Cancer52 response to NHS England consultation: Proposals for a sustainable Cancer Drugs Fund

Summary

- Cancer52 represents the very patients that the Cancer Drugs Fund (CDF) was set up to help
- Since its inception the CDF has enabled more than 55,000 people with cancer to gain access to medicines
- The CDF was developed as a 'bridge' to wider reform. This 'bridge' has failed to materialise, nor has the CDF delivered the hoped for improvements in access to new medicines
- The current focus of attention is on the CDF overspend. This is a flawed approach as we must collectively address the root causes that drive difficulties in access to new medicines
- Adding in price as a criteria to the CDF takes us further away from clinically driven decisions, contrary to David Cameron's promise in 2010
- Cancer52 does not support the proposals from NHS England because they are unpredictable. The proposals mean that medicines may be de-listed at some point in the future and risk introducing unfairness between cancer patients, some of whom will be able to receive a medicine simply because they were diagnosed before someone else. We also do not support the proposals because they lack transparency and poorly define both unmet need and rarity
- Access to new cancer medicines needs to be approached 'in the round' and in the context of broader changes including adaptive licensing, Evaluation through Commissioning, and the Early Access to Medicines Scheme

About us

Cancer52 is an alliance of 80 patient support and research charities working in the field of rare and less common cancers. The charities are united by their vision of seeing a better future for everyone affected by the rare and less common cancers, which now account for more than half of all cancer deaths in the UK[i].

We are taking up the invitation from NHS England to "receive…views on the future operation of the CDF generally" as well as providing answers to the specific consultation questions.

www.cancer52.org.uk
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Short term focus, long term problem

Cancer52 recognises the role of the CDF in delivering access to medicines for thousands of patients in England. At the same time, we know that the CDF has been little short of a sticking plaster. We set out our position September 2013 on the CDF. In that statement we said; "the CDF simply fails to get to the root causes for poor access". Nothing in the changes that NHS England are now proposing addresses this situation.

The current consultation (October 2014) is the latest in the evolution of what was intended to be a temporary policy whilst more fundamental reform took place; reform which is now effectively placed on hold as the National Institute for Health and Care Excellence (NICE) seeks further debate on Value Based Assessment (VBA) (the latest name for Value Based Pricing (VBP)). Real change may not even begin until some time after the next General Election in 2015.

Financially, not clinically, driven

Cancer52 recognises the need to take into account cost; we do not support access at any cost. However, the new proposals to change the CDF Standard Operating Procedure are driven by cost, moving further away from the promise made by (now Prime Minister) David Cameron to "enable patients to access the cancer drugs their doctors think will help them" as set out in the 2010 Conservative Manifesto.

Fix the cause

Cancer52 knows that the root causes of difficulties in accessing new cancer medicines, from improving efficiency of research and development in order to lower prices, improving the tools and processes used by NICE, and meaningful involvement of patients in decisions, are not easy to fix. But we've now spent four years with a temporary workaround and are still no closer to tackling these issues.

Access to new cancer medicines needs to be considered 'in the round' and take into account the broader changes taking place including adaptive licensing, Evaluation through Commissioning, and the Early Access to Medicines Scheme.

Cancer52 is calling for a wider debate, just as called for by NICE, to create a consensus on the problems and the solutions that we need to enable access to new medicines for those with rare and less common cancers.

Cancer 52 response to the consultation questions

Please note that the online response tool from NHS England differs in the numbering of the questions as set out in the consultation guide and includes additional questions. Our responses below use the numbering of the questions and include the questions from the online response tool.

(Questions 1,2 and 3 ask for name and organisational details)

Question 4: 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 - We agree with a clinical re-evaluation process as a point of principle Re-evaluation is a useful exercise to explore whether the evidence base has changed and should be done in any case, at regular intervals. Given the presence of a CDF audit (which is funded from the CDF funds) this should play a role in clinical re-evaluation.

We note that results from the CDF audit are not in the public domain. If this is because the audit is not sufficiently robust, then this should be addressed.

Any clinical re-evaluation must take into account unmet need and rarity. Cancer52 calls for a review of the definitions used for both unmet need and rarity. We must ensure that meeting the needs of patients with cancers that have extremely high mortality rates or where there are limited treatment options are given appropriate weight in re-evaluation.

Question 5: 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 – we do not agree with the proposals to take into account cost. The proposed changes take the CDF processes further away from the intention that the CDF would "enable patients to access the cancer drugs their doctors think will help them".

Question 6: 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?

No – we do not agree that drugs which are highly priced in relation to clinical benefit should be removed from the list.

There is a class of medicines acknowledged to be highly priced in relation to clinical benefit, and are generally described as 'high cost, low volume' drugs and are treated differently in the NHS, for example excluded from the NHS Tariff. We believe that there is widespread acceptance that the price of these medicines reflect the small size of the patient population that they treat. The proposal does not address whether these are 'over' priced rather than highly priced.

The proposal of introducing a consideration of the median cost per patient moves the CDF assessment of a medicine/indication closer to the NICE approach. However, this fails to take into account the full consideration of costs or potential cost savings. This is a poor substitute for proper consideration, with the risk of unintended consequences.

We're also concerned that since the 'threshold' used to determine continued inclusion or exclusion from the CDF is dynamic and will change, introducing the possibility that a medicine, highly priced or not, of proven clinical benefit could be ejected on grounds that are not connected to its effectiveness in treating patients.

Question 7: 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?

The pharmaceutical industry is best placed to comment here.

Question 8: Should the proposed process allow a pharmaceutical company the option of making an appropriate and confidential adjustment to its drug price to 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?

The pharmaceutical industry is best placed to comment here.

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Question 9: Are there any other considerations that you think should be addressed in developing a process for prioritising drugs for inclusion within the CDF list?

Yes – we believe that those medicines/indications that are not yet appraised, or will not be appraised by NICE, should have priority for assessment for their continued inclusion and future inclusion. This is particularly relevant for those for the rare and less common cancers as we understand that the Highly Specialised Technology appraisal programme at NICE will not be open to these medicines/indications.

Question 10: 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.

The use of a dynamic threshold will have the effect of introducing unfairness in how patients within the same condition will be treated; some patients will in effect miss out versus their peers because they were diagnosed later and/or the timing of their treatment happens to be after a previously listed medicine has been delisted.

We are naturally particularly concerned about how patients with the rarer and less common cancers will fare under the changes. Whilst there is a discussion of the issues relating to medicines for rare and less common cancers and unmet need Cancer52 calls for a review of the definitions used for unmet need and rarity.

Medicines for rare and less common cancers are invariably unable to offer classic Phase III data but are disadvantaged in the scoring tool. One example of this is the half scoring under section 1 of the scoring tool for Phase II evidence.

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Cancer52
October 2014

[i] Data taken from Cascade, National Cancer Registration Service, Public Health England, accessed 21st May 2014