National Institute for Health and Clinical Excellence

Sunitinib for the treatment of gastrointestinal stromal tumours

Comment 1: the draft remit

Section	Consultees	Comments	Response
Appropriateness	Novartis Pharmaceuticals	It is appropriate that NICE evaluates the clinical and cost-effectiveness of Sutent in order that guidance can be issued to the NHS regarding the appropriate place of Sutent in the treatment of GIST.	Comment noted. No changes to the scope required.
	Sarcoma UK	Yes. It is important that this subject is addressed as there are significant differences in clinical practice caused by inconsistent and discriminatory funding decisions.	Comment noted. No changes to the scope required.
	UK Oncology Nursing Society	This is an appropriate topic to be referred for a NICE appraisal as due to the low numbers of patients involved there are currently no clear guidance for this indication. Alternative treatment is therefore lacking, and becomes dependant upon individual clinicians and PCT's, inevitably resulting in inequality.	Comment noted. No changes to the scope required.
	Pfizer	We have undertaken a modelling exercise re: the potential number of patients eligible for treatment and therefore affected by this potential HTA and have estimated that no more than 150 patients per year would be eligible for treatment and this matches with the estimate in the draft scope. On that basis we would argue that the proposed appraisal is an ineffective use of NICE resources. should the decision be made to proceed with the referral Pfizer would argue that the MTA process is more appropriate than the STA process. the rationale for this is that an MTA process covering both imatinib and sunitinib would better inform clinical decision making in this area.	Comments noted. Drugs with orphan or ultra-orphan status are considered under our existing appraisal process. The issue of combining this appraisal with the review of imatinib and conducted as an MTA was discussed at the scoping workshop. Given that the licensed indication suggests that imatinib has failed and therefore would no longer be a relevant comparator, the Institute recommends that this appraisal be conducted through the STA process.

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	Royal College of Physicians	Important topic, needs to be addressed	Comment noted. No changes to the scope required.
	Rarer cancers forum	The population group that are likely to receive this drug come into the ultra orphan category there are between 110-150 people are a year who may need this therapy. We wonder why NICE is wasting taxpayers money undertaking this appraisal	Drugs with orphan or ultra-orphan status are considered under our existing appraisal process.
Wording	Novartis Pharmaceuticals UK	The document should consistently refer to the licensed indication as detailed in the product's Summary of Medicinal Product Characteristics (SmPC). The draft remit/appraisal objective section should therefore be amended as follows, "…within it's licensed indications for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance."	Comment noted. The remit has been amended accordingly.
	Sarcoma UK	This is an ultra-orphan condition and the criteria for clinical effectiveness and the measures of cost effectiveness which are used in more common conditions are inappropriate. The statements made by NICE during the Health Select Committee review in 2007/2008 about how procedures should be modified for appraising rare conditions should be reflected in the wording of the final remit. This will clarify openly how the procedures will differ from what we have been accustomed to.	Drugs with orphan or ultra-orphan status are considered under our existing appraisal process.
	UK Oncology Nursing Society	Yes	Comment noted. No changes to the scope required.
	Royal College of Physicians	Yes	Comment noted. No changes to the scope required.
	Rarer cancers forum	We feel that because of the patient numbers the budget impact is low . The drug is oral and there are minimal delivery to patient costs	Drugs with orphan or ultra-orphan status are considered under our existing appraisal process.
Timing Issues	Novartis Pharmaceuticals UK	The timing of the appraisal should be scheduled to coincide with the review of the Imatinib for the treatment of GIST (TA No 86).	The issue of combining this appraisal with the review of imatinib and conducted as an MTA was discussed at the scoping workshop. Given that the licensed indication suggests that imatinib has

