a PR and spin exercise?
Patient	I believe that to be supportive to best practice that supplementary advice should help to ensure tailor made packages of care and make sure that changes are easily understood and reduce as much as ambiguity as possible.
Public	Whilst we welcome further appraisal of these drugs, any further delay will be unwelcome. So please do not unnecessarily lengthen the final process as people need thse drugs NOW. - Please instruct PCTs to immediatley make these drugs available before the final decision rather than the unsatisfactory present "guideline" which has led to the present "post code lottery". - Alan Johnson has said in August 2007 that savings of Â£500 million could be made by better drug procurement. This money has therefore been wasted and urgent changes need to be made to ensure the right drugs are purchased centrally to obtain economies of scale.
NHS Professional	Thanks for patience. No reasons for my opinions to hold any weight. Sorry for writing in preliminary stage...(it did say "submit")
Carer	While applauding this small step taken to correct inequality in appraising life prolonging treatments it does not address the whole problem. QALYs discriminate against those in society who are less able to prove quality of life, the more vulnerable in our society who are told that funding for their treatment is refused as resources would be better spent elsewhere are treated less equal than others. By definition QALY favours the younger and Â healthier person over the older person with life threatening illness, it is therefore imperative this issue is debated with the view to creating a fairer methodology without delay and input from patients,carers and clinicians should form part of this debate.
NHS Professional	Implicit in this supplementary advice is the greater value placed on the final months of life by patients, their families and friends. A similar set of supplementary advice may be indicated to recognise the higher societal benefit of prevention over treatment of existing disease. There has been no indication of how this advice, if applied in previous years, would have affected expenditure on high cost drugs. The effect of this advice should be modelled for recent years. There is a danger in valuing the final stages of life over the early part of a disease that an effective

	treatment may be approved for use after third relapse (since the median survival of 24 months applies), but not at first or second relapse (since current survival expectation exceeds 24 months).
NHS Professional	None
NHS Professional	Para 1.3 talks of "small groups within larger populations". Pharma companies could make cancer drugs qualify by splitting license applications into subgroups. The main objection is opportunity costs. The proposed approach would result in more money being spent on cancer drugs, and people with other conditions would suffer. Para 1.3 - orphan drugs should also be appraised by NICE. NSCAG does not apply cost per QALY thresholds. The separate handling again fosters inequities amongst disease groups. If NICE did accept this "unequal ICERs" approach, the maximum allowable ICER should not be far above the present one - say a maximum of £40,000 per QALY.
Other	To adapt your life to live with cancer is far from easy. There is so much adjustment both physically and mentally to contend with. To have added to your condition the pressure of knowing that, for some, vital life enhancing treatment is denied is beyond comprehension. My boyfriend has been taking Sutent for 9 months with really positive results. We didnt face any funding issues and think ourselves very fortunate. But its a bitter sweet feeling as we know that not every kidney cancer patient enjoys the same story as ours. Each kidney cancer patient should have the same nationwide access to treatment. Treatment that I know that can work to give back time and hope. Its really lifting to know that the guidelines are to be re-examined
Carer	- Whilst we welcome further appraisal of these drugs, any further delay will be unwelcome. So please do not unnecessarily lengthen the final process as people need these drugs NOW. - Please instruct PCTs to immediately make these drugs available before the final decision rather than the unsatisfactory present "guideline" which has led to the present "post code lottery". - Alan Johnson has said in August 2007 that savings of £500 million could be made by better drug procurement. This money has therefore been wasted and urgent changes need to be made to ensure the right drugs are purchased centrally to obtain economies of scale.
NHS Professional	Section 2.2.1: It is commendable that you propose to use and encourage drug companies to use meaningful endpoints in their funded research, such as improved quality of life and even more importantly improved survival and avoid measures such as progression free survival. It is important that NICE takes into account affordability and estimates the likely cost of any recommended treatment to the NHS. We should bear in mind that any new cut off points (of price and prevalence) accepted will ultimately lead to and create the same problems that NHS currently encounters, as by definition, there will be some treatments that will fall below and above any cut off point. In summary, we believe that this proposal will ultimately lead to inequity. Unless a new methodological approach is adopted, in the medium future will bring us back to where we currently are.
Other	There is an implication that 7000 is applied because of the extra costs of developing medicines for smaller population. There is faint acknowledgement that manufacturers tend to go for one small indication then another one, and then another one so that the number of people on a drug grows over time. Although suggested in this document you cannot apply these principles to the first indication that a manufacturer gets marketing authorisation for and then not apply them to the next indication, if it is a similar end of life scenario. That seems unfair for patients

	and creates a lottery for funding depending on the luck of being the first indication obtained versus the bad luck of being the subsequent indications obtained.
NHS Professional	This consultation is an indication of the strength of feeling engendered, not least, but the recent ACD on renal cancer drugs. It is, as such, a measure of the failure of the HTA process currently employed by NICE. That HTA methodology should, therefore, be abandoned forthwith.
NHS Professional	I think the issue of these expensive drugs has been blown out of proportion. The benefits pale into insignificance compared to the benefits of radiotherapy. We still do not have brachytherapy in our centre! after 11 years! We still can't get our patients into hospital beds in a reasonable time-frame, if they are ill!
Public	I believe to deny NHS patients, their families and carers access to drugs that are proven to be clinically effective to be cruel and immoral. I wholly support this recommendation and applaud NICE for re-examining the guidelines on funding for 'end of life medicines.
NHS Professional	Anything which unblocks this area of medicine would be welcome but my worries are further problems with postcode prescribing. The PCT and GPs are stressed by these issues on a daily basis and time is essentially wasted trying to justify what many people regard as the unjustifiable. Hope this helps.
Local government professional	This document risks putting PCTs in the situation in which a treatment licensed in both rare & more common conditions could be authorised for use in the rare condition because the cost/QALY threshold has been raised but not in the common condition. It risks PCT having to move resources from current effective treatments to those with marginal benefit. Each rare condition may be rare but a PCT might have many patients with different rare conditions requiring treatment.
NHS Professional	This debate needs to be part of how we manage the last months of life. These drugs are already being used inappropriately, and contribute to shortening lives (NCEPOD 2008). We also know that end of life care is inadequately developed and over medicalised (NAO 2008). Any lifting of restrictions would be likely to exacerbate these problems- making end of life care more unsafe and focused on medical interventions.
Public	To deny ANY NHS patients any proven treatments is immoral and totally wrong
Public	How can any organisation deny the right to live?
NHS Professional	1. This proposition is contrary to Principle 7 as set out in Social Value Judgements, that NICE can recommend the use of an intervention is restricted to a particular group of people (in this case those with a illness meeting the criteria) only where there is increased effectiveness of the intervention in this subgroup, reasons relating to fairness for society as a whole or where there is a legal requirement. 2. The precedent set by this proposition will impact on PCT decision making limiting the ability to apply a cost per QALY threshold. We have already seen some threshold creep from the Â£20k per QALY to the Â£30k per QALY. 3. NICE in costing the impact of this proposition needs to consider past guidance as well as its forward plan, the effect of routine drug pricing to higher cost per QALY, and impacts on PCT decisions. 4. Given that NHS funding is fixed the funding for increased access to drugs and treatments for the terminally ill that comes about as a result of this proposition, will have to be found at the expense of other interventions and services. NICE would need to reduce its cost per QALY threshold for these.

NHS Professional	I would encourage NICE to seek the opinion of Palliative Care Specialists as widely as possible as we are providing palliative and supportive care to this patient group. Also to consider involving them in the decision making process for approval of these drugs.
Public	I do not feel qualified to answer the above questions, but do know that the availability of these types of drugs has enabled a very dear friend of mine to have a longer life than he would have had otherwise, and to still have a good quality of life during the process. I believe that these drugs should be made more readily available to those who can benefit from them.
Public	Issues must be considered by clinicians and their patients with a clear understanding of the effects of the treatment, the time left, the effects of non use and a rethink of the numbers. This is a problem which can only increase as new research becomes available. While this decision should be between clinician and patient there should be adequate consultation with carers, who play such an important part if patients are to be treated out of hospital. It is no longer acceptable to say that clinicians only treat the patient. The main problem at the moment is that there are choices having to be made..is it available, does it work, can I have it, will it help me, and above all is this the best way? Anything which clarifies for the patient some of these issues has to be helpful. Where a new drug works it should be available.
other	The Royal College of Radiologists looks forward to early implementation of these changes.
NHS Professional	NICE has set ICER thresholds of between £20K and £30K. NICE needs to work with PCTs and organisations that hold commissioning budgets modeling affordability.
Carer	I understand that further appraisal of these drugs is a necessity, but any further delay will not be welcome, as there are people out there who need them NOW and whole families that are suffering whilst watching their loved one clinging on to the hope that you will allow them access. Can you please instruct PCTs to make these drugs available immediately, before the final decision, rather than the present guidelines, which have produced the postcode lottery (which means my husband will not be allowed drugs at this present time, directly because of the postcode lottery). In August 2007 Alan Johnson said that 500 million could have been saved by better drug procurement...surely this means that money has been wasted and so urgent changes need to be made to ensure that there is central purchase of drugs to ensure economies of scale. The 500 million wasted is now directly causing many families distress and uncertainty and, in time I know it will be my husband needing these drugs as his condition is incurable, but controllable and this control will come from the drugs currently blocked by NICE. Please, please review your policy.
other	In my family's case, the kidney cancer drug Sutent has been shown to cause a reduction in the size of growths and to successfully extend life. It is vital that this drug be funded for those in the unfortunate position of needing it.
Other	The MND Association's vision is of a World Free of MND. Until that time we will do everything we can to enable everyone with MND to receive the best care, achieve the highest quality of life possible and to die with dignity. Last month the Association announced it will be funding a clinical trial to investigate the effects of lithium carbonate as a possible treatment for MND. This is the first time that we have been in the position to fund our

	own clinical trial. We hope that increased research into MND will result in further treatments coming through and some may need to be appraised by NICE under these proposed new measures.
Public	I have a very close friend on these medicines. The change in him since taking them is remarkable and are keeping him stable .To deny anybody the opportunity for this treatment is simply wrong. It is a cruel and nasty disease which attacks without prejudice and as such I believe they should continue to be funded for those that need them.
NHS Professional	It is a departure from the current statement in the reference case that <i>“An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit.”</i> This has implications for all appraisals. The restriction to small populations is likely to prove problematic, particularly where there are likely to be multiple indications for the same drug.
Other	I write to support the campaign to continue to provide National Health care for those who have paid for their own cancer drugs. Patients with, for instance, renal cancer have no alternative effective treatment – the extension of life with these drugs has been well established. In addition patients may have the opportunity to further extend their lives with future upcoming drugs. It seems unbelievably cruel that these cancer drugs should be widely available in Europe but denied for patients in the UK by virtue of subsequent treatment on the NHS being disallowed.
Public	I have a very close friend on these medicines. The change in him since taking them is remarkable and are keeping him stable .To deny anybody the opportunity for this treatment is simply wrong. It is a cruel and nasty disease which attacks without prejudice and as such I believe they should continue to be funded for those that need them.
Other	RESPONSE BY THE SPECIALISED HEALTHCARE ALLIANCE TO NICE CONSULTATION ON APPRAISING END OF LIFE MEDICINES The Specialised Healthcare Alliance (SHCA) is a coalition of 43 patient organisations supported by nine corporate members which campaigns on behalf of people with rare and complex medical conditions requiring specialised care. Our comments on the consultation document are as follows: 1. Summary As the SHCA understands it, NICE’s proposals flow from the review undertaken by Professor Mike Richards into top-up payments and the resulting report “Improving access to medicines for NHS patients”. To that extent, several of our remarks are addressed to the Department of Health as well as NICE and we shall be sharing this response accordingly. In particular, the key question is whether the Institute’s proposals along with Professor Richards’ other recommendations, as adopted by the Government, will be sufficient to meet his view that “the overwhelming priority should therefore be to ensure that patients get access to drugs that could potentially benefit them on the NHS” a view with which the SHCA entirely concurs. A survey conducted alongside the Richards’ Review found that of 14,000 exceptional funding applications, 8,000 related to drug treatments and 26 per cent of those to cancer. Unfortunately, it was not established how many applications related to end of life medicines and how many related to severely debilitating conditions which were not immediately life-threatening. It is, however,

