Cancer Research UK response to the NHS England consultation on the revised Standard Operating Procedures for the Cancer Drugs Fund

October 2014

Note: Submission is via an online form, our responses are outlined below.

Question 1: Do you agree with, or have any comment to make about, proposed change (A) – the implementation of a re-evaluation process which will assess the drugs on the current CDF list in respect of clinical benefit.

Yes.

In principle, the proposal to develop a re-evaluation process is a proportionate response to the challenge that the CDF has of meeting increasing demand – with 2,000 new patients accessing drugs via the CDF every month – on a fixed budget. However, the following actions should be taken:

1. The new process of evaluation must be robust and transparent. NHS England should ensure NICE is involved in the development and implementation of any new process so that there is join-up with established evaluation mechanisms.
2. The Individual Cancer Drugs Fund Request (ICDFR) route must be addressed. Since April 2013 the process has become extremely restrictive. It is absolutely vital that the process is flexible enough to ensure that individual patients with particularly hard to treat cancers are able to access the drugs they need.
3. A concerted effort should be make to establish a mechanism for robust data collection, including on efficacy and toxicity, within the CDF - potentially using an Evaluation through Commissioning type model. This should be focused on gathering data on the effectiveness of drugs in cancers where the evidence base may be harder to determine (e.g. due to small population size relevant to a specific cancer or indication).
4. In the short term, we urge NHS England to undertake a properly resourced, rapid and transparent evaluation on the data generated from patients using CDF-funded drugs since 2010, including survival and toxicity. It is not currently clear what data has already been collected, both in terms of scope and quality, as no data or reports have been published. The CDF cannot be defensible in relation to other NHS England policies if there is not a robust evaluation of its impact.

It is difficult to see at this stage what impact the proposed process will have on the CDF List and, therefore, which drugs patients will be able to access in future. More importantly, it is not clear why there is value having two parallel systems of evaluation, within both the CDF and NICE.

When it was announced in August 2014 that funding for the CDF would be increased, it was proposed that NHS England would establish an Evaluation through Commissioning (EtC) system within the CDF to use real-world patient data to assess each drug on its individual merits. This is notably absent from the current proposals. EtC if carried out well could provide a valuable mechanism to assess the effectiveness of treatments where the evidence base is harder to determine (i.e. not possible through randomised controlled trials – which should remain the gold standard for building an evidence base). However, an EtC mechanism is likely to have high resource
demands around data collection and analysis. Any proposals to develop EtC should include plans to carry out full evaluations of clinical effectiveness, akin to a phase IV trial with pre-determined end points and incorporating a robust economic evaluation.

Given currently available resources, if the CDF adopts this approach now it should only be done to generate data for indications used in relatively small populations and rarer conditions. Data on outcomes amongst these populations is much harder to collect – many in the clinical community feel that NICE’s process does not deal well with these circumstances and that the key success of the CDF has been improving access to treatments for rarer cancers or those of unmet need. The Government and CDF Panel should take pride in this.

In the longer term, NHS England could establish a formal process to consider treatments that are judged as inappropriate for the NICE process (e.g. due to issues around data) as candidates for EtC. Similarly, while there are concerns about the completeness of Systemic Anti-Cancer Therapy (SACT) data currently, in future NICE could consider how its approach to use of good-quality SACT data within appraisals for all cancers, including more common cancers.

It is also notable that the CDF does not support non-drug cancer treatments such as radiotherapy and surgery, which play a major role in curing cancer but in which variation in access is being seen as advances are being made in both. There is also no clarity on how the NHS can make molecular diagnostic tests routinely available, and whether there is a role in the short term for the CDF in this. At the same time, NICE does not regularly carry out appraisals in either treatment area, as with many non-drug treatments in other diseases. While we would not want these treatment types included in the CDF, the Government and NHS England must reconsider its approach to supporting innovation in cancer, and recognise that this is not simply a matter of increasing use of medicines. As evidenced by the need for the Radiotherapy Innovation Fund in 2012, and subsequent discussions around the use of stereotactic radiotherapy, there are endemic issues in other treatments around the need for investment and evidence needed for commissioning.

The CDF Panel already considers the clinical benefit of the drugs it looks at, so it does not seem to be possible to isolate this proposal from the issue of cost-effectiveness (as opposed to clinical effectiveness alone). Our answer to Question 2 below sets out our views around clinical and cost-effectiveness evaluation of cancer drugs in further detail.

**Question 2: Do you agree with, or have any comment to make on, proposed change (B) - the list will be re-evaluated taking into consideration both clinical benefit and cost?**

**No.**

It is concerning that the consultation suggests that the CDF should be consolidated and made permanent, when what is needed is a means to managing the CDF until March 2016 while a robust, long-term solution to access to cancer medicines is developed, with refining NICE’s process a core priority. Consensus on issues such as public willingness to pay for cancer treatments and end of life treatments, as well as the appropriate approach to assessment of and funding for drugs/indications used in small populations, is also needed.
Part of the rationale for establishing the CDF was that many cancer drugs were not well used in the UK and were struggling to gain positive recommendations from NICE. However the increased demand on the CDF has demonstrated that cost-effectiveness evaluation is crucial to securing the financial sustainability of the NHS, and of cancer services. Therefore ensuring that NICE’s process is robust, rather than creating a duplicative system, should be the priority going forward. Recent proposals to reform NICE’s process were rejected by stakeholders and reform has therefore been paused.

