

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA124; Pemetrexed for the treatment of non-small-cell lung cancer, TA162; Erlotinib for the second-line treatment of non-small-cell lung cancer and TA175; Gefitinib for the second-line treatment of locally advanced or metastatic non-small-cell lung cancer (terminated appraisal)

TA124 was issued in August 2007. The review date for this guidance was January 2010.

TA162 was issued in November 2008. The review date for this guidance was June 2010.

TA175 was issued in July 2009. A review date for this guidance has not been defined.

Background

At the GE meeting of 7 June 2011 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees	A review of the guidance should be planned into the appraisal work programme, including TA124, TA162 and TA 175. That we consult on this proposal.
Rationale for selecting this proposal	<p>A review of the TA 124 (pemetrexed) should be planned into the appraisal work programme because there are three trials comparing pemetrexed with erlotinib, and erlotinib is considered a standard comparator (in addition to docetaxel), following the publication of TA162 (erlotinib).</p> <p>A review of TA 162 (erlotinib) should be planned into the appraisal work programme because there are two trials that address the difference in effectiveness between erlotinib and docetaxel, and the targeting of specific subgroups for erlotinib. In addition, section 4.1 (Therapeutic indications) of the erlotinib SPC has been updated since the publication of TA 162. Finally, the main comparator for the erlotinib guidance (docetaxel) has gone off-patent.</p>

	<p>A review of TA 175 (gefitinib) should be planned into the appraisal work programme because there is a trial that compares gefitinib with pemetrexed, and a second non-submission by the manufacturer would not prevent the MTA from progressing as an evidence submission would be received from the Assessment Group.</p> <p>It is therefore recommended that the three reviews are combined into one MTA and that the timing be based on when new data for erlotinib will become available in or around Q2 2012.</p>
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GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with responses from the appraisal team. It is asked to agree on the final course of action for the review.

<p>Recommendation post consultation:</p>	<p>The review decision for Technology Appraisal guidance number 124 (pemetrexed) should be moved to the static guidance list (Consultees indicated that the availability of new data was unlikely to change the 'not recommended' guidance of TA 124).</p> <p>A review of TA 162 (2nd line erlotinib – positive recommendation) should be planned into the appraisal work programme. New evidence directly addressing the relevant comparison(s) is being collected in two trials-TITAN and TAILOR. The studies will address both the uncertainty identified by the Committee regarding the difference in effectiveness between erlotinib and docetaxel and the targeting of specific subgroups for erlotinib treatment. Estimated completion dates of the TITAN and TAILOR studies are 2014 and late 2012 respectively. In addition, the incremental costs related to treatment with erlotinib are likely to have significantly changed since the introduction of generic versions of docetaxel (the main comparator in TA162). Currently, pemetrexed (TA181) and gefitinib (TA 192) 1st line NSCLC treatments, and erlotinib (TA 162) 2nd line treatment are the only positive NICE recommendations. Consultees indicate that 'retreatment' with the same medicine is not usual practice when patients move from 1st to 2nd line treatment options. The draft guidance (FAD) for the ongoing appraisal of first line erlotinib is positive, includes a new discount PAS and will therefore impact on erlotinib 2nd line use and PAS in a review of TA162. The TA 162 review should be scheduled to commence now that the guidance recommendation from the ongoing appraisal for erlotinib in first line NSCLC is known.</p> <p>Technology Appraisal guidance number 175 (gefitinib) is terminated guidance. Consultees indicated that a review of the second-line gefitinib guidance (TA 175) would not provide value to the NHS. However, NICE received a remit for the appraisal of gefitinib in this 2nd line NSCLC indication; the only reason for not pursuing an appraisal at the time was a non-submission by the manufacturer. The opportunity now arises to pursue this in a multiple technology appraisal (with TA 162 erlotinib) and the technology appraisal programme recommends a review of gefitinib to commence now that the guidance recommendation from the ongoing appraisal for erlotinib in first line NSCLC is known.</p> <p>The technology appraisal programme therefore recommends that the appraisal of gefitinib as second-line treatment of locally advanced or metastatic non-small cell lung cancer (review of TA175) should be combined with the review of TA162 (erlotinib second-line treatment) in a multiple technology appraisal.</p>
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Respondent	Response to proposal	Details	Comment from Technology Appraisals
Medicines and Healthcare products Regulatory Agency	Agree	We note that a multiple technology assessment is being considered, which will take in data on erlotinib when they become available in the middle of 2012. We do not know of any compelling reason for undertaking an earlier review of the guidance on pemetrexed, erlotinib and gefitinib for the management of non-small-cell lung cancer.	Comment noted.
Healthcare Improvement Scotland	No comment	Healthcare Improvement Scotland has no comment to make on the proposal to update existing guidance.	Comment noted.
Eli Lilly	Disagree	As a guiding principle we do not believe that drugs should be re-assessed by NICE on the basis of the patent expiration of the original comparator(s) and the availability of new generic versions to the market. Taking this approach could lead to further restrictions to patients in accessing innovative medicines and increase the gaps in patient outcomes between England and Wales versus other European markets. Where the new innovative medicine has become a standard of care in the treatment of patients, a potential switch back to the previous comparator following the availability of a generic version would deny patients the accepted clinical benefits of the newer medicine and cause a significant change in practice in the NHS as clinicians and prescribing bodies comply with any new advice. This is particularly important where there has been a significant time between the initial appraisal and any subsequent appraisal where there has been significant uptake of the new agent and a new change in practice.	Comment noted. On balance, the decision to review was influenced by new data, the cost of generic docetaxel, a new erlotinib PAS and 1 st line draft positive recommendation and the fact that 2 nd line use is diminishing, because retreatment with the same medicine is not usual practice when patients move from 1 st to 2 nd line treatment options.