	<p>clear that attention needs to be given to non-pharmaceutical as well as pharmaceutical interventions and, given the minority of cancer-related applications, can reasonably be inferred that a significant proportion of cases concern severe clinical need but not of an immediately life-threatening nature. Discussion with officials at the Department of Health has indicated that access to medicines dealing with debilitating illness not falling in the end of life category will be improved by a combination of speedier NICE appraisals, better collaborative decision-making by PCTs and more flexible approaches to pricing by the pharmaceutical industry. The SHCA is not in a position to comment on the Department's assumptions but, insofar as the majority of medicines will be subject to NICE appraisal, would strongly suggest that an approach predicated purely on the end of life is inadequate. In addition, NICE's own Citizen's Council recently concluded that appraisals should take more explicit heed of clinical severity in reaching decisions. That being the case, it would seem logical for NICE to consider an incremental cost effectiveness ratio in excess of £30,000 for small patient populations not only for end of life medicines but also where severe clinical need is involved. We support funding decisions in relation to ultra orphan treatments resting with the National Commissioning Group (NCG). NCG criteria, however, revolve around services covering small numbers of patients and other factors. Ultra orphan treatments for patients in bigger services such as cancer would probably be excluded by the NCG. It is therefore important for NICE to have criteria for such appraisals which support equivalent access to other end of life medicines.</p> <p>2. Criteria for appraisal of end of life medicines The SHCA is not clear whether the definition of end of life medicine in paragraph 2.1.2 relates to treated or untreated patients. It would seem sensible for the definition to cover life-threatening conditions where treatment could extend life indefinitely (ie beyond 24 months) but this needs to be made explicit. The SHCA would also question the ethical consequences of a hard and fast definition and suggest that a guideline might be more appropriate. Similarly, in paragraph 2.2.1, the SHCA considers that it would be perverse to exclude modelled mortality gains where the effects of the intervention are on morbidity but the degree of morbidity is so severe as to curtail life or to make the quality of remaining life exceptionally poor as compared with treatment.</p> <p>3. Review of resulting guidance Given that adjustments to NICE's appraisals guidance will form part of a matrix of measures to improve access to medicines on the NHS, it is important to monitor the results closely and institute an earlier review than two years in case of need ie significant numbers of patients still being confronted with the prospect of top-up payments for efficacious treatments.</p> <p>4. Implementation and evaluation No comment.</p> <p>5. Costs The SHCA supports the adoption of innovative and effective medicines by the NHS and the use of generic alternatives when they become available. The savings arising from several major categories of treatment moving off patent over the next few years should help the NHS maintain treatment based on clinical need rather than the ability to pay, as endorsed by the Richards' Report.</p>
Public	<p>During this consultation process people will have undoubtedly died as a result of delay. These drugs are needed now. The NHS has a large enough budget to carry the increased cost through savings and rationalisation. The Postcode lottery has to stop people are in need NOW.</p>

other	<p>We hope that this review takes the opportunity to 1) increase the QALY across the board 2) incorporate diseases that affect more patients than 7,000 a year 3) particularly focuses on groups of patients who can be identified as benefiting from a treatment because of an identifiable marker (such as K-Ras) 4) consider not just increased length of life but also quality of life in its decision making processes 5) lead NICE to a situation where it routinely listens more closely to the views of patients, patient groups and clinicians where it bases its decisions upon their views more and ceases to just pay them lip service. For too long, NICE has regarded their views with suspicion for no reason other than it suited it to do so in its denial of new treatments. We hope that with this review - which we welcome - NICE is now entering a new era of trust, partnership and shared knowledge - all for the greater good of patients.</p>
NHS Professional	<p>In practical terms, funding treatments of low cost-effectiveness for a few patients at the end of their lives, will be used as a justification to put resources into pharmaceutical company profits at the expense of investing in other forms of care e.g. palliative nursing care in the community etc. There will be attempts to justify it using "rule of rescue" imagery. As usual, it will divert resources to the articulate (with well-organised, pharm-funded support groups) from the less articulate. It would be more equitable to value the benefits equally in terms of improvements in quality and/or quantity of life.</p>
NHS Professional	<p>NICE should not restrict an intervention to a small group of patients with a life threatening illness with a short life-expectancy. They need to consider carefully what would be a worthwhile mortality gain given the expense of treatment.</p>
NHS Professional	<p>There is a new generation of high cost cancer drugs and the proposed changes may over several years put considerable pressures on NHS funding during a difficult economic period. Has the potential additional cost to the NHS been evaluated? If these changes proceed, then additional ring-fenced central funding will be required in order to meet these increased costs without a detrimental effect on other services, including potentially curative treatments for cancer.</p>
NHS Professional	<p>The current position with end of life or compassionate interventions in the terminally ill is untenable, causes distress and damages the reputation of the service. NICE has to intervene in a way that removes pressure and discretion from local Exceptional Circumstances Panels.</p>
NHS Professional	<p>Section 2 states that the committee must be sure that there are substantial improvements in longevity and that the evidence for these should be robust. It is not clear, then, why there is a need to collect more data, and how this would make the decision more robust. Presumably the data collection would have to be non-comparative, as the Institute's recommendation would make comparative research almost impossible. There will then be a difficult job</p>

	for the committee in interpreting non-comparative but local data on several thousand people, set against the robust comparative data from the original appraisal. To add to this difficulty is the problem of withdrawing a recommendation for a medicine once made.
NHS Professional	absolutely opposed to supporting purchase of drugs even under the circumstances underlined by Andrew Dillon, from our Fund
Pharmaceutical Industry	1.7 " More information would be useful on what constitutes an 'appropriately designed programme of evidence development'. " The object of this program should be related more to the most appropriate use of the medicine by the NHS, rather than only to establish anticipated survival gains, as this ignores broader benefits of therapies beyond survival. " In addition, how will it be ensured that the programme is sufficiently powered and robust to demonstrate significant outcomes and control for bias in patient populations? " " Appropriately designing, powering and funding such studies will be hugely challenging. " Will input from NHS R&D or NCRI be provided to NICE to support this process? " Does NICE have the resources and skills mix to provide research development, verification and funding for these programmes? " The "£100K estimate quoted in section 5.1 seems extremely low. " In addition does NICE have sufficient resource to conduct re-reviews within a relatively tight timeframe?
Other	<p>We would like to provide feedback on two further issues contained within the consultation document and outlined in detail below:</p> <p>SECTION 1: Summary</p> <p>The consultation document makes the following statement regarding evidence generation:</p> <p><i>Subject to agreement with the Department of Health, medicines recommended for use on the basis of the criteria set out in section 2.1, will normally be subject to an appropriately designed programme of evidence development to ensure that the anticipated survival gains are evident when it is used in routine practice. The outcome of this exercise will be evaluated when the guidance is reviewed. The design of the studies will be determined by the Institute and will need to be funded centrally. NICE will be responsible for managing the data collection exercise and assessing and reporting the outcome. Manufacturers will be given access to anonymised data and a summary of the results published.</i></p> <p>In principle, where there is large uncertainty around the assumed treatment effect of a new intervention to the extent that it produces significant uncertainty around the ICER and its likely cost effectiveness, we would agree with the need to validate necessary clinical outcomes. However, we would challenge the efficiency and need to routinely attempt to validate clinical benefits within a real world setting. The extent to which such a real-world study is</p>

	<p>anticipated to improve on the existing evidence base should be clearly outlined. For example, a large phase III RCT study may provide a high degree of certainty around the treatment effects of a new intervention. In such a case there would appear limited returns to NHS resources in designing a real-world study, which may not achieve the high standards of patient randomisation usually observed within an RCT. As with other interventions funded by the NHS, the cost effectiveness of this study should be rigorously evaluated. The extent to which such external and internal validity within clinical studies are willing to be traded-off by Appraisal Committees should be made clear within the context of the suggested data collection. The opportunity for manufacturers to comment on the remit and protocol of any data collection would also be necessary to ensure both an effective and appropriate process of data collection.</p> <p>SECTION 3: Review of the resulting guidance</p> <p>We consider that the following statement within section 3 would benefit from further clarification as it currently appears contradictory in nature.</p> <p><i>“Second and subsequent licences for the same product will be considered on their individual merits. The Appraisal Committee will take into account the cumulative population for each product in considering the strength of any case, for justifying a higher ICER, which employs, in whole or part, a small population argument”</i></p> <p>Despite stating that new indications will be considered on their individual merits, it is unclear from the above statement what the term “cumulative population” refers to. For example, when considering a new indication for a treatment already licensed for a different form of metastatic cancer, would the population for the first indication be taken into account? If so, this would compromise the statement that, <i>“second and subsequent licences for the same product will be considered on their individual merits.”</i> Such an approach could potentially disincentivise clinical trials in other rarer end of life conditions if a treatment has already been licensed for one indication.</p>
other	<p>Review and Guidance (a) Previous experience suggests that data collection exercises may not be carried out expeditiously due to reluctance on the part of manufacturers. It is important that NICE considers carefully the incentives operating on all interested parties, where delay or non-cooperation may be used to avoid/delay a review</p>

	<p>which may lead to withdrawal of approval. (b) ‘Medicines approved following the application of the supplemental advice will not necessarily be regarded, or accepted, as standard comparators for future appraisals of new medicines introduced for the same condition’ This can rapidly make a nonsense of ICER thresholds as anomalies and inconsistencies accumulate, and multiple potential reference comparators are available. The threshold should be objective and subject to clear rules, independent of any particular case. (c) The concept of cumulative population is equally equivocal, and suggests that submissions may be subject to ‘gaming’ in that rare conditions are presented first to obtain easy market entry, with more common conditions offered later which are able to satisfy the normal threshold. Costs (d) This proposal effectively removes all constraints on product prices and therefore accords an infinite value to selected limited survival gains, while giving no weight to issues of utility/quality of life at a time when, for many patients, quality of life is of paramount importance. Ultimately, it promotes the medical model over the humanitarian model of end of life care. (e) If no cost limits are placed through thresholds (current or revised) then manufacturers will have clear incentives to propose treatment regimens which maximise (rather than minimise) drug use, both in terms of dosing and duration of treatment. (f) If the manufacturer intends to claim reimbursement under this scheme they should be required to include a fully developed research protocol for data collection for fast tracking as part of the submission. General comments (g) There is a danger that a plethora of drugs previously rejected will need to be re-appraised (h) There is a danger that the extraordinary circumstances will exacerbate health inequalities (e.g. it would be expected that people in higher socio-economic classes will live longer and thus be at risk of relatively rare end of life diseases than those in lower socio-economic classes) (i) Section 1.4 states that to be considered under this supplementary advice, drugs would already have to have been through an STA/MTA process – does this mean drugs first need to be rejected, leading to an additional assessment stage, thus lengthening the appraisal process? (j) To ensure that all required information is available to the ERG, a more structured and specific manufacturer’s submission template would need to be enforced by NICE, e.g. clear specification of relevant statistics required for economic modelling and interpretation of clinical data (k) A recent report by the National Audit Office (National Audit Office. (2008). End of Life Care) concluded that ‘NHS and social care services are not meeting the basic needs of many people approaching the end of their life...The majority of people would prefer not to die in hospital, but a lack of NHS and social care support services mean that many people do so when there is no clinical reason for them to be there. There is scope for more people to die in their home, care home, or a hospice by improving training of all NHS and social care staff in understanding and awareness of end of life care needs, and extending specialist palliative care services for those that need them, regardless of their condition. Improved delivery of these services will require more effective commissioning and partnership working between the NHS, social services and the voluntary sector’. Alongside investment in new drugs the department of health needs also to consider how the patients’ basic clinical needs can be met as they approach the end of their life and how the training needs of health care professionals working with patients who require a palliative can be identified and met appropriately.</p>
NHS Professional	<p>It is widely recognised from the Cancer Reform Strategy that the UK lags behind Europe in the uptake of new cancer drugs and in the improved outcomes that may result from this. It is however not clear how this proposal will</p>

	<p>improve this position, but may conversely make the position worse if end-of-life drugs are prioritised in this way. Whilst perhaps outside the remit of NICE, the recent NCEPOD report is disturbing as many patients appear to be receiving inappropriate chemotherapy. Cancer pathways and quality of care,(including palliative care) should therefore perhaps be prioritised before drugs of marginal benefit.</p>
NHS Professional	<p>Section on costs is far from clear– especially 5.2. What does the Â£100,000 refer to? What is the data collection exercise? Who will do it? I do not agree with 5.1. This will definitely not be a small impact, especially in cancer care, where the <7000 cases limit will bring in all cancer sites except the main 4, and even some of those cases. Â Given new cancer drugs in the pipeline, the impact on PCTs will be considerable if NICE is effectively unable to reject drugs which are not cost effective. The reason some new drugs are deemed not to be cost effective is that they are overpriced. The MD and owner of Celgene is on public record that he fixed the price of the recently licensed thalidomide at Â£20,000 per annum to be comparable with bortezomib – and it is clear that the cost of lenalidomide was then scaled up from this. Back in the 1960s thalidomide cost pennies, the product is identical, and the only ‘added value’ is the pregnancy prevention package, which is irrelevant to almost all patients with multiple myeloma. This document only refers to drugs used to extend life, but what about other interventions which may become the subject of NICE technology appraisals eg gamma knife?</p>
other	<p>The BMA supports the work of NICE and recognises the challenges it faces in developing guidance for the NHS in the context of ever-rising public and patient expectations, the increasing costs of new medicines and technologies and the realities of an NHS operating in the context of finite resources. Most recently, the outcome of the Richards Review, the subsequent draft Department of Health guidance on NHS patients who wish top pay for additional private care and the proposals contained in the NHS Next Review report, High Quality Care for All, have each highlighted the complex issues with regard to access to medicines and the means by which they are appraised and recommended for use in the NHS. In this environment, the BMA welcomes both the opportunity to engage in an informed debate on these matters and the renewed focus on further improving the way in which NICE makes its recommendations and conducts it business. In its own submission to the Richards Review the BMA proposed that key elements of the role and function of NICE be re-examined, in particular the speed and transparency of decision-making in respect of its appraisal processes. The current consultation demonstrates a willingness to do so. Given the stated intention to implement this new guidance in January 2009 we would like to see further detail as to what mechanisms are to be put in place for review and feedback in order to assess whether the new methodology is achieving its aims.</p>
NHS Professional	<p>The information on supporting mechanisms detailed in section 1, 3 and 4 is welcomed and will be useful to ensure that, if supported, there is a robust mechanism to assess that the potential benefits to treatment are realised when the treatment is in routine use.</p>
Patient	<p>This is a most welcome move. It is not tolerable for patients in other countries to have standards of care which are higher than those in England/Wales, especially when the nature of the illness is life limiting.</p>
Pharmaceutical Industry	<p>Paragraph 1.7 “... medicines recommended for use on the basis of the criteria ... will normally be subject to an</p>

