### General

Cancer Research UK is pleased to have the opportunity to respond to this consultation. Cancer Research UK is the world’s largest independent cancer charity dedicated to saving lives through research. It supports research into all aspects of cancer and this is achieved through the work of over 4,000 scientists, doctors and nurses. In 2016/17, we spent £432 million on research in institutes, hospitals and universities across the UK. We receive no funding from the Government for our research and are dependent on fundraising with the public. Cancer Research UK wants to accelerate progress so that three in four people survive their cancer for 10 years or more by 2034.

We believe that all patients should have access to the best, evidence-based treatments for their condition. NICE has a critical role in supporting patient access to cancer drugs, which can improve patient survival, allow people to return to work, look after their families, and lead more active and fulfilling lives.

We welcome NICE’s ambition to increase its technology appraisal (TA) programme capacity through changes to the appraisal process. We note the recent increase in the number of decisions on cancer drugs being taken by NICE through the TA programme, rising from an average of 14 drugs receiving decisions annually between 2011 and 2015, to 41 drugs in 2016 and 31 drugs in the first eight months of 2017.
This increase is explained in part by the Rapid Reconsiderations process undertaken in implementing reforms to the Cancer Drugs Fund, but also by the number of new drugs which emerged from the cancer drugs pipeline over this period. Globally, it is estimated the oncology pipeline contains over 600 potential therapies in late stage development,\(^1\) so this trend is unlikely to reverse in the near future.

Evidence also suggests that patient uptake of the newest cancer drugs is slower in the UK than in other G5 countries.\(^2\) The length of the approval processes used in the UK, including NICE’s TA process in England, must be recognised as a contributor to this relative disadvantage for patients. In this context, further capacity must be released within the TA programme, to both increase the numbers of new medicines which can be assessed, and the speed at which those treatments can be approved and made available for patient uptake.

We particularly welcome NICE’s efforts to streamline the TA process in light of the recommendations of the Accelerated Access Review (AAR) and the Life Sciences Industrial Strategy (LSIS). We believe that NICE is right to place the changes proposed in this consultation in this wider context, acknowledging that streamlining drug approval processes has the potential to speed up patient access to new medicines and other technologies as well as to make best use of NICE’s internal capacity.

Cancer Research UK welcomes the proposal to invite companies to start developing an evidence submission for NICE in parallel with their submission to the relevant regulatory agency. This will help to achieve the “closer alignment of regulatory and NICE data requirements and processes” outlined as an ambition in the AAR. We are keen to see more drug approvals decisions being made as close to the point of licensing as possible, to minimise delays for patients.

In implementing this change, a key focus should be better join-up across the pathway, particularly between the Early Access to Medicines Scheme (EAMS) and NICE’s TA programme, to accelerate the transition of successful EAMS drugs to a wider patient cohort. Medicines in EAMS have been independently identified as having high potential to effectively address unmet clinical need, and to date most EAMS medicines have been for oncology indications.

Cancer Research UK believes the ambition should be for medicines to cross over from EAMS to commissioning in line with NICE guidance as quickly and as seamlessly as possible, and that implementation of the proposed change noted above should be used as an opportunity to clearly define and deliver on this ambition. NICE should ensure that its procedures for monitoring EAMS medicines allow it to fast-track TAs associated with those medicines, to minimise the time between an EAMS medicine receiving its marketing authorisation and NICE issuing its own guidance.

We acknowledge that NICE approval can already happen more quickly for medicines on EAMS. But there is still often a delay of several months between the EAMS process expiring and NICE granting a positive recommendation. For example, pembrolizumab for the treatment of metastatic melanoma was available under EAMS from March 2015 until July 2015 (when it received EMA marketing authorisation), but was not granted a positive recommendation by NICE until September 2015. The proposed change could be an important step in reducing such gaps in the future.

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We welcome the proposal for earlier submission of evidence to NICE by the company, to allow earlier and enhanced engagement between NICE and pharmaceutical companies' representatives.

Cancer Research UK supports the measures outlined in the AAR and LSIS to accelerate market access for new medicines. We welcome NICE's recognition that earlier dialogue with companies will help in realising this ambition, as well as increasing its TA capacity. This engagement is a crucial part of delivering the “focus on streamlining routes to market and improving process across the system” outlined by the Government in its response to the AAR.

Together with the possibility of conditional approval via the Cancer Drugs Fund (CDF), we hope that this emphasis on early engagement and a flexible approach to evidence assessment by NICE will encourage companies to begin the appraisal process for their medicine at an earlier stage of evidence maturity. Ultimately, this should reduce the time patients have to wait for widespread access to new medicines.