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			failed and therefore would no longer be a relevant comparator, the Institute recommends that this appraisal be conducted through the STA process.
	Sarcoma UK	This review is important because this technology has now been licensed for nearly two years and the practice of PCTs in funding it differs widely.	Comment noted. No changes to the scope required.
	UK Oncology Nursing Society	Urgent, due to late presentation and current lack of clear guidance	Comment noted. No changes to the scope required.
	Royal College of Physicians	It is urgent, currently sunitinib can only be provided in most cancer networks by direct appeal to individual PCTs leading to an unacceptable degree of variability in access to the drug, i.e. "post-code prescribing"	Comment noted. No changes to the scope required.
	Rarer cancers forum	Patients are in need of this therapy and as per the CRS there should be a speeding up of the appraisal of these drugs	Comment noted. No changes to the scope required.
Additional comments on the draft remit	Pfizer	Best supportive care can best be defined as palliative care (symptomatic relief) with no active therapy. Sunitinib could be considered an alternative to increasing the dose of imatinib - this is supported by the sunitinib marketing authorisation.	Best supportive care will need to be clearly defined during the appraisal, based on information received at the scoping workshop. The issue of double-dose imatinib as a comparator for sunitinib was discussed at the scoping workshop. Given that the licensed indication suggests that imatinib has failed and therefore would no longer be a relevant comparator.

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	Rarer cancers forum	We understand that the company is providing the first cycle free of charge and then they are reducing the cost of future cyles by 5%. We hope that these figures are refected in the discion made by NICE	Comment noted. Resource costs will be considered in the framework of the appraisal in accordance with the methods guide. No changes to the scope have been made.

Comment 2: the draft scope

Section	Consultees	Comments	Response
Background information	Novartis Pharmaceuticals UK	Paragraph 2, 2nd sentence This section suggests that the proportion of patients who will develop primary resistance is around 21%, however, based on the literature the percentage of patients who develop primary resistance is around 12-14%.(1,2)	Comment noted. The scope has been amended accordingly
		This section states that 80% of patients initially respond to treatment, however, this figure should be 84% clinical benefit rate (4).	Comment noted. The scope has been amended accordingly
		Paragraph 3, 2nd sentence This section states that there is no guidance for patients with unresectable and/or metastatic GISTs who have failed imatinib treatment due to resistance or intolerance. However, it should be noted that the UK Guidelines for the management of gastointestinal tumours (GISTs) state, "On disease progression, dose escalation of Glivec to 600mg or 800mg/day should be considered". (5) In addition, the European Society for Medical Oncology (ESMO) clinical recommendations for the diagnosis and the treatment of GIST state, "The standard approach in the case of tumour progression is to increase the imatinib dose to 800mg daily." (6)	This sentence reflects that the current NICE guidance does not extend to patients who have unresectable and/or metastatic GISTs who have failed imatinib treatment due to resistance or intolerance. No changes made to the scope.
		Paragraph 3, last sentence This section states that few people survive beyond 5 years. However, it should be noted that median survival of Glivec patients with unresectable and/or metastatic GISTs is 57 months.	Comment noted. The scope has been amended accordingly to reflect the poor prognosis of patients who do not receive

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		(1) Demetri GD et al. N Engl J Med. 2002;347:472-480. (2) Martine Van Glabbeke et al ; Journal of Clinical Oncology, Vol 23, No 24 (August 20), 2005: pp. 5795-5804 (4) Blanke C et al. Journal of clinical Oncology Vol 26;No 4; February 1 2008 (5) Guidelines for the management of gastrointestinal stromal tumours (GISTs) January 2007 (6) Casali PG et al. Gastrointestinal stromal tumours: ESMO Clinical Recommendations for diagnosis, treatment and follow-up. Annals of Oncology, 19 (Supplement 2):ii35-ii38, 2008	treatment.
	Sarcoma UK	The last sentence of the Background is incorrect. It should read: The prognosis for people with unresectable and/or metastatic GISTs is poor unless treated, with few people surviving untreated beyond two years. Following relapse on treatment with imatinib and in the absence of further treatment, survival is usually less than one year	Comment noted. The scope has been amended to reflect the poor prognosis of patients who do not receive treatment.
	UK Oncology Nursing Society	Accurate but more evidence of efficacy needed	Comment noted. The scope is intended to provide only a brief summary of the condition and technology. More detail will be encompassed in the framework of an appraisal. No changes to the scope have been made.
	Pfizer	Both accurate and complete	Comment noted. No changes to the scope required.
	Royal College of Physicians	Incomplete, it doesn't address any of the complex molecular issues alluded to below The first comment concerns the subgroups most likely to benefit. It has already been shown that sunitinib appears to be more effective against GIST with activating mutations in KIT exon 9, at least compared to standard dose imatinib, and also those tumours with no detectable mutations in KIT or PDGFRA (termed wild-type). In addition, secondary mutations that arise in patients on imatinib, most commonly in those with activating mutations in KIT exon 11 at the outset (the commonest group), may confer resistance to imatinib but not to sunitinib (generally these are second	Comment noted. The scope is intended to provide only a brief summary of the condition and technology. More detail will be encompassed in the framework of an appraisal. No changes to the scope have been made.