	<p>appropriately designed programme of evidence development to ensure that the anticipated survival gains are evident when it is used in routine practice. The outcome of this exercise will be evaluated when the guidance is reviewed. The design of the studies will be determined by the Institute and will need to be funded centrally. NICE will be responsible for managing the data collection exercise and assessing and reporting the outcome. Manufacturers will be given access to anonymised data and a summary of the results published.” – The need for a programme of evidence development is unclear given the criteria set out in paragraph 2.1.3. Since if the criteria that “There is sufficient evidence to indicate that the medicine offers a substantial extension to life, compared to current NHS treatment” has been met then why would further evidence development be necessary. However, in the event that evidence development is considered appropriate we would encourage the Institute to work in partnership with the pharmaceutical company who developed and sought regulatory approval for the m</p>
Pharmaceutical Industry	<p>Eisai understands the need to gather further evidence on real world clinical and cost effectiveness for such technologies. However, as described in the draft guidance, NICE will be fully responsible for the design of studies to collect these data, with technology sponsors just "given access to anonymised data and a summary of the results published". Eisai considers that optimal study design would be best achieved by a partnership approach between NICE and technology sponsors on the design and analysis of future research studies to determine post-approval clinical and cost-effectiveness. Such partnership would ensure the harnessing of technology sponsors unique and deep understanding of their products, and contribute to robust research design.</p>
Public	<p>Of course it is important to think about the patient, to extend and improve the quality of life and extending, but I also feel when making these decisions, you need to try and quantify the impact and the value of the family, friends and carers. You never really appreciate what you have until it is at risk, and this opportunity gives everyone time and improves the quality of life.</p>
Public	<p>A good friend has been taking the kidney cancer drug Sutent for the past 9 months. His disease is deemed to be stable in fact he’s actually still experiencing reductions in the size of some growths. It is not an exaggeration to say this drug is keeping him alive and without it his consultants say that, at best, he would have just 6 months to live. At just 46, this is an unbearable prognosis. I believe to deny NHS patients, their families and carers access to drugs that are proven to be clinically effective to be cruel and immoral. I wholly support this recommendation and applaud NICE for re-examining the guidelines on funding for ‘end of life medicines’.</p>
Public	<p>I have a 46 year old friend who has been taking the kidney cancer drug Sutent for the past 9 months. His disease is deemed to be stable to the point where he’s actually experiencing reductions in the size of some growths. It is not an exaggeration to say this drug is keeping him alive and without it he would have just 6 months to live. I believe to deny NHS patients, their families and carers access to drugs that are proven to be clinically effective to be cruel and immoral. I wholly support this recommendation and applaud NICE for re-examining the guidelines on funding for ‘end of life medicines’.</p>
Carer	<p>We keep hearing about the cost of the new drugs yet Interferon, which is funded quite readily has poor results it would seem for most patients. Can the cost of Interferon not be laid off towards the cost of the new more effective</p>

	drugs. We also find it incomprehensible that the buying process is not carried out on a national basis, whereby it would give greater purchasing power to the NHS.
Pharmaceutical Industry	Section 3.2 states that the resultant medicines may not necessarily be used as an acceptable comparator in future submissions. This may create an unfair first mover advantage as this will artificially raise the bar for the second entrant treating a particular disease. For example the first medicine, A, may be judged to have an ICER of £38 000 per QALY, and meet this guidance and thus be recommended. A second medicine, B, introduced 6 months later may be more effective at a similar price and produce an ICER of £34 000 per QALY vs. the same gold standard comparator as used by A, but would under this advice not be recommended, even though it would likely be cost effective vs A and provide additional benefit to patients. We would recommend this advice be removed. In addition if a new treatment represents a paradigm shift for the treatment of a condition the original gold standard may rapidly become outdated and defunct. In this instance the new treatment should be the standard comparator for future appraisals rather than the original treatment as suggested in section 3.2. which states, "Medicines approved following the application of the supplemental advice will not necessarily be regarded or accepted as standard comparators for future appraisals of new medicines introduced for the same condition." In addition, regarding subsequent data collection as outlined in 3.1, it is not clear how this would work. In particular the studies commissioned are likely not to be as robust as the original data set submitted and the NHS infrastructure may not exist to be able to implement robustly these studies. We would ask for clarity here.
NHS Professional	<ul style="list-style-type: none"> In summary, we believe that the proposal will ultimately lead to inequity, create a number of methodological questions that are difficult to answer and in the medium future will bring us back to where we are now.
other	PHARMAC appreciates the opportunity to make a submission on the NICE consultation. We have emailed our consultation response (which clearly identifies the questions we are providing responses to) to Mr Andrew Dillon and ask that this be considered alongside other submissions.
NHS Professional	5. The Richards Review recommends improvement in verbal and written information, giving a clear, balanced view of the risks and benefits, and stresses this will be important to ensure patients have realistic expectations when treatment is initiated. If NICE's proposals are implemented the patient information usually provided alongside NICE guidance will importantly meet this need, supplement verbal sources and provide consistency. 6. The plans (referred to in 1.7 and 3 of the consultation) are a key factor in gaining the PCT's support. The introduction of a centrally and appropriately designed programme of evidence development to ensure the anticipated survival gains are evident when used in clinical practice is welcomed. At the review stage, normally 2 years, it will be important that NICE very clearly set out any decisions to overturn the initial recommendation to the NHS if the outcomes do not support continued NHS funding. It is also crucial that pricing is also reviewed when the guidance is reviewed. If these proposals are introduced NICE should ensure patient groups are very aware of the review period and need for further evaluation of the benefits in clinical practice.
Public	all medicines should be available to all patients who want them, regardless of LOCATION. In the case of Sutent, kidney cancer patients should be offered this treatment in spite of its cost. I understand that it is not available to

	patients in Oxfordshire. The criteria should always be, would the PM want it to be available for his family? If the answer is `yes, then it should be available to all who want or need it.
Pharmaceutical Industry	Pharma Mar would like to congratulate NICE for proposing this scheme which we feel has the potential to make a significant difference to the way in which new treatments for patients nearing the end of life are appraised. The proposed scheme has significantly altered the health technology assessment landscape in England. As such, we expect it to have significantly altered the thinking of a number of registered stakeholders to NICE's current work programme, including manufacturers and patient representatives. Given this, we believe that it is important that NICE is flexible with its timetables for its current programme of appraisals. Such flexibility is in the interests of patients, the NHS, manufacturers and the appraisal committees themselves. NICE is also aware of the considerable confusion that has arisen in its current work programme in relation to how to handle treatments for rare conditions. According to NICE's 'Social Value Judgements' document, appraisals will not be conducted for 'ultra orphan' conditions. However, Pharma Mar is aware that a number of treatments (including trabectedin for metastatic soft tissue sarcoma, which is manufactured by Pharma Mar) which could be considered as 'ultra orphan' have been included in NICE's current programme of work. In order to avoid future confusion on this issue, we consider that it is imperative that NICE clarifies how it will handle such treatments in future and how (if at all) the new scheme will impact upon this.
Pharmaceutical Industry	We believe it essential that manufacturers are in some way involved, ideally partners, in these programmes. We note also in 5.2 that a budget of around £100,000 is anticipated for each data collection exercise. While this might be achievable in pre-existing cancer registries, some disease areas (particularly those with small populations) might not have similar infrastructure and therefore costs could be considerably higher. •We note that in 3.1 that NICE recommend that guidance is reviewed within 2 years after publication. MSD would request that a review date is set on publication of guidance. •"Second and subsequent licences for the same product will be considered on their individual merits... will take into account the cumulative population for each product" MSD would welcome further clarity on how this provision should be interpreted. If a cumulative population is considered alongside a 7000 patient threshold, this runs the risk of excluding many new indications particularly in oncology, where multiple indications are common. • MSD believes that in order to avoid arbitrary discrimination, that the treatment population for different indications should be considered independently.
Pharmaceutical Industry	•2.2.1We welcome the acknowledgement that it is acceptable to infer a survival advantage in a trial where direct survival data might not be available and note that Progression Free Survival (PFS) is demonstrated to be a very good surrogate outcome of Overall Survival (OS) in cancer trials. We would, however, disagree that it is not sufficient to infer a survival gain from morbidity benefit. This is particularly important because biomarkers can be a very accurate predictor of long term survival. Whilst agents in such therapy areas may not fit all the criteria in 2.1, given the known associations and causative relationships between many biomarkers and outcomes, 2.2.1 seems highly restrictive. To require the level of evidence specified may result in delays in patient access due to extended trial programmes, or agents which meet all other criteria being excluded from consideration • For patients during the

	<p>end stages of life, the quality of life can be as important as an extension of life. These are intrinsically linked. To disregard the benefits of quality improvements would seem inappropriate and MSD believes the criteria should address this in some way.</p>
Public	<p>To be welcomed as a principle. The decision-making is likely to be difficult – what is an appropriate ICER for increased length/quality of life?</p>
Public	<p>We are writing to participate in the NICE consultation on the use of medicines for treating certain rare conditions which extend life at the end of life. We are concerned particularly with kidney cancer, and we have a close relative with Renal Cell Carcinoma but the points made below can relate to, and your consultation should consider, other terminal medical conditions and the treatment thereof.</p> <p>We feel strongly that the NHS must make all drugs that substantially extend life, available in “end of life” situations, no matter how rare the medical condition and no matter how small the number of actual or potential patients. There should be positive action for these patients in their incredibly distressing situations and, where the finite NHS budget requires, priority funding.</p> <p>Rules on the cost effectiveness of the drugs for patients with terminal conditions should not be applied rigidly. Cost effectiveness must take into account a person’s age, family and personal circumstances and his/her present/future quality of life.</p> <p>Your consultation process must take these two points into account in the interests of the patients and their families. Patients must be given every possible help and not left to premature and unavoidable deaths. Emphasis on such issues will also address the critically important matter of research and development by charities and drug companies which must be stimulated, encouraged and supported.</p>
Other	<p>Paragraph 1.7 “... medicines recommended for use on the basis of the criteria ... will normally be subject to an appropriately designed programme of evidence development to ensure that the anticipated survival gains are evident when it is used in routine practice. The outcome of this exercise will be evaluated when the guidance is reviewed. The design of the studies will be determined by the Institute and will need to be funded centrally. NICE will be responsible for managing the data collection exercise and assessing and reporting the outcome. Manufacturers will be given access to anonymised data and a summary of the results published.” – The need for a programme of evidence development is unclear given the criteria set out in paragraph 2.1.3. Since if the criteria that “There is sufficient evidence to indicate that the medicine offers a substantial extension to life, compared to current NHS treatment” has been met then why would further evidence development be necessary. However, in the event that evidence development is considered appropriate we would encourage the Institute to work in partnership with the pharmaceutical company who developed</p>

	<p>and sought regulatory approval for the medicine. This would be beneficial for a number of important reasons. Firstly, to our knowledge the institute is not experienced in the design or implementation of developing clinical evidence. Secondly, it is very unlikely that any other party would know more about the specific medicine than the company who developed the medicine. Thirdly, the company who developed the medicine will have considerable experience in developing evidence within the specific disease area and for the specific medicine as they have developed the evidence required to gain regulatory approval of the medicine. Fourthly, it is common for the regulatory authorities such as the EMEA to authorize the marketing of a medicine under the condition of further evidence development. It would be sensible from an efficiency point of view for the Institute to make use of such evidence development and this would be possible through partnership with the individual pharmaceutical company. In addition, we would welcome clarification from the Institute on exactly what is meant by “funded centrally”.</p> <p>Paragraph 5.2 “Although the cost of each data collection exercise will vary from case to case, it would be reasonable to budget for around £100,000 for each medicine approved under the proposed scheme” – We would welcome clarification from the Institute on the source for their £100,000 budget estimate for evidence development. We believe that this is a worrying unrealistically low estimate of the cost of developing robust evidence that the “anticipated survival gains are evident when it is used in routine practice”.</p>
Public	<p>There are patients I am aware of, who are dying because we take too long to authorise use of new treatments. Â NICE need to find a way to fast track potential life extending treatments.</p>
Pharmaceutical Industry	<p>Overall, AstraZeneca commends the Institute for looking into this difficult area, and asks the Institute to look at quality as well as length of life. Â With respect to the data collection piece, AstraZeneca supports this approach. Â In order for the effectiveness of the medicine to be assessed, comparative data will need to be collected and there is the question of who would decide which comparator medicines would be included in the database. Â Additionally, AstraZeneca suggests that it would be beneficial to allow the data to be collected by another independent group. Â This would allow NICE to make judgements on receipt of the data, without the risk of NICE being deemed judge and jury by its stakeholders. The statement in section 3.2 appears a reasonable approach to take in order to ensure robustness of the NICE system in the future. There is a question in terms of clarity regarding section 5.2. Â In the current text it is unclear exactly to what the cost of Â£100,000 per medicine relates – is this for the NHS to implement usage of the medicine or is this the cost to NICE (or the NHS) for collecting the effectiveness</p>