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		<p>The use of pemetrexed for second-line treatment of non-squamous NSCLC is minimal due to the negative recommendation in TA124. Thus, we are of the opinion that it would be of limited value (for all parties) to review pemetrexed in an MTA for second line NSCLC. However, we are willing to prepare a submission to support NICE processes should this review proceed as proposed.</p> <p>We are not aware of any additional evidence that suggests an earlier review would be beneficial.</p> <p>Please note that Section 7 of the proposal (page 3) states that there has been no change to the acquisition price of pemetrexed since publication of TA124, but that any reduction in the acquisition cost of docetaxel resulting from it going off-patent would result in an increase in the ICER for pemetrexed and therefore no change to the recommendation in TA124. This statement does not take into account the narrowing of the marketing authorisation for pemetrexed that occurred following TA124. TA124 considered the use of pemetrexed versus docetaxel in 2nd-line NSCLC using the ITT population from the JME1 study (Hanna et al 2004). Subsequently, post-hoc analyses of this and other studies led to a narrowing of the licence, restricting the use of pemetrexed in patients with tumours that are not predominantly squamous (i.e. non-squamous NSCLC). As a result of this the ICER that was considered in TA124 is no longer applicable.</p>	<p>Following consultation the technology appraisal programme recommends that TA 124 (pemetrexed for the treatment of non-small cell lung cancer) should be placed on the 'static guidance list'.</p> <p>Comment noted.</p>

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Royal College of Nursing	No comment	Nurses who care for and treat people with lung cancer were invited to comment on the proposal to update the existing guidance. There are no comments to submit at this stage on behalf of the Royal College of Nursing.	Comment noted.
Royal College of Pathologists	Agree	Please note that the Royal College of Pathologists believes there is no evidence to suggest an earlier review would be beneficial, and the list of organisation appears appropriate.	Comment noted.
AstraZeneca UK		<p>Firstly, it is important to highlight that gefitinib [IRESSA] is indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) <u>with activating mutations of EGFR-TK</u>. Please see SPC. As such, any review of gefitinib must be within this group of patients. Please note that this marketing authorisation is different from that which was anticipated during the scoping stage for TA175. This license change led to a submission by AstraZeneca for TA192 and was the reasoning behind the previous non submission for TA175.</p> <p>Secondly, I would like to draw attention to the following abstract, recently presented at the 2011 Meeting of ASCO [American Society of Oncology]: Randomized phase III trial of gefitinib or pemetrexed as second-line treatment in patients with non-small cell lung cancer previously treated with platinum-based chemotherapy (KCSG-LU08-01). This document is freely available on the internet and can be accessed via the following link http://www.asco.org/ascov2/Meetings/Abstracts?&vmview=abst_det ail_view&confID=102&abstractID=80152</p>	<p>Comment noted.</p> <p>The technology appraisal programme recommends that the appraisal of gefitinib as second-line treatment of locally advanced or metastatic non-small cell lung cancer (review of TA175) should be combined with the review of TA162 (erlotinib) in a multiple technology appraisal.</p>