In the short term, it is appropriate to manage the CDF optimally; however it was always intended as a temporary system pending reform of NICE. It is now more important than ever to understand what needs to change to ensure appropriate access to new cancer treatments. To start with, NICE could examine:

1. Its long-established cost-effectiveness thresholds – some economists have argued that these are too high for most new treatments, but for some treatments NICE may wish to be more flexible based on willingness to pay
2. Public willingness to pay for certain types of treatments or conditions (i.e. cancer or end of life care), building on the social research that NICE already carries out
   o If the public’s willingness to pay remains equal across all conditions, other payment or negotiation mechanisms (see below) will need to be considered, as the list price of the treatment may ultimately be pivotal. Patient Access Schemes already perform a valuable role here
3. The extent of any problems obtaining adequate data in order to confidently determine clinical and or cost-effectiveness, and the implications of this for diseases with varying population sizes/levels of need (i.e. where good data is difficult to obtain, NICE could formally recommend that NHS England establish an Evaluation through Commissioning programme)
4. The approach Trusts take to plan for the introduction of NICE Technology Appraisal Guidance, and how this fits into broader financial planning for other service expenditures

However, ensuring appropriate access to drugs will not simply depend on changing the NICE process, although it is a core component. Wider issues around NHS financial planning and how NICE technology appraisal guidance is accounted for, the role of the Individual Funding Request Process, and medicines pricing mechanisms are should also be considered and NHS England should work with NICE, industry and other major stakeholders in doing so.

We have significant concerns around the financial sustainability of the CDF and the potential impact of this on wider cancer services. Decision making around funding for the CDF has not been transparent, and at a time when all NHS services are under financial constraints, the implication to the wider clinical community is that funding allocations are not being made equitably or based on adequate forward planning. There is also a worrying implication that innovation in cancer is viewed to be an issue around medicines alone.
**Question 3: Do you agree with, or have any comment to make about, proposal (C) – that drugs which are highly priced in relation to clinical benefit should be removed from the list?**

Don't know.

The issues covered above about the role of cost-effectiveness/economic evaluation and where this responsibility lies also apply here.

It is also difficult to understand which drugs would be likely to be removed from the list because it would depend on a) the cohort of drugs and indications on the CDF list being considered at a given time, which will change regularly and b) cost negotiations with manufacturers, which are confidential so observers are unable to understand the impact of cost.

An alternative to this approach could be to suggest a defined period of time that a drug is on the list. This time would then enable the gathering of real-world data on effectiveness of the drug (e.g through an EtC model) or provide companies the chance to revise their pricing.

Should drugs be removed, NHS England should publish full impact assessments for those drugs, as there is a major concern that patients will ultimately miss out on certain treatments if NHS England and manufacturers are not able to come to a consensus on cost. There is currently no available data on patient outcomes amongst those accessing drugs via the CDF – this data should be made publicly available, at minimum in summary form, with more extensive data accessible to researchers upon request.

Furthermore, it is absolutely vital that a robust and flexible system of individual funding requests (IFRs) (through the CDF or otherwise) is in place to ensure some patients can continue to access drugs that are not on the list – particularly if more drugs are de-listed in future. We understand that clinicians are having particular difficulties accessing treatments they believe to be appropriate since the IFR system became more restrictive in April 2013, which is extremely concerning.

**Question 4: Do you agree with, or have any comment on, the proposal that, in order to protect current and potential future pricing arrangements between pharmaceutical companies and NHS England, which differ from the public list price of drugs, the proposed process should treat the scoring bands for assessment of drug cost and the individual cost scores of drugs as confidential.**

Don't know.

An element of confidentiality has been important in the past to allow the NHS to secure good value on the treatments it purchases. NICE plays an important role in this through negotiating Patient Access Schemes. However, further disclosure of confidential information is likely to be problematic. We would, however like to see as much transparency as possible in the processes of decision-making, and potentially the principles around setting cost bands, within the CDF in order to be clear what patients will be able to receive. It will also be important to communicate all other parts of the assessment process such as the scores on clinical effectiveness.
The CDF Panel should therefore ensure that every decision is communicated in a manner that is clear to patients, and gives advance notice where a drug may be likely to come off the list. Patient information is an important part of this, which Cancer Research UK has supported the CDF panel with.

Furthermore, the Panel should ensure that all clinical information considered is published in full, so that there is evidence to help the public to understand whether clinical or cost factors were pivotal to decisions.

**Question 5 : Should the proposed process allow a pharmaceutical company the option of making an appropriate and confidential adjustment to its drug price to allow the drug/indication to remain in the CDF?**

Yes.

**Question 6: Are there any other considerations that you think should be addressed in developing a process for prioritising drugs for inclusion within the CDF list?**

Our comments on the evaluative roles that both the CDF and NICE could play are set out above.

In general, where non-mainstream mechanisms like the CDF must exist, drugs or indications used within small populations should be prioritised.

**Question 7: Please provide any comments that you may have about the potential impact on health inequalities which might arise as a result of the proposed changes that we have described. Please also comment on any impact you consider there may be on equality matters more broadly**

Ensuring that there is robust patient information in place to help patients and the public understand how the CDF operates, and how delisting decisions might affect them, will also be crucial to ensuring that health inequalities are minimised.

We would like to see the CDF Panel reaffirm its commitment to producing appropriate patient information, including publishing lay summaries of CDF decisions.