	evidence? It would be useful to clarify this prior to publication. AstraZeneca also notes that if this current approach is adopted relating to end of life treatments, the Institute may need to update certain sections of the Social Value Judgements document regarding rare conditions and rule of rescue.
other	We welcome the measures to review the resulting guidance to ensure that the parameters outlined reflect new treatment developments to enable patient access at the earliest opportunity.
NHS Professional	The proposal itself is likely to be inflationary and encourage pharmaceutical companies to focus on researching margin improvements in survival from their drugs whilst pushing their prices to a level that will fit within the proposed new guidance. This will be at the expense of a reasonable quality of life for terminally ill patients many of whom will suffer serious side-effects in an attempt to prolong their life. Overall, if these proposals went ahead, it would establish precedents that would then need to apply to other conditions and the NHS could end up spending large sums on relatively poor value treatments. If NICE really wants to consider changing its advice to its appraisal committees then it should be possible to ask for a piece of work that models the proposed changes and evaluates the impact both for the intended patients and for the NHS. Given the underlying issues this may well be a substantial evaluation but NICE should be well placed to commission something like this given its experience in this area. What is surprising is that NICE has not thought to underpin its proposal with more data and evidence so as to have a more measured and balanced debate.
other	There needs to be a full public debate on whether the objective is appropriate before discussing the details of implementation. What does the NICE Citizens Council think? What does the Health Select Committee think?
other	I am concerned about the opportunity cost of potentially more favourable recommendations for high cost drugs for people with terminal illnesses. I think the public needs to be assured that the money used to fund such favourable recommendations is not taken away from other end-of-life care such as palliative/ hospice care to help people to die under dignified circumstances. In terms of supporting future research into societal preferences, it would be useful to find out what choices people would make if extra funds were available in end-of-life situations: would people who receive a terminal illness diagnosis - given a choice - buy the intervention or would they use the money otherwise, for example to do something special with their families, or to improve their chances of spending their last few months in specialised care facilities.
Other	Overall, there is insufficient detail in the consultation document considering the QALY ceiling and end of life medicines and as expressed above further clarification is needed. We also wonder why the title "End of Life Medicines" has been chosen. One might not necessarily call some of the expensive rare and less common cancer therapies in development "end of life medicines" but nevertheless, there are situations where patients need to access these vital cutting-edge therapies although they have not yet necessarily reached "end of life". We wonder how an arbitrary, overall threshold of 24 months can be applied to the definition of end of life as the end of life process can include a range of physical, psychological and emotional transitions which vary from person-to-person and disease-to-disease. There are some diseases where a pre-

	<p>malignant condition may inevitably transform to a malignant condition with all of its terminal aspects. But what situation would that patient find himself or herself in regarding access to more expensive therapies with a higher QALY if their overall prognosis is greater than 24 months but they still have a terminal disease? This would potentially apply to our patients with cystic lesions, IPMN or having undergone surgery and requiring adjuvant treatment. Also neuroendocrine type patients have much better prognosis in general but some can die within 24months if not given cutting edge treatment or the disease has progressed too far before diagnosis. They are only 10% or less of our patients so rare but the definition of terminal may affect access to treatment under this new criteria. (this requires more input from specialists in neuroendocrine type pancreatic cancer)</p> <p>Additionally, although it may be outside of the scope of this appraising end of life medicines document, we would like to make a procedural point. We ask NICE to ensure that on every Appraisal Committee evaluating new therapies for rare and less common cancers, there should be at least one expert clinician with specific experience of the relevant disease for which the appraised therapy is being considered.</p>
Other	<p>We warmly welcome the opportunity to contribute to this consultation. The Rarer Cancers Forum's recent reports <i>Taking Exception</i> and <i>Exceptional England?</i> both demonstrate the critical importance of having timely and appropriate guidance available to the NHS on the use of treatments for cancer. Without such guidance, too many patients are forced to rely on exceptional cases processes to determine whether the NHS will fund the life sustaining treatment they need.</p> <p>This scheme should make a significant contribution to ensuring that more appropriate guidance is issued to the NHS. However our audit of PCT exceptional case processes showed that by far the most prevalent form of exceptional case requests is for treatment on which NICE has yet to issue guidance. Therefore it is critically important that NICE redoubles its efforts to ensure that its guidance is issued in a timely manner and – where this is not possible – that alternative sources of guidance are available to the NHS.</p>
Other	I can see no justification for isolating this group as a special case
Other	<p>Bayer are pleased to see that NICE recognise that the value of new innovative technologies that extend life in terminally ill patients cannot always be summarised in the traditional cost per QALY threshold range.</p> <p>In addition to our comments above, we would like to raise the following points:</p> <p>Section 1.7: for the final document, it may be helpful for the Appraisal Committee to know what type of evidence could be collected in the programme of evidence development, particularly when they are considering any areas of uncertainty.</p> <p>The current consultation document does not provide a cost per QALY threshold beyond which technologies that</p>

	<p>meet the “end of life” criteria will not be accepted. We understand that to do so may restrict the flexibility the Appraisal Committee have when considering other important factors. We would like to see guidance to the Committee issued on how other factors should be considered, as well as explicit consideration of the factors in the decision-making process contained within issued guidance documents. This would aid the consistency and transparency of the three Appraisal Committees.</p> <p>Section 4.2 states that an independent evaluation will be undertaken, although the independence of this evaluation may be compromised if the Institute “design and manage the evaluation”, as stated in 4.4.</p>
NHS Professional	<p>End of life medicines is an inappropriate title. Perhaps "life-extending medicines for terminal illnesses" would be better.</p>
NHS Professional	<p>The current TA Methods Guide Updated June2008 already contains a clear statement which would allow appraisal committees to make decisions beyond the £30,000 per QALY gained. The proposed change will act to segment the NHS population into groups who, by the rarity of their condition may have access to therapies which may deflect funding from other locally identified priorities. Commissioners have consistently argued against the ‘rule of rescue’ as a basis for commissioning policy and decision making, and will find it difficult to maintain a differential basis applied solely to a minority of their population who fall within the arbitrary threshold: the consultation document includes the criterion that “No alternative treatment with comparable benefits is available through the NHS”. The proposed new threshold is likely to limit Commissioning policies and/or the Exceptional Treatments process’s ability to decline funding for treatments with a lower QALY. This is likely to be irrespective of the relative frequency of the condition in order to avoid the inequity of arbitrary numbers. Whilst accepting that the current process is not without issues, the PCT would prefer to retain the current guidance (June08) supplemented by more work within commissioning PCT’s to implement appropriate exception treatment processes.</p>
NHS Professional	<p>These proposals undermine the fundamental principles of NICE and the right spending of public money - and do not represent good stewardship fo NHS resources. They will establish precedents which are then hard to resist for any treatment or intervention. The whole issue needs a balanced and extensive debate, including the views of the general public about priority setting, and to be based on proper data and evidence, with clearer definitions.</p>
other	<p>This is a highly emotive and political area however, the PCT would welcome. Given the relatively short extension to life guidance set out by NICE. anticipated from many of these treatments, it is important that the approval process is as quick and as simple as possible. Similarly, particularly given the recent report into the deaths occurring within a month of palliative chemotherapy, it is important that guidance should be very clear about the performance status of patients for whom treatment is being appraised. PCTs should NOT be expected to fund palliative Chemotherapy for patients of a poor performance status (in whom the treatment might shorten, rather than lengthen life.) All patients in this situation should also have access to specialist Query whether the marketing lead of one drug company which palliative care. reimburses the cost of the drug where it clearly has had no response benefit to an individual could be held up as best practice by companies seeking recognition for their products?</p>

Pharmaceutical Industry	<p>The Richards Report on Top Up Care in the NHS clearly states that within a publically funded NHS system, which is founded on the principle of being free at the point of care, patients who pay privately for their own medical treatment should be the exception and not the rule. Currently there are frequent instances where a drug is licensed and available on the UK market, but Primary Care Trusts (PCTs) have no guidance from NICE on which to base their decisions about funding a particular treatment. The speed with which PCTs make such decisions when funding requests are sought by clinicians is evidently very variable, as is the consistency and transparency with which decisions are made across NHS PCTs. This can lead to long delays for patients and clinicians in securing funding and to the inequities of post code prescribing. When patients are seeking such treatments at the end of life, days count. The Richards report comments that for one NHS Hospital Trust, the mean time to receive funding approval (which would enable the patient to commence therapy) from PCTs was 38 days, with a range of 0-231 days. The fact that many of these high-tech, high cost treatments are currently excluded from Payment By Results, even if NICE approved, means that clinicians may have to seek funding by direct requests to commissioning PCTs rather than automatically being funded through a costed HRG Tariff. This system in itself introduces delays in accessing medicines, which could be addressed by adopting an alternative tariff approach. We are aware of a case where a clinician has sought PCT funding for the use of a Genzyme product, Clofarabine in acute myeloid leukaemia (currently an unlicensed indication), as the only viable treatment option, where the patient concerned died before the PCT responded to the request. Such a case illustrates the difficult process challenge that needs to be addressed within the NHS alongside the issues that are being tackled within this End of Life Medicines Consultation process. As such, we welcome the measures the Government and NICE are already taking to improve the timeliness of NICE guidance. While not an issue for NICE, the proposed steps to improve the speed, quality and transparency of PCT decision making on funding of new drugs as set out in the Richards Review are also welcome. We hope that these comments are helpful to NICE in shaping the way forward on this positive proposal and look forward to the outcome of the consultation process. Andy Fenton Head of Health Outcomes and Strategic Pricing Genzyme Therapeutics Ltd, UK Tuesday 9th December, 2008</p>
NHS Professional	<p>Several points in the consultation document are contrary to the June 2008 NICE Guide to Methods of Technology Appraisals, specifically:-</p> <ul style="list-style-type: none"> • "The Institute is asked to take account of the overall resources available to the NHS when determining cost effectiveness. Therefore, decisions on the cost effectiveness of a new technology must include judgement on the implications for healthcare programmes for other patient groups that may be displaced by the adoption of the new technology." • "The Committee will take into account how its judgements have a bearing on distributive justice" • "Given the fixed budget of the NHS, the appropriate threshold to be considered is that of the opportunity cost of programmes displaced by new, more costly technologies." <p>The justification for the proposed change as cited is weak:-</p> <ul style="list-style-type: none"> • "It may sometimes be the case that the costs involved in developing medicines for small groups of patients need to be reflected in a higher price, at least for the first indication". <p>However as noted previously many if not most drugs developed for a single relatively rare cancer move into widespread use (within or outwith their licensed indications)</p>

NHS Professional	Approval of this proposal while expedient to some, will result in a range of unaffordable, unintended consequences:- (i) distortion of NHS funding towards relatively cost-ineffective drugs postponing death for a few with cancer (ii) a range of drugs will be priced at the new ICER threshold and it will be impossible to decline funding of these for other conditions outwith the population incidence threshold (iii) NICE and the NHS will have established a rule of rescue policy that will further distort NHS funding priorities and have opportunity costs for NHS prevention and more cost effective symptomatic palliation for a wide range of conditions: maternity, children, mental health and end of life care are stated NHS priorities. The inherent inequity is contrary to all NHS policy
other	1. If the technology will have demonstrable survival benefits and data proving its worth beyond that normally accepted by the Appraisal Committee there is possibly less need for the follow up data collection and more need for that data collection to be done where the evidence base is less strong. 2. The reviews mentioned in 3.1 - do these relate to the proposals for whether or not the guidance requires an update or the actual updating of the guidance? Thought needs to be given to the volume of work for these topics being updated and how that will decrease the appraisal programmes ability to issue guidance on new technologies as the work is all being done updating existing guidance.
other	<p>Paragraph 3.2 appropriately anticipates that a medicine listed following this criteria may be followed by another medicine and states that the comparator's price will not necessarily become the new benchmark. However, it is not clear what will happen if the new medicine produces a substantial extension to life compared to the first one, especially when the eligible "rare" population is those who are refractory to the first medicine, ie becomes the next "line of therapy". There is practical experience of this in other jurisdictions. Other jurisdictions have also had practical experience of two medicines being considered at about the same time for the same disease. If both extend life to about the same extent, how will this new approach be applied?</p> <p>Paragraphs 1.7 and 5.1 commit to following up use of a medicine recommended on this basis in a single-arm registry format and reporting on observed survival. This type of evidence development will prove problematic if the survival appears different from the projection based on the randomised trials, which may have been premature in reporting overall survival. If it is lower, is that because the patients are different or the benefit of the medicine was overestimated? This question is essentially unanswerable because by definition it will not be in the highly unusual circumstance of the survival gain is way beyond any impact of confounding factors. Knowingly committing to an "only in research" type project where the new evidence generated will be less convincing than the original evidence is hardly a satisfactory way to address uncertainty over the extent of survival gained and the extent of the resulting incremental cost-effectiveness ratio. Rather a much weaker rationale seems to be implied, namely that it gives some sense of reassurance that the new medicine is being monitored and that any unexpected results might form the trigger for subsequently generating a more conclusive trial design.</p>
other	Paragraph 1.7 proposes that use of medicines recommended under these new rules will be accompanied by the