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		mutations in exons 13 and 14 of KIT coding for the ATP binding pocket) but on occasion confer resistance to both drugs (especially exons 17 and 18, coding for the activation loop). The commonest secondary mutation is in exon 13. It has been shown that patients with exon 9 mutations have an increased likelihood of response and longer progression-free survival if treated with imatinib at 800 mg daily. This was confirmed by a meta-analysis of data from 1650 patients presented at ASCO in 2007 by van Glabbeke and colleagues. It is not yet known whether imatinib 800 mg or sunitinib is to be preferred for treating exon 9 mutant GIST. This group comprises about 15% of all GISTs. What is clear is that standard dose imatinib is suboptimal but that whatever treatment is currently given they have a poorer overall survival than patients with exon 11 mutant disease, at least when treated in a standard fashion. They are more likely to arise in the small bowel, a site which is associated with more aggressive behaviour. It is unclear whether the anti-angiogenic properties of sunitinib are important in the treatment of imatinib-refractory GIST	
	Rarer cancers forum	Again it wouls be helpful if NICE bothered to give references for its materila This would aid understanding and is a professional way to proceed	Comment noted. The scope is intended to provide only a brief summary of the condition and technology. All evidence used in the appraisal phase is clearly referenced. The purpose of the scope is to define the questions to be asked.
The technology/ intervention	Novartis Pharmaceuticals UK	Paragraph 1, 2nd sentence This section states, "It specifically inhibits the platelet…" It should be noted that sunitinib is a non-specific inhibitor of platelet derived growth factor receptor (PDGFR).	Comment noted. The scope has been amended accordingly
	Sarcoma UK	Yes	Comment noted. No changes to the scope required.
	UK Oncology Nursing Society	Yes	Comment noted. No changes to the scope required.
	Pfizer	Yes	Comment noted. No changes to the scope required.
	Royal College of	'tolerance' should read 'intolerance'	Comment noted. The scope has

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	Physicians		been amended accordingly.
	Rarer cancers forum	YES	Comment noted. No changes to the scope required.
Population	Novartis Pharmaceuticals UK	The document should consistently refer to the licensed indication as detailed in the product's Summary of Medicinal Product Characteristics (SmPC). The draft remit/appraisal objective section should therefore be amended as follows, "…within it's licensed indications for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance."	Comment noted. The scope has been amended accordingly.
	Sarcoma UK	The population is defined adequately. It should be noted that there is a subgroup of patients aged from <10 yrs to late 30s (with a female bias) who suffer from 'paediatric GIST'. One characteristic of these patients is that the tumour mutation is categorised as 'wild type'. Response to imatinib is usually poor but there are known good responses to sunitinib. Numbers are so small that trials are not feasible.	Comment noted. This was discussed at the scoping workshop and agreed that at this stage the evidence will not allow subgroups to be identified. No changes have been made to the scope.
	UK Oncology Nursing Society	Population is reasonable well defined but would all the patients counted be able to take this drug. Is there a subgroup of these patients who would not benefit, i.e poor performance status or co-morbidities	Comment noted. This was discussed at the scoping workshop and agreed that at this stage the evidence will not allow subgroups to be identified. No changes have been made to the scope.
	Pfizer	The marketing authorisation mentions both resistance and intolerance to imatinib - is the use of the term refractory intended to cover both of these?	The scope and remit have been amended to more accurately reflect the marketing authorisation of sunitinib.
	Royal College of Physicians	Yes	Comment noted. No changes to the scope required.
	Rarer cancers forum	The population group is so small that subgroups are not viable. There is nothing to offer these patients when they fail imatinab and the prognosis is poor some five years	Comment noted. No changes to the scope required.
Comparators	Sarcoma UK	There is no standard treatment in the UK for GIST refractory to imatinib in first line. From a patient viewpoint there is no "best alternative care". Inadequate pain relief leading to certain death is the "alternative". When viable and licensed technologies are	Comment noted. No changes to the scope required.