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Roy Castle Lung Cancer Foundation	Disagree	As far as we are aware, there is no new research evidence, associated with these particular guidance, which would necessitate a change to current clinical practice. With this in mind, we do not see the need (with the obvious resource implication), to update these particular reviews.	<p>Comment noted.</p> <p>Following consultation the technology appraisal programme recommends that TA 124 (pemetrexed for the treatment of non-small cell lung cancer) should be placed on the 'static guidance list'.</p> <p>The technology appraisal programme recommends that the appraisal of gefitinib as second-line treatment of locally advanced or metastatic non-small cell lung cancer (review of TA175) should be combined with the review of TA162 (erlotinib) in a multiple technology appraisal.</p> <p>The technology appraisal programme recommends that a review of TA 162 (erlotinib) should be planned into the appraisal work</p>

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			programme. On balance, the decision to review was influenced by new data, the cost of generic docetaxel, a new erlotinib PAS and 1 st line draft positive recommendation and the fact that 2 nd line use is diminishing, because retreatment with the same medicine is not usual practice when patients move from 1 st to 2 nd line treatment options.
Roche Products	Disagree	<p><u>Erlotinib 2nd line (NICE TA162) Re-Review Consultation Response</u></p> <p>In addition to providing an update on the relevant ongoing clinical research, Roche would like to take the opportunity to highlight some wider issues related to the re-review of TA162. These issues may have implications not only for patients directly affected by the Guidance but also for UK access to new medicines and for the conduct of clinical research in the UK.</p> <p>Whilst the pursuit of technical efficiency within the NHS is important, other dynamic factors and consequences from re-reviews with specific characteristics may have sizeable implications for the future of the treatment of metastatic non-small-cell lung cancer (mNSCLC) in the UK. As these implications are beyond the scope of the NICE</p>	<p>Comment noted.</p> <p>The technology appraisal programme therefore recommends that the appraisal of gefitinib as second-line treatment of locally advanced or metastatic non-small cell lung cancer (review of</p>

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		<p>MTA re-review process, we believe it is important that they are considered fully prior to determining whether the scheduling of the proposed appraisal is appropriate.</p> <p><u>Current place of erlotinib in clinical practice</u></p> <p>Since the publication of TA168, erlotinib now represents three-quarters of all second-line therapy on the NHS. This has happened in an environment where both drugs were actively promoted, there was no significant cost-difference and there was no evidence that either drug offered a superior survival outcome.</p> <p>Clearly, other factors led clinicians to favour erlotinib over docetaxel – convenience of the oral over the IV route for patients, reduced pressure on IV chemotherapy suites, much reduced chances of fatal side-effects or serious adverse events requiring hospitalisation and better tolerability of treatment are those most frequently cited by clinicians. Some of these are captured in conventional cost-effectiveness analysis but other important ones are not – which explains why, at the time of the original appraisal there appeared to be a profound mismatch between the desire of clinicians and patients to access erlotinib and the perception of the Appraisal Committee that erlotinib and docetaxel produced very similar outcomes.</p> <p><u>The role of erlotinib in ongoing clinical research</u></p> <p>The UK is not unique in putting erlotinib at the centre of treatment for relapsed NSCLC. Consequently the drug has now become an internationally recognised standard therapy which likely forms the most widely used control therapy in clinical trials in relapsed NSCLC</p>	<p>TA175) should be combined with the review of TA162 (erlotinib second-line treatment) in a multiple technology appraisal. On balance, the decision to review was influenced by new data, the cost of generic docetaxel, a new erlotinib PAS and 1st line draft positive recommendation and the fact that 2nd line use is diminishing, because retreatment with the same medicine is not usual practice when patients move from 1st to 2nd line treatment options.</p>