	<p>collection of further evidence about their effectiveness in practice. This may be a good use of research funds in some cases, but it is not clear that it will always be so. By definition, the number of people affected will be small, so the potential gains from further information will be modest. Spending on evidence development for these medicines should be assessed alongside other uses of limited research funds. In essence these proposals, however well-meaning, compound and conflate three quite separate issues: of values for last years/months of life costs of developing interventions for small indications, and recommendations with evidence development funded by NICE. Each issue needs to be dealt with separately, consistently and systematically not combined in one arbitrarily defined 'special circumstance'. The current proposals will undermine the logic of much of NICE's work and will lead to inconsistencies and hence an appeal lawyer's dream!</p>
Pharmaceutical Industry	Schering-Plough is grateful for the opportunity to comment on this supplemental guidance.
other	We strongly welcome this consultation and the willingness to consider the important issues behind it which do affect women with ovarian cancer, who have very limited treatment options, and often because of allergic reaction or development of resistance to chemotherapy involving platinum based compounds. We would in addition like to seek clarity on the timescales in question to the proposed review processes: ie will this take place only once the initial appraisal has been rejected, and in which case, what timescale is envisaged for this type of appeal.
other	This may risk previous successful measures where manufacturers have reduced prices or introduced schemes to improve the cost/QAly. Thus it may increase NHS expense. Is this not a way for a drug to be used in and experience gained which could then lead to using the drug at an earlier stage of treatment? How will the PPRS announcement affect the pricing, especially with a sliding scale? If we put a higher quality on this disease are we not developing a post code prescribing for disease states?
other	With many new chemotherapy and targeted drug treatments in the pipeline and many existing secondary breast cancer drugs now being used in the primary breast cancer setting, it is important that effective clinical options are successfully appraised by NICE and not excluded on cost alone.
NHS Professional	I am concerned primarily about the opportunity costs to other patient groups of this proposal. I am also concerned that this will skew research and development of drugs onto those drugs which may prolong life and this may have the twin effects of the NHS spending resource on poor value treatments and also investing less in drug developments in other important areas
Pharmaceutical Industry	Sanofi-aventis agrees with the proposed changes to the NICE review process with regards to treatments with less than 7,000 eligible patients.
Pharmaceutical Industry	<ol style="list-style-type: none"> 1. Whilst the consultation recognises the proportionally higher costs associated with developing medicines for conditions affecting a small group (not normally exceeding 7,000 patients per annum), this is not just true of the first indication. We believe that further end of life indications should also be judged against the higher limit. 2. Clarification would be helpful as to which point in the appraisal process manufacturers will be informed that their medicine is subject to these new appraisal criteria. 3. It will be important to ensure that NICE is properly resourced to undertake these reviews, re-reviews and post-guidance audits and additionally, that the NHS has adequate

	resources to implement the guidance.
Other	<p>We welcome the opportunity, on the behalf of the School of Health and Related Research Technology Assessment Group (SchHARR-TAG) to comment on hypothesised changes regarding the cost-effectiveness criteria for 'end of life medicines'.</p> <p>SchHARR-TAG recognises that the current methodology may not appropriately capture society's values of disutility; an estimated QALY gain of 1 may be viewed differently were this to be obtained through the treatment of an identified patient who would die within 2 years without treatment, or through treating a cohort of 1,000 people of whom an unidentifiable patient is estimated to die, or through treating a cohort of 1,000 patients all of whom would benefit from 0.001 QALY. Whilst intuitively this may be plausible, SchHARR-TAG is unaware of any research that has shown this to be the case. SchHARR-TAG would welcome empirical data to enable differential weighting of QALY gains, if appropriate, to allow care to be provided more closely to society's wishes.</p> <p>SchHARR-TAG believes that the adjustment of utility gained whilst maintaining the same cost per QALY ratio for all medicines would be the most appropriate approach. This approach is consistent with the theory that the cost per QALY threshold represents the opportunity costs of the activities displaced due to funding additional interventions and is consistent with the goal of maximising societal health.</p> <p>It is acknowledged that the research required to allow an accurate assessment of the true weighting of utility would not be completed in a short period of time and that NICE has to make decisions in the immediate future. SchHARR-TAG recommends that explicit sensitivity analyses are undertaken to ascertain the relative weighting that would be required to form a cost per QALY of £20,000 and £30,000. This would allow the appraisal committee an indication of the likely increase in weight that would be needed in order to be cost-effective. Whilst the threshold for weight would still be non-defined it is expected that the knowledge of whether the weight needed to be, for example, twice that normally assumed or twenty times that normally assumed would be extremely useful to the committee.</p> <p>Allowing an increased (and non-defined) cost per QALY threshold for certain diseases would not be consistent with maximising societal health as the QALYs gained through those interventions that would be displaced would be greater than those produced by the treatment. The increased threshold would also be liable to creep into areas of healthcare. For example, were an intervention to be accepted with a cost per QALY of £100,000 then the relatively cost-effectiveness of preventative measures, that may delay the patient receiving the intervention, is automatically improved compared with a scenario where the intervention was not accepted. Furthermore, an increased threshold could also be seen as a disincentive for pharmaceutical industries to reduce acquisition costs.</p> <p>SchHARR-TAG did not understand the rationale behind limiting those disease areas where increased cost per QALY thresholds may be applicable based on a (potentially arbitrary) number of patients with the disease. SchHARR-TAG</p>

	<p>believes that the number of patients with a disease should be independent of the threshold, excluding considerations regarding the volume and opportunity costs of those interventions that would be displaced.</p> <p>SchHARR-TAG notes that the wording of the consultation document is relatively ambiguous. This is likely to put the onus on appraisal committee members who will need to decide whether an average of 24 months refers to a mean or a median, whether the data represents a 'substantial' extension to life, whether the estimate is 'robust' in addition to having to set a potentially arbitrary cost per QALY threshold at which the intervention would not be considered to be cost-effective.</p> <p>It is noted that there is no comment on the maximal increase in life expectancy that should be considered; a intervention with a cost per QALY of £150,000 may be seen as justified if the treatment duration is for 6 months only, but possible not if the treatment was needed to be maintained for 20 years</p>
Pharmaceutical Industry	<p>We have also commented on Criteria for appraisal of end of life medicines, paragraph 2.3 and Implementation and evaluation, paragraph 4.4. I have sent a word version of our submission to the email provided by you. Eolmedicines@nice.org.uk</p>
Pharmaceutical Industry	<p>The consultation document makes the following statement regarding evidence generation:</p> <p><i>Subject to agreement with the Department of Health, medicines recommended for use on the basis of the criteria set out in section 2.1, will normally be subject to an appropriately designed programme of evidence development to ensure that the anticipated survival gains are evident when it is used in routine practice. The outcome of this exercise will be evaluated when the guidance is reviewed. The design of the studies will be determined by the Institute and will need to be funded centrally. NICE will be responsible for managing the data collection exercise and assessing and reporting the outcome. Manufacturers will be given access to anonymised data and a summary of the results published.</i></p> <p>It appears that evidence development programmes will be initiated for all medicines which are recommended for use on the basis of the criteria set out in Section 2. We believe the focus of this evidence collection should be related as much to the most appropriate use of the medicine by the NHS as to establish anticipated survival gains. The extent to which such a real-world study is anticipated to improve on the existing evidence base should be clearly outlined.</p> <p>Clarity should be given as to what the Institute considers an 'appropriately designed programme of evidence development'.</p> <p>In designing the programmes we recommend that the Institute provides manufacturers with the opportunity to</p>

	<p>comment on the remit and protocol of any data collection to ensure the considerable expertise of companies on the product and the therapy area is maximised.</p> <p>On the two-year time period for review, does this refer to the start of the review (i.e. at the point NICE considers whether it is appropriate to do a re-review) or to completion of the review? This has substantial impact on timings – if the two years date from the initiation of the re-review, it could be another two years before completion i.e. four years from the initial decision.</p> <p>The statement requires further clarification:</p> <p><i>“Second and subsequent licences for the same product will be considered on their individual merits. The Appraisal Committee will take into account the cumulative population for each product in considering the strength of any case, for justifying a higher ICER, which employs, in whole or part, a small population argument”</i></p> <p>While it is stated that new indications will be considered on their individual merits, it is unclear what the term “cumulative population” refers to. For example when considering an adjuvant indication for a cancer medicine, will the existing metastatic population be considered as part of a “cumulative population”? To include other populations that inform an alternative ICER and appraisal would appear inappropriate. The ABPI considers that the population criterion should be applied <i>independently</i> to each indication NICE reviews.</p> <p>We note that a budget of around £100,000 is anticipated for each data collection exercise. While this might be sufficient for those programmes where pre-existing cancer registries can be used, it is unlikely to be enough in those disease areas where such registries are not available. We recommend that prior to publishing a final figure the Institute investigates the costs which may be required for those disease areas for which registries do exist and/or for which there are low patient numbers. In these situations, international data may be required and would greatly increase the costs required to conduct appropriately designed research.</p>
NHS Professional	<p>The proposal itself is likely to be inflationary and encourage pharmaceutical companies to focus on researching marginal improvements in survival from their drugs whilst pushing their prices to a level that will fit within the proposed new guidance. Â This will be at the expense of a reasonable quality of life for terminally ill patients, many of whom will suffer serious side-effects in an attempt to prolong their life. Â Costs – we disagree with NICE’s statement that these changes will be likely to affect “small number” and therefore, in inference, will not increase costs significantly. Â We estimate that the impact for a population the size of Oxfordshire – over 600,000, could be possibly Â£2 million per year. Overall, if these proposals went ahead, it would establish precedents that would then need to apply to other conditions and the NHS could end up spending large sums on relatively poor value treatments. Â If NICE really wants to consider changing its advice to its appraisal committees, then it should be possible to ask for a piece of work that models the proposed changes and evaluates the impact both for the intended patients and for the NHS. Â Given the underlying issues this may well be a substantial evaluation but</p>

	<p>NICE should be well placed to commission something like this given its experience in this area. What is surprising is that NICE has not thought to underpin its proposal with more data and evidence so as to have a more measured and balanced debate.</p>
other	<p>Will this affect any of the processes leading up to the appraisal commencing. For example will the scoping process and topic selection need to take this into account when working with proposed topics that may fit this criteria. If a proposed topic does fit this criteria, or is felt that it may do during the appraisal should this be recorded within the draft and final scopes (as other considerations)? Is there anything that needs to be done to make the Department of Health aware of this before the formal referral of the topic? Should draft scope consultations and scoping workshops have the capacity to incite a discussion on this issue of it is relevant to the proposed technology? Is there the potential for topic selection consideration panel scoring of proposed topics to differ or be biased in regards to this issue?</p>
Other	<p>1.7 In principle we welcome the proposal in the consultation for a programme of data collection which will be commissioned by NICE. There is no indication as to how this element of the proposal will be executed and we would value more information.</p> <p>It also appears from the consultation document that manufacturers will not be consulted or involved in the design of research activity supporting their products. We believe that manufacturers should have the opportunity for some involvement in this exercise and avoid duplication.</p> <p>EMG believe that in final guidance issued for a medicine undergoing this process, it must be made explicitly clear how additional guidance and criteria were applied by the Appraisal Committee.</p>
Pharmaceutical Industry	<p>We note that acceptance of a medicine under these criteria is to be in the context of an 'appropriately designed programme of evidence development'. While we fully recognise the need to ensure that anticipated survival gains are indeed evident in routine practice we are concerned as to the probability of effectively gathering this data in terms of the timelines for review of the decision and also in terms of the capacity of the NHS to deliver sufficiently robust data given the budget allowed.</p> <p>The schedule for review suggested within this consultation is after a period of two years. Obviously this will not allow for the data collection needs in areas where the existing life expectancy is close to this period and the revision schedule will need to be adjusted accordingly.</p> <p>The capacity to undertake long term real life data collection is not sufficiently developed within the NHS. For example, existing cancer registries are not set up to deliver the level of data required, primarily recording incidence and prevalence of disease and little in the way of outcomes measures. Any existing NHS organisation routinely treating patients with rare disease would need considerable restructuring in order for them to be able to report detailed information on particular treatment and duration, patient follow-up, detailed diagnostic and prognostic information etc. in a manner which could be pooled for national analysis. While this could be achieved it is unlikely</p>

	that £100,000 will be sufficient to deliver the robust evidence that would be required.
Pharmaceutical Industry	Subsection 1.7: The programme of evidence development may benefit from greater involvement of the manufacturers especially in the design of the studies and the data analyses. Manufacturers are often asked by regulatory bodies to collect such data either in the form of patient registries or through post-marketing authorisation commitments and phase IV trials. There may be an opportunity to adapt the design of such programmes to meet the needs of the proposed evidence development whilst also generating valuable data around other additional parameters. A collaboration between NICE and manufacturers may serve better to maximise the potential benefits of such work. Subsection 3.2: Given the high cost of development of each individual indication, second and subsequent indications should indeed be considered on their individual merits. It is not therefore appropriate to consider the cumulative population for each product when considering the strength of any case for justifying a higher ICER.
other	1) If the emphasis was not on life expectancy then I might agree in principle with prioritising rare conditions on equity grounds. But I'm not sure what the incentives are for research. If a drug company is receiving £100k per QALY for its drug then maybe it won't have an incentive to develop a cheaper drug. 2) Another concern with the proposed approach is that there might be a sort of diagnostic creep, especially if it were to be applied in Clinical Guideline development. If for a population of 20,000 something is found to be not cost-effective at conventional thresholds then pressure might come from an interest group or GDG members to divide the main group into three and then one or all of the subgroups might qualify for the intervention.
NHS Professional	The other concerns we would have is the effect this will have on pharmaceutical companies, whether they will keep prices in line with the higher cost effectiveness ratio. We also feel that a more explicit guidance should be issued by NICE with regard to the research process to ensure that quality of life and increased survival are issues addressed during drug trials.
NHS Professional	I note that there seems to be a lack of methodological reasoning to the proposals such as to SVJ papers. I believe that would make the proposal more robust especially when trying to decide whether it applies to certain conditions.
NHS Professional	<p>1. I have significant concerns about the validity of evidence to support making a special case for terminal disease with short survival <u>at the expense of</u> other conditions</p> <p>2. I think there is the danger that this becomes a back door approach of increasing the profits of industry while squeezing out treatments and services that don't come to the attention of NICE (eg supportive palliative and end of life care): any increased generosity shown by NICE should be backed up with additional funding to resource them</p> <p>3. There are implications for NICE regarding the messages we send out to patients, in particular the danger of raising false hopes and expectations. If we make special arrangements for end of life treatments we may reinforce</p>