Section	Consultees	Comments	Response
		known to be available but cannot be accessed this situation is akin to institutionalised cruelty.	
	UK Oncology Nursing Society	More detail regarding comparators and their estimated costs is required	Comment noted. The scope is intended to be a brief summary of the appraisal topic. More detail will be encompassed within the framework of an appraisal. No changes have been made to the scope.
	Pfizer	Yes	Comment noted. No changes to the scope required.
	Royal College of Physicians	Many would now consider the comparator to be the continuance of standard dose imatinib rather than best supportive care (although this is not reflected in the current NICE guidance, which is itself due for review having been initially published in 2004) The comparator for exon 9 mutant GIST and for GIST that has become resistant to standard dose imatinib is higher dose imatinib - generally 800 mg daily. It is only a small minority of patients who are amenable to local treatment such as RFA and it is incorrect to say that the comparator is best supportive care. This is not the case in any country outside the UK, either in Europe or North America. Higher dose imatinib is licensed for this indication, it is proven to be superior for KIT exon 9 associated disease compared with standard dose imatinib, and may be effective in other cases for reasons of pharmacokinetics. If a trough level in excess of 1000 ng/mL is not achieved with standard dose it has been shown that imatinib will produce an inferior rate of response and shorter progression-free survival (Demetri, GI ASCO, 2008). Some patients simply require a larger dose and there may be a time factor to this since it has been shown that the clearance of imatinib increases over time in patients with GIST (Judson et al, Cancer Chemother Pharmacol 2005;55:379-86)	The issue of comparators was discussed at the scoping workshop. Given that the licensed indication suggests that imatinib has failed and therefore would no longer be a relevant comparator. It was agreed at the scoping workshop that the comparator should be best supportive care.
	Rarer cancers forum	There is no compoarator except best supportive care and we will be asking for the modle used by NICE concerning best supportive care. We need to be sure that what is suggested is realistic supportive by paaliative care physiains radiotherapists macmillan Nurses and GIST consultants	Comment noted. No changes to the scope required.
Outcomes	Sarcoma UK	Social issues are important too, although we understand the limitations that currently apply in considering these. In common with many sarcomas GIST patients may not be	Comment noted. Quality of life outcomes will be encompassed in

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		'unwell', while being seriously ill. Many patients live a full life and their boundaries are not constrained by a 'pill-a-day' treatment. Thus the social opportunity of treating a patient (or costs of failing to treat them) should be considered.	the framework of the appraisal in accordance with the methods guide. No changes to the scope have been made.
	UK Oncology Nursing Society	Yes	Comment noted. No changes to the scope required.
	Pfizer	Yes	Comment noted. No changes to the scope required.
	Royal College of Physicians	Yes	Comment noted. No changes to the scope required.
	Rarer cancers forum	No the most impotant outcome is that patients with no other therapy availbale could be offered treatment	Comment noted. No changes to the scope required.
Economic analysis	Sarcoma UK	There is never a perfect timing for a study in this disease setting. The progress of research in establishing the multitude of variations in the biological nature of GIST means that this is a disease which could justify individualised treatment within a relatively sort timescale. A failure to take the opportunities offered by this technology now would potentially delay progress towards this objective, which is clearly expressed in the core principles of the NHS.	Comment noted. No changes to the scope required.
	UK Oncology Nursing Society	Agree, this should be long enough to determine efficacy and cost effectiveness bewteen this drug and best supportive care but should be mindful of the short life expectancy of these patients.	Comment noted. No changes to the scope required.
	Pfizer	Time horizon as worded appears to allow for appropriate nmodelling based on the life expectancy of patients with this condition.	Comment noted. No changes to the scope required.
	Royal College of Physicians	Difficult without knowing how these calculations are made	Comment noted. No changes to the scope required.
	Rarer cancers forum	We need to ensure the cost model the company are using is inclused in the committees work	Comment noted. No changes to the scope required.
Equalities	UK Oncology Nursing Society	Need to be clear about biological factors of patients who are likely or unlikely to benefit, i.e. performance status, polypharmacy, ability for compliance/ concordance and how this will be determined, this is an oral, self-administered treatment.	The issue of subgroups was discussed at the scoping workshop. Currently there is no evidence on different subgroups of patients. No changes to the scope have been made.