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		<p>(which still represents an area of high therapeutic need and active research). In such trials it is either used as a comparator in head-to-head trials (e.g. vandetanib, PF-299, BMS-68014), as the second-line treatment patients should have received prior to study entry (e.g. afatinib, cetuximab), or the foundation to which new interventions are added. Some of these such as crizotinib, MetMab and tivantinib are specifically designed to enhance the activity of erlotinib. The manner in which the assimilation of erlotinib into routine clinical practice has resulted in it becoming the foundation of clinical research protocols is illustrated in Table 1 showing recently reported and ongoing trials in relapsed NSCLC.</p> <p><u>Table 1: Reported and ongoing trials featuring erlotinib in relapsed NSCLC</u></p> <table border="1" data-bbox="658 783 1639 1305"> <thead> <tr> <th data-bbox="658 783 788 879">Drug</th> <th data-bbox="788 783 1032 879">Class</th> <th data-bbox="1032 783 1151 879">Trial Phase</th> <th data-bbox="1151 783 1393 879">Trial Design</th> <th data-bbox="1393 783 1639 879">Clintrial.gov ID</th> </tr> </thead> <tbody> <tr> <td colspan="5" data-bbox="658 879 1639 946">Ongoing studies</td> </tr> <tr> <td data-bbox="658 946 788 1031">PF-299</td> <td data-bbox="788 946 1032 1031">Irreversible pan-HER TKI</td> <td data-bbox="1032 946 1151 1031">III</td> <td data-bbox="1151 946 1393 1031">PF-299 vs erlotinib</td> <td data-bbox="1393 946 1639 1031">NCT01360554</td> </tr> <tr> <td data-bbox="658 1031 788 1117">Tivantinib (ARQ 197)</td> <td data-bbox="788 1031 1032 1117">MET TKI</td> <td data-bbox="1032 1031 1151 1117">III</td> <td data-bbox="1151 1031 1393 1117">Erlotinib +/- tivantinib</td> <td data-bbox="1393 1031 1639 1117">NCT01244191</td> </tr> <tr> <td data-bbox="658 1117 788 1219">Selumetinib (AZD6244)</td> <td data-bbox="788 1117 1032 1219">MEK 1/2 inhibitor</td> <td data-bbox="1032 1117 1151 1219">II</td> <td data-bbox="1151 1117 1393 1219">Erlotinib +/- selumetinib selumetinib +/- erlotinib</td> <td data-bbox="1393 1117 1639 1219">NCT01239290</td> </tr> <tr> <td data-bbox="658 1219 788 1305">Pazopanib</td> <td data-bbox="788 1219 1032 1305">VEGFR/PDGFR inhibitor</td> <td data-bbox="1032 1219 1151 1305">II</td> <td data-bbox="1151 1219 1393 1305">Erlotinib +/- pazopanib</td> <td data-bbox="1393 1219 1639 1305">NCT01027598</td> </tr> </tbody> </table>	Drug	Class	Trial Phase	Trial Design	Clintrial.gov ID	Ongoing studies					PF-299	Irreversible pan-HER TKI	III	PF-299 vs erlotinib	NCT01360554	Tivantinib (ARQ 197)	MET TKI	III	Erlotinib +/- tivantinib	NCT01244191	Selumetinib (AZD6244)	MEK 1/2 inhibitor	II	Erlotinib +/- selumetinib selumetinib +/- erlotinib	NCT01239290	Pazopanib	VEGFR/PDGFR inhibitor	II	Erlotinib +/- pazopanib	NCT01027598	
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		Sorafenib	VEGFR/PDGFR/ Raf inhibitor	II	Erlotinib +/- sorafenib	NCT00600015	
		Celecoxib	Cox-2 inhibitor	II	Erlotinib +/- celecoxib	NCT00499655	
		BMS-690514	Pan HER inhibitor	II	BMS-690514 vs erlotinib	NCT00743938	
		CS-7017	PPARgamma agonist	II	Erlotinib +/- CS-7017	NCT01101334	
		Bexarotene (Targretin)	RXR inhibitor	II	Erlotinib + bexarotene	NCT00411632	
		IMC-A12	Anti-IGF-1R antibody	II	Erlotinib +/- IMC-A12	NCT00778167	
		Volociximab	Anti $\alpha 5\beta 1$ integrin antibody	II	Erlotinib + Volociximab	NCT00278187	
		Apricoxib	Cox-2 inhibitor	II	Erlotinib +/- apricoxib	NCT00652340	
		U3-1287 (AMG888)	Anti HER3 antibody	Ib/II	Erlotinib +/- U3-1287	NCT01211483	
		GSK 1363089	MET/VEGFR2 inhibitor	I/I	Erlotinib +/- GSK1363089	NC 01068587	
		Cabozantinib (XL184)	MET/VEGFR2 TKI	Ib/II	Erlotinib +/- Cabozantinib	NCT00596648	
		AMG 102	HGF/FS agonist	Ib/II	Erlotinib + AMG 102	NCT01233687	
		Dalotuzumab (MK0646)	Anti-IGF-1R antibody	Ib/II	Erlotinib +/- Dalotuzumab	NCT00729742	