	<p>impressions made by the press and internet, that these drugs are the 'best' option. A recent BMJ editorial (Munday and Maher BMJ July 2008) notes that patients are 'having to decide whether or not to have treatment at the same time as facing the harsh realities of dying'.while noting a study showing large inconsistencies in how oncologists share information about survival benefit and alternatives to active treatment (Audrey et al BMJ July 2008). If we do continue with special generosity when making end of life drugs available, does NICE have a responsibility to revisit its patient information to make it clear that patients may wish to consider alternatives to life prolonging drugs (in line with the advice we may in future produce to help people decide about paying for tops)?</p>
NHS Professional	<p>Whilst we recognise that the concept of evidence development is one way of attempting to ensure value for the NHS, we have concerns about the logistics and the consequences of such an evaluation. How will the data be collected and who will lead on this? How will the fact that clinical reality does not mimic trial conditions be accounted for? Will the treatment be removed from the NHS if the evaluation finds it to be less effective in clinical practice? What about the ethical consequences of this for patients?</p> <p>Finally, we want to seek clarity on section 1.4. Will the additional guidance apply as part of the appraisal process or only after a negative ACD has been developed, as the wording currently suggests? Surely the former makes more sense, financially and time-wise.</p>
Other	<p>To increase the speed of NICE technology appraisals and to increase the range of drugs approved is the single most important step in maintaining the NHS as free to all, regardless of their income. If appraisal processes are prolonged and a significant number of clinically effective drugs continue to be turned down, the problems about paying for extra NHS care, if one can afford it, will not go away</p>
Other	<p>In response to your request for comments on the proposal to issue supplemental advice to Appraisal Committees when appraising end of life medicines, NHS North Yorkshire and York asks you to note the following points:</p> <ol style="list-style-type: none"> 1. Affordability <p>Overall, the PCT is concerned that the proposed changes will result in the funding of medicines, to the detriment of other areas of healthcare. The PCT does not therefore, support the proposed changes.</p> <ol style="list-style-type: none"> 2. Distortion of overall priorities <ol style="list-style-type: none"> 2.1. The proposed changes will distort priorities across the spectrum of health and health care. In particular, we believe that the proposals run counter to the purpose of world class commissioning, which seeks a balance that takes full account of the areas with less articulate advocates, for example in mental health, to

ensure that “the quieter voices” are heard.

2.2. The proposed changes could result in the paradoxical situation whereby some treatments are only funded during the latter stages of life.

2.3. The proposed changes distort the emphasis away from primary prevention.

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2.4. The proposed changes provide an inequitable focus on relatively rare conditions. They confuse the '*merit of the individual and their disease*' with the '*merit of the intervention*'. It appears irrational and unethical to judge one disease or health state more or less deserving than another. Basing decisions on the merit of the intervention is more reasonable and objective.

3. Opportunity costs within End of Life care

The proposed changes will undermine implementation of the recent National Audit Office report on End of Life care. Under the proposed conditions, NICE technology appraisals will be more likely to approve medicines for use at NHS expense, so incurring appreciable opportunity costs for Primary Care Trusts (PCTs). In the absence of additional funding streams, this will be to the detriment of funding for other end of life care. Funding end of life medicines should not be seen in isolation from the rest of end of life care, which includes enabling dignified and pain-free death at home or in a hospice. Within the programme budgeting approach, there is an opportunity cost within the cancer programme. A greater priority than medication would be NHS hospices, for example.

4. Length of life compared with quality of life

4.1. The focus on improvements in life expectancy represents a preference for length of life over quality of life in terminal disease, but for many people the latter is more important. Improvements in quality of life (morbidity) are explicitly excluded from this special status. Work on value-based judgements suggests that the public, as opposed to cancer patients, give added value for improvements in quality of life for people with terminal disease, but no special value for extension to life of people with terminal disease.

4.2. Inappropriate chemotherapy can hasten death with poor quality of remaining life. This point is highlighted in the recent NCEPOD report reviewing the care of patient who died within 30 days of receiving systemic

anti-cancer therapy.

5. 'Rule of rescue'

Funding on the basis of a 'rule of rescue', where treatment is funded because there is no alternative treatment available with comparable benefits, is not a good basis for commissioning policy and decision-making. It is difficult to maintain a differential basis applied solely to a minority of the population who fall within an arbitrary threshold.

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6. Cost-effectiveness of drugs

6.1. Many of the drugs do not provide good "value for money" and, at launch, are often supported by immature evidence, which does not permit adequate assessment of clinical or cost-effectiveness. In terms of survival, overall survival benefit used to be the only outcome measured; the use of "progression-free survival" should be confined to the adjuvant setting, not end of life care. Funding for some new cancer drugs is requested on the basis of trials which show only a small increase in median overall survival (eg 2-3 months) but no significant difference in median time to symptomatic progression. Again, this raises the question of whether increasing quality of life in terminal disease is more important than increased quantity.

6.2. Further definition of the necessary benefit, currently referred to as a 'substantial extension of life' is crucial.

6.3. The lack of an indicative upper value for the ICER per QALY gained is an important omission. In the absence of such a threshold, we believe that there will be no incentive for manufacturers to price products affordably.

	<p>6.4. To allow a higher cost per QALY for an intervention which may (or may not) extend life by a little seems illogical if one were to compare the cost effectiveness of the intervention with the value of the health state. It is clear that there are health states that are worse than death; surely we should pay more for these than for treatments which in actual fact could <u>only potentially</u> extend life by a little but prolong the time spent in poor health state? With such poor evidence of clinical effectiveness, to fund treatments that are way beyond the normally accepted (and affordable) cost effectiveness thresholds is in effect, funding expensive hope.</p> <p>7. Perverse incentives for drug companies</p> <p>The proposed changes will provide perverse incentives for drug companies, encouraging them to focus R&D efforts on relatively rare diseases and away from population health needs (i.e. drugs which provide more benefit to more people with commoner conditions (which are therefore more cost-effective)). We believe that this threatens the approach to value-based pricing. It also discourages developments of treatments that improve the quality of a patient's life by explicitly excluding such treatments from any end of life premium. There is likely to be 'threshold creep' and liberal interpretation of 'not normally' and 'substantial'.</p> <p style="text-align: right;">Cont. /</p> <p>8. Potential impact of treating these patient groups</p> <p>8.1. The proposed changes represent a fundamental new development in the terms of reference for NICE if it is to consider <i>"the costs involved in developing medicines for small groups of patients need to be reflected in a higher price, at least for the first indication."</i> (1.3). This appears to over-rule consideration of the value of the health it produces in relation to alternative uses of the NHS budget and suggests that NICE will no</p>
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longer provide a means for promoting efficient use of NHS resources to promote population health..

8.2. With an incidence of 7000 p.a. and an average life expectancy of up to 24 months; the actual population likely to receive treatment (and thus the budgetary implications) may be considerably larger; depending upon the distribution of the life expectancy generating a mean of 24 months, the expected duration of treatment and the effectiveness of the treatment. If we assume a price tag similar to the renal cancer drugs (at £29k a year), the budget impact for treating 14,000 patients (7000 p.a. for 2 years) is over £400M.

9. Communication between oncologists and patients

There is much that needs to be addressed regarding communication between oncologists and patients, particularly with regard to patient expectations. Oncologists have recently been shown as not communicating the true risks and benefits of further treatment to patients. The NCEPOD review demonstrates their problems in estimating life expectancy and the appropriate timing for raising the issue of palliative care.

10. Comparison with recent Appraisal Guidance

Several points in the consultation document are contrary to the June 08 NICE Guide to Methods of Technology Appraisals, specifically:-

- *"The Institute is asked to take account of the overall resources available to the NHS when determining cost effectiveness. Therefore, decisions on the cost effectiveness of a new technology must include judgements on the implications for healthcare programmes for other patient groups that may be displaced by the adoption of the new technology." (6.2.13)*
- *"The Committee will take into account how its judgements have a bearing on distributive justice... in relation to human rights, discrimination and equality" (6.2.20)* What about the inequity of a higher ICER change for potentially life extending interventions (this is one of the key points: none are consistently life extending) for conditions which affect only 7000 a year as opposed to those of potential benefit to the common conditions which affect the many in the last 24 months of life?

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- *"The Appraisal Committee takes account of how the incremental cost effectiveness of the technology being*

	<p><i>appraised relates to other interventions/ technologies currently being applied in the NHS. In addition, as far as possible, the Committee will want to ensure that their judgements regarding the cost-effective use of NHS resources are consistently applied between appraisals" (6.2.15)</i></p> <ul style="list-style-type: none"> • <i>"Given the fixed budget of the NHS, the appropriate threshold to be considered is that of the opportunity cost of programmes displaced by new, more costly technologies." (6.2.21) If this proposal is approved, it will make it much harder to decline funding for any 'rule of rescue' end of life treatment of marginal benefit.</i> <p>11. The need for evidence development</p> <p>While we support further research to increase our knowledge-base for new treatments, this should be done systematically in the context of randomised controlled trials. Collecting outcome data from a highly selected group of patients, each treated with an individual trial of a drug, does not provide robust data to inform prospective use. It is also not clear how such data will be used. For example, will costs be refunded or discounted during the assessment period if a drug is not found to be as effective as in clinical trials?</p> <p>12. Possible alternative methods</p> <p>The final question about “Whether there are valid alternative methods which might be used to achieve the same ends, in the short or long term” raises the question of what are these ends? If the ultimate aim is to ensure that patients have appropriate access to new and affordable cost-effective drugs in a timely fashion, then the fast-track approach of the Scottish Medicines Consortium could be adopted. Drugs are appraised according to the evidence base and approved rapidly “where the economic case has been demonstrated”.</p> <p>On the other hand, the objective might be that every cancer sufferer gets a chance to die with dignity and minimum of suffering in a place of their choosing – i.e. everyone gets a positive “end of life plan” and we do not spend disproportionate sums in areas of less value.</p> <p>We hope these comments are helpful and look forward to hearing the outcome.</p>
NHS Professional	<p>Breakthrough feels that the figure of 7,000 people or less for whom the medicine is indicated and licensed is too restrictive and that end of life medicines which make a difference to patients’ lives should not be limited in this manner. While the premise that developing medicines for small populations is costly and therefore results in a higher price may be true, there are also medicines for populations greater than 7,000 people that are costly for other reasons (such as being the result of the latest innovations and technology, being targeted treatments which attack only cancer cells while avoiding healthy cells, resulting in fewer side effects or being licensed in combination</p>

	<p>with another drug which can increase the price). These medicines should be given equal consideration. Also, clarification is needed regarding the 7,000 population wording to ensure that this value does not just refer to a condition, but could also pertain to a specific sub-set of a condition (e.g. the population is not restricted to breast cancer but could be in reference to breast cancer patients who have HER2 positive early breast cancer, for example).</p> <p>Drugs are becoming more expensive, both to produce and to purchase as they become ever more advanced in their design. If these treatments are consistently rejected by NICE for regular use in the NHS due to cost alone, this may create a disincentive for innovation and improvements to vital medicines not just for breast cancer, but for all conditions.</p> <p>Breakthrough Breast Cancer is the UK's leading breast cancer charity committed to fighting breast cancer through research, campaigning and education, and has established the UK's first dedicated breast cancer research centre, together with three new research units, in order to obtain our vision – a future free from the fear of breast cancer. Breakthrough campaigns for policies that support breast cancer research and better services, as well as promoting breast cancer education and awareness amongst the general public, policy makers, healthcare professionals and the media.</p> <p>This submission reflects the views of Breakthrough, based on our experience of working with people with personal experience of, or who are concerned about, breast cancer. We regularly consult with members of our Campaigns & Advocacy Network (Breakthrough CAN) for their views on a range of breast cancer issues. Originally founded by women with personal experience of breast cancer, Breakthrough CAN brings together over 1100 individuals, regional groups and national organisations to campaign for improvements in breast cancer research, treatments and services. Through supporting and training members to become patient advocates in their own right, Breakthrough CAN aims to increase the influence of patients in decisions regarding breast cancer issues.</p>
NHS Professional	<p><u>Evidence development:</u> I note that 1.7 of the paper and the cost impact presented in section 5 suggest that for all topics that have been accepted for EoL consideration an evidence development exercise should be set up to 'ensure that the anticipated survival gains are evident when it is used in routine practice'. I see no benefit in this activity. Mostly because the criterion of robustness of the evidence ways, and it should do, so heavily on the decision for Committee to do more. If, and that's what the methods say, Committee has to be pretty certain that the survival benefit seen in the trials is real than why do we need more 'routine practice' evidence? I am not disputing</p>