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			The equality issues were discussed at the scoping workshop. No changes to the scope required.
	Pfizer	n/a	Comment noted. No changes to the scope required.
	Rarer cancers forum	The therapy meets unmet need and in the interest of equality of care it is important to offer this	The equality issues were discussed at the scoping workshop. No changes to the scope required.
Other considerations	Sarcoma UK	This appraisal should actively consider the resources available to the MDT and the specialist oncologist, who treat advanced GIST, to the extent of defining where/who should be authorised to prescribe this treatment. Key issues include access to mutation analysis, trials and current understanding of research.	Comment noted. Resource costs will be considered in the framework of the appraisal in accordance with the methods guide. No changes to the scope have been made.
	UK Oncology Nursing Society	None additional	Comment noted. No changes to the scope required.
Questions for consultation	Novartis Pharmaceuticals UK	Could sunitinib be considered as an alternative to increasing the dose of imatinib (in patients refractory to imatinib)? Is this within the terms of the marketing authorisation. Sunitinib should not be considered as an alternative to increasing the dose of imatinib. In the sunitinib registration study, 81% of patients received > 400mg imatinib prior to treatment with sunitinib ie the majority of patients had received dose escalation prior to sunitinib therapy.(3) (3) Demetri GD et al., Lancet online Oct 10, 2006 Which process would be the most suitable for appraising this technology, the single technology process or multiple technology process? We believe that sunitinib should be appraised using the multiple technology appraisal process in order to provide clear and comprehensive guidance to the NHS for the treatment of patients with GIST. In addition, comprehensive guidance will facilitate implementation by the NHS.	The issue of combining this appraisal with the review of imatinib and conducted as an MTA was discussed at the scoping workshop. Given that the licensed indication suggests that imatinib has failed and therefore would no longer be a relevant comparator, the Institute recommends that this appraisal be conducted through the STA process.
	Sarcoma UK	Could sunitinib be considered as an alternative to increasing the dose of imatinib (in patients refractory to imatinib)? Is this within the terms of the marketing authorisation? Currently an escalated dose of imatinib is not NICE approved although it has been	The issue of combining this appraisal with the review of imatinib and conducted as an

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		licensed for over three years and is standard practice worldwide. Many PCTs accept it as a valid stage in treatment. Sunitinib is a valid alternative for some patients and possibly not for others. It is within the marketing authorisation of both products.	MTA was discussed at the scoping workshop. Given that the licensed indication suggests that imatinib has failed and therefore would no longer be a relevant comparator, the Institute recommends that this appraisal be conducted through the STA process.
		Are there any subgroups of patients in whom sunitinib is expected to be more clinically effective and cost effective or other groups that should be examined separately? For example, is it appropriate to consider subgroups according to attributes such as performance status or prior therapy? It is appropriate to consider subgroups defined by mutation analysis (C-Kit and PDGFRa). Sunitinib is toxic and cannot be tolerated by many patients. However there are no prognostic indicators for intolerance.	The issue of subgroups was discussed at the scoping workshop. Currently there is no evidence on different subgroups of patients. No changes to the scope have been made.
		How should best supportive care be defined? Palliative surgery is not an option in many cases although on its own it can provide a progression free interval (usually no more than a few months), but there are cases of long overall survival when coupled with imatinib or sunitinib. Numbers are inevitably small and we know of no data reporting this situation, it is all anecdotal. However we have one patient now 9 years from first diagnosis and over 33 months on sunitinib post surgery (multiple surgeries). In most cases 'best supportive care' is withdrawal of all interventions other than painrelief, with rapid decline and death.	Comment noted.
		Which process would be the most suitable for appraising this technology, the single technology or multiple technology process? Although both imatinib at escalated dose (>400mg/d) and sunitinib are licensed for second-line in GIST there are no direct comparative data and no randomised trial in second-line is planned. We believe that each treatment should be examined separately	See response above.