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		RO4929097	Gamma-secretase/Notch pathway inhibitor	I	Erlotinib + RO4929097	NCT01193881	
		IMO-2055	TLR 9 agonist	I	Erlotinib + bevacizumab + IMO-2055	NCT00633529	
Published studies							
		Afatinib	Irreversible EGFR TKI	III	After erlotinib/ gefitinib failure	Miller et al. ESMO 2010 (LBA1)	
		Sunitinib	VEGFR/PDGFR inhibitor	III	Erlotinib +/- sunitinib	Scagliotti et al. ESMO 2010 (LBA6)	
		Pemetrexed	antifolate	III	Erlotinib vs pemetrexed	Vamvakas et al. ASCO 2010 (7519)	
		Vandetanib	VEGFR, EGFR antagonist	III	Erlotinib vs vandetanib	Natale et al. ASCO 2009 (8009)	
		Figitumab	Anti-IGF-1R antibody	III	Erlotinib +/- figitumab	Pfizer oncology	
		MetMAB	Anti MET antibody	II	Erlotinib +/- MetMAB	Spigel et al. ESMO 2010 (LBA15)	
		Pralatrexate	Antifolate	II	Erlotinib vs pralatrexate	Kelly et al. ESMO 2010 (LBA17)	
		Cetuximab	Anti EGFR antibody	II	Erlotinib + cetuximab after erlotinib failure	Riely et al. ASCO 2010 (7557)	
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		Cetuximab	Anti EGFR antibody	II	Erlotinib + cetuximab after erlotinib failure	Riely et al. ASCO 2010 (7557)	
		MM-121	Anti-HER3 antibody	I/II	Erlotinib + MM-121	Sequist et al. ASCO 2011 (TPS215)	
		Everolimus	mTOR inhibitor	II	Erlotinib +/- everolimus	Leighl et al. ASCO 2010 (7524)	
		<p><u>Wider considerations</u></p> <p>The potential removal of a standard of care for NSCLC patients due to the loss of patent protection from a comparator without any new clinical evidence or a change in the cost of the standard of care medicine carries wider implications beyond this specific re-review of erlotinib for NSCLC patients:</p> <ul style="list-style-type: none"> • Since erlotinib is now the standard of care and is consequently used by almost all new, ongoing and planned trials in relapsed NSCLC, a lack of availability of erlotinib for routine treatment will have grave consequences for future research in the UK and future potential access to new medicines for this disease setting in the UK. • Pharmaceutical companies and academic research groups alike will be unable to carry out trials that have relevance to the rest of the world since the standard of care in the UK will become so divergent from that in other similar countries that: <ul style="list-style-type: none"> ○ Trials with an erlotinib control arm will, from a UK perspective, have two “non-standard” arms with 					