	<p>the need for routine practice evidence in general in HTA but I see no added benefit for this scheme. Not in the least because EMEA are also going to be demanding such evidence for those drugs for whom this scheme might be applicable.</p> <p><u>Other DH initiatives:</u> The Institute has to be careful not to undermine some of the flexible pricing initiatives identified in PPRS. Clear processes need to be developed for combining EoL and flexible pricing when Committee is to consider both in its deliberations. It will be very important to consider what Committee is to consider first; is this an EoL appraisal with the possibility of benefits having been missed, and allowing the manufacturer to target their flexibility towards inclusion of some EoL notion? Or first 'negotiate' on the cost side of the argument and only at the very last instance consider the EoL argument?</p>
NHS Professional	It should be expected that the range of medicines that this guidance is relevant to in children is very small and that adapting the phrasing for those <16yrs will not impact in any substantial way on the healthcare budget of the nation.
NHS Professional	The Prostate Cancer Charity supports the need for an independent evaluation of the new criteria to ensure they achieve their purpose.
Other	We also wonder about the actual title of the consultation "Appraising End of Life Medicines". One might not necessarily call some of the expensive brain tumour therapies in development "end of life medicines" but nevertheless, there are situations where patients must be able to access these vital cutting-edge therapies although they have not yet necessarily reached "end of life". We wonder too if instead of using the word "medicines", a broader description should be used such as "therapies" or "treatments" which allows consideration of innovative medical devices which might also be applied in an "end of life" situation and which involve additional monitoring costs. We can think of an example of a brain tumour treatment device currently in clinical trials in the United States when

	<p>such a situation could arise.</p> <p>Additionally, although it may be outside of the scope of this appraising end of life medicines document, we would like to make a procedural point. We ask NICE to ensure that on every Appraisal Committee evaluating new therapies, particularly for rare and less common cancers like brain tumours, there should be at least one specialist clinician with substantial experience and expertise of the relevant disease (or grouping of diseases) for which the appraised therapy is being considered.</p>
Other	<p>Overall, there is insufficient detail in the consultation document considering the QALY ceiling and end of life medicines.</p> <p>Other comments:</p> <p>(1) Although it is a bit of an academic argument at this stage, we wonder where the QALY of £30,000 originally came from and why it hasn't risen, for example, in line with inflation or the additional costs of developing cutting-edge therapies.</p> <p>(2) We also wonder why the title "End of Life Medicines" has been chosen. One might not necessarily call some of the expensive rare and less common cancer therapies in development "end of life medicines" but nevertheless, there are situations where patients need to access these vital cutting-edge therapies although they have not yet necessarily reached "end of life". There are some diseases where a pre-malignant condition may inevitably transform to a malignant condition with all of its terminal aspects. But what situation would that patient find himself or herself in regarding access to more expensive therapies with a higher QALY if their overall prognosis is greater than 24 months but they still have a terminal disease?</p> <p>(3) Additionally, although it may be outside of the scope of this appraising end of life medicines document, we would like to make a procedural point. We ask NICE to ensure that on every Appraisal Committee evaluating new therapies for rare and less common cancers, there should be at least one expert clinician with specific experience of the relevant disease for which the appraised therapy is being considered.</p>
Other	<p>When considering the final guidance that the Institute will give its Appraisal Committees. We also urge NICE to consider what other improvements may be made to their current system of appraisal.</p> <p>An intelligent approach to decision making</p> <p>For many treatments given to patients at the end of their lives, those with rare cancers, and those with conditions for which there are few or no other treatments, it is often not</p>

	<p>possible to produce evidence of sufficient robustness to fit NICE's process of rigorous appraisal.</p> <p>We consider the additional weight placed on proven survival benefits is particularly important given the complications associated with <i>proving</i> effectiveness in these patients. We think the same principles should be applied to all situations in which evidence is difficult to obtain.</p> <p>Although the proposals within this consultation are aimed at extending the lives of patients, in an ideal world we would also like to see flexibility within the system that also recognises the importance that some new drugs bring in terms of quality of life. For many cancer patients, an improved quality of life can, in effect, give life back to patients that they would otherwise be denied. An example of this might be a new growth factor that abolishes neutropenia or oral mucositis, or a formulation that avoided cardio-toxicity. While these will not translate into increases in overall survival, they may well also mean that patients previously considered too frail to treat effectively could be fit enough to receive a treatment that could extend their life.</p> <p>We are therefore pleased that NICE will be reconsidering whether their current costeffectiveness threshold is appropriate for all types of drugs in all conditions. We look forward to continuing to work with NICE on this issue.</p> <p>The way that NICE calculates value</p> <p>When considering the cost-effectiveness threshold, it is also important that NICE ensure that the methodology they are applying to reach a measure of 'value' is still valid. We understand that there are some questions about whether the EQ-5D scale is appropriate for all types of drugs and in all conditions, particularly for cancer. We seek commitments from NICE that they will turn their expertise to tackling this problem.</p> <p>Expert involvement in NICE appraisals</p> <p>Recent examples of appraisals where NICE's decision has been at odds with the majority of clinical opinion are worrying. Increased flexibility in the threshold at which NICE will allow drugs to be recommended on the NHS, should be accompanied by an increased focus on clinician involvement to better inform these decisions.</p> <p>I</p> <p>mpact of changes to drug pricing</p> <p>We would also welcome discussion on how the announcements by the Department of Health on changes to the current system of drug pricing will impact on NICE's appraisal process. Recent announcements that the lung cancer drug Tarceva (erlotinib) will be made available to lung cancer patients have been a long time in coming. We are certain that the irony of this being the second drug to enter into NICE's 'fast track' Single</p>
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	<p>Technology Appraisal is not lost on the Institute. However, we appreciate that the burden of responsibility does not lie entirely with NICE—had the pharmaceutical industry stepped in earlier to offer a negotiated price, this drug would have been available to cancer patients many months ago. We would welcome details of how NICE will tackle these situations in the future. We look forward to working with NICE as they implement these changes. If all of the measures announced in the last month are taken forward, tens of thousands of cancer patients will benefit.</p>
Other	<ul style="list-style-type: none"> • 1.7 MSD welcomes the proposal to support the new process with a programme of evidence development. However, we believe it essential that manufacturers are in some way involved, ideally partners, in these programmes. We note also in 5.2 that a budget of around £100,000 is anticipated for each data collection exercise. While this might be achievable in pre-existing cancer registries, some disease areas (particularly those with small populations) might not have similar infrastructure and therefore costs could be considerably higher. • We note that in 3.1 that NICE recommend that guidance is reviewed within 2 years after publication. MSD would request that a review date is set on publication of guidance. • "Second and subsequent licences for the same product will be considered on their individual merits... will take into account the cumulative population for each product" <p>MSD would welcome further clarity on how this provision should be interpreted. If a cumulative population is considered alongside a 7000 patient threshold, this runs the risk of excluding many new indications particularly in oncology, where multiple indications are common. MSD believes that in order to avoid arbitrary discrimination, that the treatment population for different indications should be considered independently.</p>
NHS Professional	<p>The guidance in section 1.7 seems to be suggesting that further research is warranted to demonstrate that the survival benefits will be achieved in practice. However, condition 2.1.3 states that sufficient evidence should be available to indicate that the medicine offers a substantial extension to life, with section 2.2.1 suggesting that survival benefits 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) would be sufficient. Further details need to be given</p>

	<p>in section 1.7 on the type of evidence that is to be collected through the evidence development programme and whether this type of evidence is likely to be useful in the situation where survival benefits can be inferred but not proven from the clinical trial evidence already available. We would suggest that further research should focus on areas of uncertainty which may significantly alter the cost-effectiveness estimate and should be based on expected value of sample information analysis. In some cases further information on patient's preferences or quality of life measurement may be more beneficial to decision makers than obtaining a more exact estimate of the survival gains. It is also not clear from section 1.7 whether there would be a requirement for all patients receiving the intervention to be enrolled with the evidence development programme studies or whether patients would be able to receive the treatment without participating in the development of further research.</p> <p>The requirement in section 2.1.1 for the medicine to be indicated for a small population of patients contradicts NICE's current position on rare conditions given in section 4.4 of "Social Value Judgements: Principles for the Development of NICE Guidance" (2nd edition, July 2008) which says that NICE will appraise drugs to treat rare conditions in the same manner as any other treatment.</p> <p>The proposed guidance is focused on end of life medicines and does not mention other technologies which fall within the remit of NICE's technology appraisal program. No rationale is given for why similar considerations are not valid for life-extending medical devices or surgical procedures.</p> <p>This proposal seems to be trying to address several different issues at the same time; the importance of life to those with terminal illnesses and whether this should result in additional weight being placed on survival benefits in this group of patients; the high cost of developing medicines that will be used only by a small number of people; uncertainty in the reproducibility of survival benefits outside of clinical trials and the need to encourage innovation that may benefit future NHS patients. The proposals seem to have been developed as a pragmatic solution to the difficult decisions facing appraisal committees without proper consideration being given to how each of these issues can best be addressed.</p>
Pharmaceutical	<p><i>Section 1.4</i></p> <p><i>To be considered under this supplementary advice, a medicine will need to have been through a single or multiple technology appraisal by NICE where the most plausible point estimate or range for the ICER exceeds the upper end (£30,000) of the range normally considered by the Appraisal Committees to represent a cost effective use of NHS resources.</i></p>

This wording implies that the proposed criteria will be applied retrospectively only after the medicine has undergone appraisal. We are concerned that this may delay the issuing of guidance on new medicines to the NHS and patients unnecessarily, when it may be reasonably obvious at various stages of an appraisal that the medicine will fulfil the eventual criteria. We suggest that steps are built into the appraisal process for evaluating whether a medicine is eligible for consideration under the proposed criteria, at various stages, e.g. scoping, submission, assessment by TAG/ERG, and Appraisal Committee meetings.

We understand that NICE do not intend to review guidance that has already been issued prior to the effective implementation of this consultation until a review of such guidance is planned. We would urge that consideration is given to schedule an early review in such cases, in order that patients have the potential to benefit from these medicines are able to do so as soon as possible, and not unfairly disadvantaged. For those medicines where the appraisal is not yet finalised the terms of this guidance should be considered as part of the ongoing appraisal rather than delaying to any review.

Section 1.7

Subject to agreement with the Department of Health, medicines recommended for use on the basis of the criteria set out in section 2.1, will normally be subject to an appropriately designed programme of evidence development to ensure that the anticipated survival gains are evident when it is used in routine practice. The outcome of this exercise will be evaluated when the guidance is reviewed. The design of the studies will be determined by the Institute and will need to be funded centrally. NICE will be responsible for managing the data collection exercise and assessing and reporting the outcome. Manufacturers will be given access to anonymised data and a summary of the results published.

We support the commitment of NICE to evaluate the survival gains in routine clinical practice, but challenge the proposal on several points:

1. Whether NICE has the resources to conduct such research;
2. Whether data collection will be needed for every medicine appraised under the proposal, e.g. for those medicines where the evidence base is well established and benefits are unequivocal;
3. Whether the estimated average of around £100,000 will be sufficient to undertake robust data collection.

We suggest that a collaborative approach between NICE/NHS and manufacturers might be a sensible option in order to capitalise on existing registries and/or data collection exercises (e.g. expanded access schemes), as well as established expertise in the area of evidence collection.

Section 3.2

Medicines approved following the application of the supplemental advice will not necessarily be regarded or accepted as standard comparators for future appraisals of new medicines introduced for the same condition. This will be to ensure that a high ICER does not automatically become the benchmark for the assessment of medicines subsequently introduced for the same indication.

Whilst we appreciate the motivation behind this criterion, we believe that if medicines that have been appraised under the terms of the proposed criteria are not accepted as standard comparators, then they cannot be considered as alternative treatments with comparable benefits, as in section 2.2.3.

Second and subsequent licences for the same product will be considered on their individual merits. The Appraisal Committee will take into account the cumulative population for each product in considering the strength of any case, for justifying a higher ICER, which employs, in whole or part, a small population argument.

Whilst we agree that second and subsequent licences should be considered on their individual merits, this appears inconsistent with the second statement that suggests that the individual populations would be considered cumulatively. We believe that it is inappropriate to consider different licences collectively as the development costs apply separately and fully to each indication.

General comments

Given the variability between disease areas in terms of life expectancy, expected benefits of new medicines, and degree of unmet medical need, we suggest that the proposed flexibility in the thresholds is decided on a case by case basis.

For every case considered under these criteria the basis for rejection or acceptance should be transparent to all stakeholders.