We acknowledge that there is a limit to which the TA process can practically be accelerated in some cases, as a result of specific evidence limitations. NICE should ensure its processes are sufficiently flexible to allow constructive collaboration with pharmaceutical companies, achieving the appropriate balance between evidence maturity and accelerated patient access to medicines in each case.

In particular, this flexibility will be critical in evaluating the most innovative new drugs, which may be targeted at stratified (and therefore smaller) patient populations, and which are frequently given in combination with other treatments. These developments will challenge traditional assessment methodologies. In such cases we urge NICE to consider options which allow evidence to be gathered from real clinical practice, for example through managed access schemes like the CDF.

Cancer Research UK supports the proposal to introduce a technical engagement step, including the option for further commercial dialogue, prior to the technology assessment committee meeting.

We believe this is a sensible proposal in terms of making best use of the committee members’ time and reducing the number of meetings needed to arrive at a decision. By enabling earlier discussion of clinical evidence and facilitating open scientific dialogue, this step could save time and ensure a more efficient use of resources for both parties.

We also reiterate our support for flexible pricing arrangements such as those outlined in the AAR. There must be a flexible approach to commercial dialogue, including on reimbursement, if this engagement is to secure the best possible value for money for the NHS and successfully streamline the TA process in the way the consultation envisages.

However, it is imperative that the transparency of this engagement, currently guaranteed by the public setting of the committee meeting, is not jeopardised by this change. We recognise the discussions between NICE and the company at this stage will likely involve a degree of commercial sensitivity; however these conversations should be documented as fully as possible in order to preserve transparency. This is crucial to maintaining public and patient confidence in NICE and its appraisals system.
We are concerned about the proposed changes to patient and clinical involvement in the technology appraisal process. Face-to-face interaction between patient and clinical experts, and the committee members, provides significant benefits which cannot be derived from a written submission alone. We therefore disagree with the suggestion in the consultation document that “it may not always be necessary for clinical, patient, and commissioning experts to attend the committee meeting”.

We acknowledge the advantage of securing earlier input from the patient and clinical experts, and we welcome the opportunity for these to provide a written statement at the same time as NICE receives the company’s initial evidence submission. We also acknowledge that this practice is currently being implemented for Fast Track Appraisals. However, we believe that the experts’ physical presence in the room during the committee meeting serves two vital functions:

- Firstly, they are able to provide answers and information pertaining to the clinical or patient experience in real time. It is likely to be difficult for the technical team to anticipate precisely the questions regarding that experience which may arise during the committee meeting and include all relevant points in their need assessment. This may be especially important in relation to clinical experts, given the diverse clinical backgrounds of technology appraisal committee members. The continued presence of the experts in the room ensures such questions can be answered rapidly should they arise.

- Secondly, with specific regard to the patient experts, their presence (and their account of their experience) helps to keep the needs of patients at the forefront of committee members’ minds when making decisions.

The recent Montgomery Review into Access to New Medicines in Scotland showed that patients believe meaningful measures of success for new treatments extend beyond traditional outcomes measures. Patients also value patient-reported outcomes and measures of societal impact, such as the ability to work and maintain physical and financial independence. It is important that this perspective is included in the committee meeting.

Cancer Research UK has commissioned internal analysis of the Detailed Advice published by the Scottish Medicines Consortium as part of its decisions. This analysis has found that PACE (Patient and Clinician Engagement) meetings, introduced in May 2014, have helped to provide additional insight into the value patients attach to the clinical benefits of the drugs: for example, improved progression-free survival means that patients can continue with some level of normal life and activities, while having future treatment options available reduces anxiety about the future for patients and families.\(^3\) While we are not advocating specifically for the introduction of a PACE-equivalent step to NICE’s appraisals process, we do believe this demonstrates the value of face-to-face patient engagement to the TA process.

As we noted in our submission to NICE’s consultation on improving patient and public involvement in developing NICE guidance and standards earlier this year,\(^4\) we believe that there is already a disappointing lack of clarity on how patient experience is taken into account by NICE. There is insufficient evidence and information on how patient input is captured and used, and its level of impact on decision-making.

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Anecdotal evidence suggests that patients and industry currently feel frustrated that the issues most important and urgent to patients are not fully considered in NICE processes. We are concerned the proposed changes may exacerbate this problem.

We therefore oppose the proposed changes to patient and clinical expert involvement. As an absolute minimum, greater clarity and transparency is needed in defining the “sufficient” degree of clarity in a patient or clinical expert’s written statement which would make their presence at the committee meeting unnecessary.

To submit your comments, please email this form to: TAconsultation2017@nice.org.uk

Closing date: Thursday 16 November 2017, 5pm
PLEASE NOTE: The Institute reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of the Institute, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.