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		<p>neither representing the local standard of care, making ethical review and patient consent problematic</p> <ul style="list-style-type: none"> ○ If trials specify that patients should have received prior erlotinib therapy then there will be no relevant patients in the UK ● Future relapsed NSCLC NICE appraisals will unlikely contain relevant comparable clinical trial evidence because global trials will be carried out in patient populations and against control treatments that bear little relevance to UK clinical practice. This will be of particular relevance when Appraisal Committees are faced with the impossibility of conducting indirect comparisons of future biomarker targeted 2nd line therapies against docetaxel. Given erlotinib is the preferred reference arm in the vast majority of 2nd line RCTs ongoing there will be no data on the efficacy of docetaxel in these biomarker targeted populations. This lack of data will present a sizeable challenge for future appraisals of mNSCLC therapies as it will not be possible to assess the relative efficacy of new technologies to the appropriate comparator in the specific population of interest. Therefore this issue has important longer term implications for the future development and appraisal of later line mNSCLC therapies within the UK. <p><u>TAILOR Study</u></p> <p>If a re-review is still considered appropriate it should be noted that the TAILOR study is still currently recruiting and results suitable for</p>	

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		<p>integration in a meta-analysis (as would be required for an appraisal) are unlikely to be published in a journal until around Q2 2013. Whilst there is a possibility that an abstract may be presented at ASCO in June 2012 (if recruitment occurs promptly) this is highly unlikely to contain sufficient detail to enable a formal meta-analysis of the TAILOR study and the TITAN study. As TAILOR is not a Roche conducted study we will be unable to provide the data required to conduct such an analysis prior to the publication of the study in a journal.</p> <p>Therefore if a re-review is to occur we suggest it should commence around Q2 2013 so that the full evidence base on the efficacy of erlotinib compared to docetaxel in a range of biomarker defined groups may be properly evaluated. If a re-review is initiated prior to the full availability of this data it is highly likely that any assessment report produced and submissions provided will be irrelevant at the point the TAILOR study is fully published.</p> <p><u>Comments on Inclusion of TA124 and TA 175</u></p> <p>We would question the value of investing NHS resources in a review of gefitinib and pemetrexed in relapsed NSCLC since, even if endorsed by NICE, usage of either agent in relapsed NSCLC would, in all probability, be minimal, for the following reasons:</p> <p>Since TA124, the pemetrexed Marketing Authorisation has been extended to include its use as a first-line agent and as a maintenance agent after non-pemetrexed induction therapy for patient with non-squamous tumours. Both of these additional indications are endorsed by NICE and pemetrexed-platinum is the most widely used induction regimen for patients with non-squamous</p>	<p>Comment noted.</p>

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		<p>tumours. It is anticipated that a further license extension will be sought to cover the use of pemetrexed maintenance after pemetrexed-based induction chemotherapy, based on the recently reported PARAMOUNT study.</p> <p>In view of the above, the pool of patients with non-squamous tumours reaching second-line treatment without prior exposure to pemetrexed is likely to be very small indeed. Since, there is little logic in using pemetrexed at second-line in patients who have received it at first-line or for maintenance it is hard to see the value of any guidance concentrating specifically on pemetrexed in second-line.</p> <p>Similar issues arise with gefitinib. This already has NICE endorsement for use as a first-line treatment for patients with NSCLC bearing activating EGFR mutations where an EGFR inhibitor is now the standard of care. With such treatment continued until disease progression, it is difficult to see a need for guidance on gefitinib in the relapsed setting.</p> <p>If any review of pemetrexed or gefitinib guidance were to be conducted, it would appear more logical to review all of the product-specific indications together to establish the best place for these agents in the treatment algorithm.</p> <p><u>Conclusion</u></p> <p>A re-review and the potential reversal of the positive guidance for erlotinib in 2nd line due to the recent availability of a generic comparator is liable to have consequences to UK mNSCLC patients (in terms of both denial of access to erlotinib and future mNSCLC</p>	<p>Following consultation the technology appraisal programme recommends that TA 124 (pemetrexed for the treatment of non-small cell lung cancer) should be placed on the 'static guidance list'.</p> <p>The technology appraisal programme therefore recommends that the appraisal of gefitinib as second-line treatment of locally advanced or metastatic non-small cell lung cancer (review of TA175) should be combined with the review of TA162 (erlotinib second-line treatment) in a multiple technology appraisal.</p>