NHS Professional	<p>1. The RCN welcomes the consultation on this important issue. The RCN wishes to raise a number of issues in relation to the approach of NICE. These include:</p> <ul style="list-style-type: none"> a) The value for money of different treatment options (and not just for medicines but for the range of treatments available to treat conditions); b) The need for an evidence base and full public debate on the cost per QALY threshold; c) The need for consistency in the way that resource allocation decisions are made both locally and centrally within England; d) The need for greater implementation of NICE guidance (and not just relating to technology appraisals) and discussion of how to incentivise this as there is evidence of poor implementation of Technology Appraisals despite PCTs being required to fund positive recommendations within 3 months of their publication; e) The need to fully consider the implications of coverage with evidence development programmes; <ul style="list-style-type: none"> • for speed of access (presumably it will take time to set up such arrangements); • for patients (for example what information will be collected from them, how it is used); • confidentiality issues; • for staff (for example if they will need to gather information to be used in such programmes); f) The need to consider the cost consequences of allowing a higher threshold (and this may well have an impact across different countries expenditure on health). g) The need to assess the risk that the proposed approach will increase or decrease geographic differences in access across the four countries of the UK; and <p>An ethical analysis of these issues.</p>
NHS Professional	<p>Although I can see that there are some strong reasons for proposing this I think NICE will be at risk of losing its credibility in terms of treating all interventions and conditions equally. This could set a dangerous precedent and will undoubtedly infuriate those with chronic and painful conditions and may be seen as unfair to people with conditions that are not the focus of large lobbying organisations.</p> <p>This proposal also seems to reinforce the opinion that drugs are at the heart of medical treatment, suggesting that palliative care, surgical interventions and other therapies are less important. I am concerned that other services will suffer as a result of the NHS having to pay for more expensive drug treatments.</p> <p>It would appear that the Appraisal Committees already have the scope to recommend interventions over the £30k limit as detailed on p.1 of the consultation document. Given the expense of, for example the RCC drugs recently</p>

	<p>appraised, how much more weight would one need to attach to life expectancy in order to make them cost effective? Would there be a new 'upper limit' for drugs appraised using the supplementary advice? Would adopting the supplementary advice actually make any difference if the cost per QALY is so high?</p> <p>Given that NICE consistently asserts that it 'has to make best use of NHS resources' will PCTs be able to meet the cost of interventions approved by NICE under the supplementary advice? Has this been investigated?</p> <p>Is the original QALY 'limit' actually reflective of the money available within the NHS to pay for interventions approved by NICE? And why has this been immune to the effects of inflation?</p> <p>Re: para 1.7 I am slightly concerned that by having NICE undertake the analysis of further data regarding survival gains suggestions might be made regarding the independence or lack thereof of such a report.</p>
Other	<p>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.</p> <p>BMS supports the introduction of this new advice to the appraisal committee in relation to end of life medicines. Access to end of life medicines in the NHS is currently unnecessarily restrictive and this approach should improve the situation to the benefit of NHS patients. We believe that a number of points in section 2 require clarification.</p> <p>What clarity will NICE be giving to its Appraisal Committees in the application of a new higher cost effectiveness threshold? Will the new threshold vary from one appraisal to the next or depend on the amount of survival benefit provided by the medicine being appraised?</p> <p>BMS would seek further clarity from NICE concerning how uncertainty around the population size & life expectancy qualifying criteria would be handled. Would, for example, a medicine where the best estimate of patient population was 7,200, but there was uncertainty of +/- 5% be considered for inclusion? We believe that the application of the qualification criteria to specific appraisals should be discussed at the scoping stage, so as to provide guidance for the manufacturer in preparing its submission, rather than being left for the Appraisal Committee to decide at a later point, without consultation. Such an approach would reduce the risk of the application of the qualifying criteria becoming another point of issue at a subsequent appeal.</p> <p>BMS believes that further clarification is needed on how a medicine would be appraised where it is licensed for the treatment of patients at different stages of a particular disease, and where patients in an earlier stage might be expected to live, on average, for longer than two years, but patients in the later stages are likely to die before two years. Similarly, the total indicated population could be over 7,000, but the number of patients in the later stage</p>

	<p>could be below the qualifying number. Would a product in this position in effect be appraised in two different ways, applying different criteria depending on the stage of the disease, and how would this be reflected in the guidance produced by NICE?</p> <p>BMS supports the use of progression-free survival (PFS) as the most appropriate measure of whether a medicine is life-extending or not, given the circumstances in which this methodology will be applied for products used in the treatment of end-of-life disease. It is right to recognise in these circumstances that the evidence base is likely to be immature and overall survival is often not measured in early trials.</p> <p>BMS queries the use of the word “substantial” in section 2.1.3 and believes that it should be removed from the description of the qualifying criteria. We note that this new guidance for the appraisal committee is designed to apply to medicines that have a “demonstrable” survival benefit (section 1.1) and that this is consistent with the approach as announced to Parliament by the Secretary of State for Health when he described it as applying to medicines “which have been shown to extend the lives of terminally ill patients” (Hansard, 4th November 2008, col. 132).. Such statements we believe should be taken to refer objectively to the evidence-base available from a medicine’s clinical trials. The use of the term “robust” to describe estimates of the extension of life can be taken as meaning the same.</p> <p>“Substantial”, however, implies a further hurdle that would take the form of a subjective judgement applied by the Appraisal Committee. Such judgements could vary from appraisal to appraisal, especially in the absence of more detailed guidance as to how “substantial” is defined. We believe that the introduction of ambiguity around the application of such value judgements would be unhelpful in a process that should tend towards the objective so far as it is possible. Moreover, we feel that the introduction of the “substantial” qualification creates an additional, and more burdensome, test that was not envisaged by the Secretary of State when he set out the intent of the scheme to Parliament. BMS believes that this new process should apply to all medicines that extend life, as measured by PFS or overall survival.</p> <p>In section 2.2.3 referring to alternative treatments, it is not clear how “comparable benefit” will be defined and from where the relevant data should be derived.</p>
Other	<p>1. The prospective evaluation of the treatment needs to be taken into account in further and future guidance.</p> <p>I acknowledge the contributions of Professor Tony Avery, Dr Andrew Ross, Dr Clare Gerada and Dr K Sivakumar towards the above comments. While contributing to this response, it cannot be assumed that those named all necessarily agree with all of the above comments</p>

TA Committee Member	I feel increasingly uncomfortable about the fudges we are being asked to apply to medicines which prolong life for patients with terminal disease. Whilst I see the purpose of the NICE appraisal process as a means of rationally distributing the NHS cake such that all might benefit in some equal measure from it I also recognise that this can not be a purely mathematical calculation but that we have to balance equity with cost-effectiveness. However when our patients council asked us to give extra attention to life-prolonging medicines I started to worry that we were moving back to the position of funding going to “heart string” drugs as opposed to providing an adequate supply of incontinence pads and that our decision were being unduly influenced by tabloid campaigns which affected public sentiment. It is of course important to balance the old medical profession tendency to be paternalistic with listening to the public.
TA Committee Member	I think NICE having been involved in this process had to respond and been seen to address the issues in a positive an innovative way without compromising, as far as possible, its founding principles.
TA Committee Member	Given that it is suggested that this will apply to relatively small numbers of patients, and given also that the cost for some individual patients may be very high, is there a case for some central funding arrangement?
TA Committee Member	I am sure that you will have had input from more than one ethicist, and I hope that this comes out in the debate.
TA Committee Member	Understandable response to media controversy. The proposal, while well intentioned, is misguided in my belief. Variation to the decision making framework should be based on empirical work, special cases may be made for many different groups of NHS users, who are yet to press their claim or grievance. Admittedly, cancer sufferers are a very large single group. The proposal as it stands, seems to weaken NICE and undermines its principles. Speeding up decision making should not be conflated with speeding up access by increasing positive appraisals.
TA Committee Member	Raftery pointed out in his review of NICE decisions (2) in 2001 that all but one technology had cost per QALY below £30,000. The exception was the drug riluzole for motor neurone disease (amyotrophic lateral sclerosis (ALS) with a relatively high cost per QALY of £34,000 - £44,000. NICE cited the “the severity and relatively short lifespan of people with ALS ...” in reaching the decision. This suggests that

	<p>NICE appraisal committee members at that time held the view that a higher threshold was acceptable for an end of life treatment. I suggest (as mentioned above) that consideration is given to adding clarity about assessment of the <u>quality</u> of life during the extended period of life and also adding a note about stopping rules for treatment when harms of treatment become greater than benefits. Ref (2) NICE: faster access to modern treatments? Analysis of guidance on health technologies. James Raftery. BMJ 2001; 323:1300-1303</p>
<p>TA Committee Member</p>	<p>The proposed changes to the NICE guidance to incorporate end of life changes would, in my opinion, do untold damage to the reputation of NICE, and would result, in many cases, in unworkable rulings where the courts ruled on each and every case.</p> <p>Let me give some examples: NICE approves a drug that is anticipated to be applicable to 6500 patients who are expected to die within the next 23 months....Suppose for reasons of immigration that expected population rises to 7001, then does the guidance no longer follow and funding is stopped?</p> <p>Lets take a more likely scenario, oncologists interpret the rules meaning that the figures modelled are wrong and we end up treating 14,000 – do we only fund it for the first 7000 every year? What about if the anticipated life expectancy was 25 months, or 26, or 27? – would it be ethical to say that because you are living longer we are going to value your life at a lower level? What about paediatric terminal illness – for example some of the chromosomal abnormalities – where life expectancy is still significantly reduced, making 25 yr modelling illogical.</p> <p>Looking at it an alternative way it does bring two new concepts into NICE that have up to date been forbidden: Life expectancy is taken into account – thus, for example we could take life expectancy into account when considering putting cochlear implants in 85 yr olds, or treating AMD, or alzheimers drugs... using modified age mortality charts it would be easy to include anticipated life expectancy into the equation....Availability of financial resources and financial impact – give the arbitrary anticipated death rate and arbitrary anticipated numbers these figures clearly have a cut off that has a financial impact – we could have a sliding scale on both counts – so that if the effected population was millions the NICE threshold would be much lower than £20K, whereas if it was just one or two the cost would be much higher.</p>

	<p>NICE isn't perfect, but at least at the moment it is consistent, and any change to this would seriously undermine its credibility. It would become the thin edge of the wedge that could result in huge case to case variability. Ultimately I think it would result in several things: drugs companies would price their drugs according to the higher threshold for end of life drugs. NICE guidance would end up being decided by the courts, not the appraisal groups in most cases. Or NICE effectively says yes to anything, and either bankrupts the NHS or stops any procedure happening that hasn't been NICE appraised due to lack of funds in PCTs – probably a mix of both.</p> <p>This is, one of the worst ideas I have seen from NICE, and if implemented I would seriously consider whether I could continue to defend, and therefore be associated with the organisation.</p>
TA Committee Member	<ol style="list-style-type: none"> 1) If we were to move to a position where we were to look at how we might recommend higher ICER treatments for these groups of patients, then you might like to consider first of all as to whether a shorter predicted life expectancy for a given circumstance deserves more "compassion" in our calculations, and how we might measure this quantitatively or qualitatively 2) Should we be positively discriminating in favour of a small group of patients, perhaps at the cost of much larger groups of patients whose ICERS are similar and, are equally as "deserving"(however that may be quantified).3)Is the additional "weight" that we apply to this much smaller group of patients that we might be minded to recommend for, a reflection of the pressure that NICE feels from the public and media as a result of some of our decisions?
TA Committee Member	It appears NICE has already decided so why ask us? The BMJ editorial (15 nov) states that NICE have already instructed their committees to give more weight to end of life decisions.. (p1122)
TA Committee Member	It appears vague and confused. It doesn't say how EoL will be treated differently from all the other 'soft' factors.
TA Committee Member	The proposals could inflict serious reputational damage on the Institute. The institute must resist it!
TA Committee Member	The Institute is in a difficult position but the wording of section 2 is from my perspective likely to make things more difficult in committee, especially 2.1.1 but I would be interested to hear what others think. If there is to be a change I would favour a more radical rethink.

TA Committee Member	I think that the overall problem will be if a drug is recommended under these 'special' criteria of use in a disease not exceeding 7000 new patients per annum, but then subsequently not allowed in a similar condition which is above this level of incidence ceiling; NICE could be accused of unfairness. It might also lead to the thought that getting a license and NICE guidance for the use in a disease of less than 7000 patients first, could be then used as a way of getting the drug used more widely in other diseases where the ICER is set at £30k. There will still be a finite budget and developing differing criteria will certainly effect what money can be spent, unless there is provision or more funding to match.
TA Committee Member	I agree with the proposition. I suspect society would support the proposition. I have accompanied terminally ill patients to hospital where they were told "nothing else can be done for you." The effect was devastating. Extending life and/or improving the quality of life of terminally ill patients (who wish to accept treatment) is the action of a caring and compassionate society. Showing people at the end of their life that they matter is important. Although the ICER may be above £30,000, the implementation costs will not be large within overall budgets because of the relatively small numbers involved and the duration of treatment.
TA Committee Member	A very good start, but much more careful debate is needed. Unless there is a very well understood and acceptable set of criteria, drug companies, vested interests and members of the public will challenge them at every turn.
TA Committee Member	<p>I will want to see even more emphasis in relevant appraisals on the risks as well as the benefits of approved medicines. The recent report by the NCEPOD into chemotherapy for seriously ill cancer patients reportedly had some disturbing conclusions ie more than 1 in 4 of patients studied died as a result of drug side-effects rather than the cancer and in 19 per cent of cases the decision to treat was inappropriate. Some doctors will understandably be tempted to give the gloomiest prognosis so that their patients meet the 24 months criterion. While many terminally ill patients wish fervently to prolong their lives as far as possible, others choose to live their last months without the demands and discomfort of further treatment .</p> <p>It would be unfortunate if this initiative promoted the notion that life should be prolonged at all costs and discouraged patients and doctors from choosing palliative care when that could be the patient's preference. The session on the Away Day will be a welcome opportunity to hear about the</p>

	<p>background to this proposition. I would like to know how many treatments have been approved under para. 6.2. 25 (and equivalent para. in old version) of the methods guide , and for which conditions and what ICERs. Implementing this additional guidance will be an interesting challenge for ACs which I look forward to.</p>
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