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		and that guidance should ensure that identified specialist clinicians with knowledge of this fast developing field) should be authorised to make decisions on a per-patient basis. The longer timescales of a NICE multiple technology appraisal will not result in new knowledge relevant to a decision on each single technology.	
	UK Oncology Nursing Society	Agree, need for clarification of best suppprtive care.	Best supportive care will need to be clearly defined during the appraisal, based on information received at the scoping workshop.
	Pfizer	Best supportive care can best be defined as palliative care (symptomatic relief) with no active therapy. Sunitinib could be considered an alternative to increasing the dose of imatinib - this is supported by the sunitinib marketing authorisation. The question has been asked whether there are subgroups of patients in whom sunitinib can be expected to be more clinically effective. There is limited Phase II data that suggests that patients can be classified by KIT mutation. Pfizer is committing to clinical trials to explore this further. It is unclear how the evidence base as it currently stands allows for subgroup analysis within the context of the NICE HTA process (whether STA or MTA).	Best supportive care will need to be clearly defined during the appraisal, based on information received at the scoping workshop. The issue of double-dose imatinib as a comparator for sunitinib was discussed at the scoping workshop. Given that the licensed indication suggests that imatinib has failed and therefore would no longer be a relevant comparator. The issue of subgroups was discussed at the scoping workshop. Currently there is no evidence to inform any subgroup analyses. The scope will not be amended.
	Royal College of Physicians	1. Sunitinib could be considered as an alternative to dose-escalated imatinib for imatinib-refractory patients - no evidence as yet to say which intervention is optimal. This would be within the terms of the marketing authorisation.	The issue of double-dose imatinib as a comparator for sunitinib was discussed at the scoping workshop. Given that the

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			licensed indication suggests that imatinib has failed and therefore would no longer be a relevant comparator.
		2. Subgroups for whom sunitnib is more likely to be clinically effective and cost effective - good performance status, younger, fewer prior therapies.	The issue of subgroups was discussed at the scoping workshop. Currently there is no evidence to inform any subgroup analyses. The scope will not be amended.
		3. Best supportive care - need to consider continuation of imatinib - see above. 4. No. 5. Might be worth considering sunitinib alongside dose escalated imatinib 800mg (another option for patients who have relapsed on imatinib 400mg). Given that high dose imatinib has yet to be appraised by NICE, owing to the fact that the re-appraisal, due in 2007, hasn't happened, it could be argued that this should be considered at the same time, since the underlying biology is similar and imatinib 800 mg is a more appropriate comparator than best supportive care, which is not in line with the standard of care worldwide for this disease.	See response above. The issue of combining this appraisal with the review of imatinib and conducted as an MTA was discussed at the scoping workshop. Given that the licensed indication suggests that imatinib has failed and therefore would no longer be a relevant comparator, the Institute recommends that this appraisal be conducted through the STA
Additional comments on the draft scope.	Sarcoma UK	There are, so far, few long term survivors taking sunitinib and there is no clear understanding of long term treatment effects. This emphasises the importance of our comments about the crucial role of the GIST 'expert' oncologist. While we believe that uniformity of access to sunitinib is important for patients and for the NHS we are concerned that in the absence of any open clarification from NICE about the process to be used for appraising an ultra-orphan drug-condition pairing this will be a futile exercise. GIST is an ultra orphan condition and the small subset of patients who will benefit from sunitinib means that the overall cost implications for the NHS are small - estimated to	Drugs with orphan or ultra-orphan status are considered under our existing appraisal process.

Section	Consultees	Comments	Response
		be of the order of £3m per annum. The Cancer Reform Strategy clearly states that referral to NICE will be "providing that NICE agrees that there is a sufficient patient opoulation and evidence base on which to carry out an appraisal". As the total annual cost to the NHS in the UK of approving sunitinib for second-line in GIST is small, the scale of effort required by NICE to run this appraisal (at a time when its resources are scarce) is probably disproportionate. We would appreciate your comments on these points.	

Comment 3: Regulatory issues

Section	Consultees	Comments	Action
Current or proposed marketing authorisation	Pfizer	Gastrointestinal Stromal Tumour (GIST) SUTENT is indicated for the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) after failure of imatinib mesylate treatment due to resistance or intolerance. Metastatic Renal Cell Carcinoma (MRCC) SUTENT is indicated for the treatment of advanced and/or metastatic renal cell carcinoma (MRCC). Nil further [proposed indications] at present.	Comments noted. No changes to the scope required.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

Royal College of Anaesthetists
Welsh Assembly Government
NHS Quality Improvement Scotland
Royal Pharmaceutical Society
Royal College of Pathologists