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		<p>innovations) and both the UK mNSCLC clinical trial and clinician community, with the removal of an established standard of care in favour of a highly toxic but inexpensive chemotherapy now only utilised in a minority of mNSCLC patients.</p> <p>Whilst technical efficiency is important, the removal of a standard of care due to patent expiry of a comparator medicine sends a clear signal to the pharmaceutical industry that the UK intend to 'free-ride' from NSCLC innovation funded by the rest of the world in favour of rewarding generic manufacturers upon patent expiry. Furthermore such outcomes may also be inconsistent with two of the fundamental objectives of the current PPRS agreement; that of encouraging innovation and secondly ensuring stability, sustainability and predictability.</p>	

No response received from:

<p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> • Afiya Trust • Black Health Agency • British Lung Foundation • CANCERactive • Cancer Black Care • Cancer Equality • Chinese National Healthy Living Centre • Counsel and Care 	<p><u>General</u></p> <ul style="list-style-type: none"> • Board of Community Health Councils in Wales • British National Formulary • Care Quality Commission • Commissioning Support Appraisals Service • Department of Health, Social Services and Public Safety for Northern Ireland • National Association of Primary Care • NHS Alliance
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- Equalities National Council
 - Helen Rollason Heal Cancer Charity
 - Macmillan Cancer Support
 - Maggie's Centres
 - Marie Curie Cancer Care
 - Muslim Council of Britain
 - Muslim Health Network
 - South Asian Health Foundation
 - Specialised Healthcare Alliance
 - Sue Ryder Care
 - Tenovus
 - UK Lung Cancer Coalition
- Professional groups
- Association of Cancer Physicians
 - Association of Respiratory Nurse Specialists
 - British Association for Services to the Elderly
 - British Geriatrics Society
 - British Psychosocial Oncology Society
 - British Thoracic Society, Lung Cancer and Mesothelioma Working Party
 - Cancer Network Pharmacists Forum
 - Cancer Research UK
 - National Lung Cancer Forum for Nurses
 - National Pharmacy Association
 - Primary Care Respiratory Society UK
 - Royal College of General Practitioners
 - Royal College of Physicians
 - Royal College of Radiologists
 - Royal Pharmaceutical Society

- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

Comparator manufacturers

- Actavis UK (docetaxel)
- Hospira UK (docetaxel)
- Sanofi-Aventis (docetaxel)

Relevant research groups

- British Thoracic Oncology Group
- Cochrane Lung Cancer Group
- Institute of Cancer Research
- MRC Clinical Trials Unit
- National Cancer Research Institute
- National Cancer Research Network
- National Institute for Health Research
- Research Institute for the Care of Older People

Assessment Group

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

Associated Guideline Groups

- National Collaborating Centre for Cancer

Associated Public Health Groups

- None

- | | |
|---|--|
| <ul style="list-style-type: none">• Royal Society of Medicine• Society and College of Radiographers• United Kingdom Clinical Pharmacy Association• United Kingdom Oncology Nursing Society | |
|---|--|

Others

- Department of Health
- Bexley Care NHS Trust
- NHS Gateshead
- Welsh Government

GE paper sign-off: Frances Sutcliffe, Associate Director – Technology Appraisals Programme

Contributors to this paper:

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26 April 2012