16 September 2008

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Appraisal consultation document

Bevacizumab, sorafenib, sunitinib and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma

Dear Sir,

The National Kidney Federation is the National Charity (No1106735) representing the interests of some 2.5 million patients with Kidney problems including those with Renal Cell Carcinoma. We have read the above appraisal consultation document and although as a patient body we must leave the technical comments to the Clinicians and Drug companies we do wish to make a number of comment on behalf of the patients we represent.

We are frankly appalled and extremely concerned at what we consider to be a cold and callous financial decision by NICE completely deviod of patient concern. This decision will leave the patients concerned with few options for treatment. The disease is highly resistant to chemotherapy and radiation treatment. Immunotherapy treatment using the drug Interferon Alpha only has a modest effect in prolonging survival and Interleukin 2 is not proven to increase survival and has substantially negative side effects.

There is also a proportion of patients who may be unsuitable for immunotherapy, primarily due to poor performance status and because of the toxicity of interferon (and the even greater toxicity of IL2). This set of patients also include poor risk patients (who are estimated to comprise 28% of advanced RCC cases. The decision seems to abandon the needs of all of these patients leaving them in a desparate situation with little hope for the future and the prospect of an early death.

It is a decision against all sense, and contrary to the situation in the rest of Europe and in the United States, where these drugs are being made available to such patients. In Sweden particularly where there is a comparable health system to are own, their equivalent organisation to NICE has already approved two of the drugs concerned as suitable for state Finance.

To deprive this small group of patient of access to these new drugs, (that your own ACD accepts are clinically effective), is to totally deprive them of any hope for the future. Their only alternative will be to fall back on what happens at present and that is to find some way of paying for the treatment themselves. Few will be able to achieve this without involving their families in serious hardship and if they should pay privately for NHS denied treatment under present arrangements they may find they will be excluded from further NHS treatment.

Such is the callous nature of this decision, a cost effectiveness judgement as apposed to a cost benefit assessment. The need to consider the severity of the condition, clinical need and other factors that contribute to social value judgement should be weighed alongside cost effectiveness in the context of a compassionate NHS; a view supported by the recent NICE Citizen's Council on Quality Adjusted Life Years and the Severity of Disease.

The Citizen's Councils also questions the EQ-5D which they thought was too blunt to capture all the factors relevant to the definition of a good or bad quality of life. They felt that it should take more account of the views of those who have first hand experience of the circumstances being rated, stating; *the EQ5D measures what people imagine the experience of various health conditions to be like. Clearly most of us never have experienced most of them and never will*. We think these comments are very relevent to the case in consideration and that there is a clear gap in the appreciation of what this decision really does mean to the patients concerned.

We feel strongly that the present assessment is flawed. The methodology and the current threshold set by NICE will make it very difficult for these small numbers of patients with metastatic disease to gain any access to any of the new inovative treatments. We have therefore withdrawn from a new proposed Technology Appraisal on two further RCC drugs since we believe the result will inevitable be the same if the methodolgy remains the same.

This NICE decision seems to indicate that a substantial number of new highly inovative drugs for diseases of this nature affecting small numbers of patients will fall foul of the NICE threshold level and the rigidity of the cost effectivness assessment.

If to many drugs collide with this threshold or are refused assessment then we could see inovative drug development and the availability of variations in treatment to patients being inhibited. As we have previously indicated in our first submission, breast cancers patients survival rates have increased as the range of therapies available increased.

We would ask how this NICE threshold was determined and why after a number of years has it remained at the same level despite the fact that NHS spending has risen threefold in that period. *(Health Select Committee report on NICE).* Surely there should be a special category / threshold for diseases of this nature where the number of patients is small perhaps similar to those that should be taken into account with orphan and ultra orphan disease categories.

As we pointed out in our original submission we need to consider budget impact as well as cost effectiveness. Although the individual treatments in this case may be expensive, because the number of people involved is very small, it will have a small effect on the overall NHS budget.

We believe fair and equally high standards of care should be available to everyone. To achieve this however, it may be necessary to spend more on some people with more complex problems than on others. We don't feel that this minority should be penalised for the sake of the majority, and we are concerned that once we start to discriminate against a minority of people with a condition such as RCC, who knows which group of essential treatment may be regarded as not cost effective and not affordable next. We have always been assured by Government and the NHS that treatment would be Quality driven not Finance driven.

Patients count good days rather than bad days. Good days are when they feel on top of the problems associated with the disease. This decision by NICE will most certainly contribute very few good days to the future of these vulnerable people. The four new drugs in this appraisal are capable of reversing this situation offering Patients and Clinicians important further alternative therapies and advantages in treatment. They will give help and hope to a small group of patients who will otherwise certainly die. We ask not only for a reconsideration of this appraisal but also a review of the methodology to ensure that future decisions made comply with the compassionate, patient centred and egalitarian ideals of the NHS.

National Kidney Federation
August 2008