

## **Cancer52**

### **Response to proposed changes to the Standard Operating Procedures: The Cancer Drugs Fund 2015-16**

## **FULL TEXT OF CONSULTATION RESPONSE**

### **Introduction**

#### ***About Cancer 52***

[Cancer52](#) is an alliance of more than 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.

#### ***Proposed changes under ‘delegated authority’***

The consultation focuses on a narrow set of questions with other changes to the Cancer Drugs Fund (CDF) Standard Operating Procedure (SOP) considered under ‘delegated authority’ dealing with what NHS England (NHSE) sees as clarification and corrections.

In addition to responding to the main questions, we would also like to comment on some of these clarifications and corrections, as follows, particularly where significant additional text has been added.

#### ***Principle of wider clinical engagement***

We are concerned that the new text in para 1.6 p72 of the new SOP appears to dilute the potential influence of clinicians outside of the National CDF (NCDF) panel in decision making. We would like to see the principle of wider clinical engagement retained.

#### ***Patient access to delisted treatments***

We believe that one of the changes creates the potential for greater uncertainty for patients by drugs being on the list at one point in time, then off the list at another. Under para 6.15 p.18 of the new SOP, patients who don't start within three months on a drug that is subsequently delisted lose that option. While the intention of this change might be to stop ‘gaming’ by clinicians, we believe that losing the particular treatment option should be related to a change in clinical circumstances and not a result of the fact that the NHS can no longer afford it, even though it could have been available just a few weeks before.

#### ***Collective decision-making***

Para 6.16 p.18 of the new SOP appears to give a great deal of leeway to the Chair to decide the fate of a drug if a company proposes a commercial deal. As a matter of good practice and governance, we believe that decisions such as these should be a NCDF collective decision, unless there are exceptional circumstances to justify not doing this (in which case these should be clearly and publicly recorded). The patients and patient organisations involved with Cancer 52 would like to see companies come to the table quickly, in a timescale that will allow the NCDF to review the proposal and its implications on the media cost and the balance of cost and benefit.

*No alternative treatment*

Regarding p60 of the new SOP where the reference to “no alternative treatment exists” has been deleted, it may be that this is due to the overall wording of that section being tautologous. We would be grateful for NHSE clarification on this point.

*A bridge to a value-based pricing system*

Finally, the SOP on p.8 retains the reference to “act[ing] as an effective bridge to the Government’s aim of introducing a value-based pricing system for branded drugs”. Given the reality of this aim – where to all intents and purposes VBP has been ‘paused’ – we would suggest that it would be wise to drop this and request that NHSE work closely with colleagues involved in the Accelerated Access Review (AAR) (also known as the Innovative Medicines and Medical Technology Review).

**Responses to formal consultation questions**

**1. What is your name?**

Jane Lyons

**2. What is your email address?**

[jane.lyons@cancer52.org.uk](mailto:jane.lyons@cancer52.org.uk)

**3. What is your organisation?**

Cancer52 represents more than 80 predominantly small cancer charities united by their vision of seeing a better future for everyone affected by rare and less common cancers. Given our membership, we are particularly concerned about ensuring that those with rare and less common cancers are not left behind.

**4. Do you agree with, or have any comment on, Proposal A1 - the requirement for evidence to be both published and peer reviewed in order for it to be given a QOL score?**

**No**

Comments:

Our primary reason for disagreeing with this proposal is that for rarer and less common cancers evidence that is both published and peer-reviewed may simply not be as readily available as for other more common cancers. NHSE should not discount data that is not yet published, as long as it can be assured about how it is generated and the company concerned is in the process of publishing the data.

A related issue is how the NCDF will draw on evidence that is generated over time to inform future decisions about keeping/restricting/delisting drugs. Insights that we hope are available via the CDF audit (although we understand that this still, after five years of operation of the CDF, has not been placed into the public domain) and the Systemic Anti Cancer Therapy (SACT) dataset should be used in future decision making. This is

particularly relevant for rare or less common cancers where the evidence at launch or shortly after launch may still need to rely on small sample sizes.

*Background/context*

To place our comments into context, we would like to reiterate the Cancer52 position on the CDF (available in a briefing on our website here: <http://www.cancer52.org.uk/wp-content/uploads/2013/03/Cancer52-Position-Statement-on-Cancer-Drugs-Fund.pdf> and our response to the last consultation on the SOP here: <http://origin.library.constantcontact.com/download/get/file/1103464048926-694/Cancer52+CDF+Consultation+response....pdf>)

Cancer52 believes that the problems of poor access are not just about funding, but relate to more fundamental issues in the way that research and development is conducted including whether it could be made more efficient and hence result in lower prices, the tools that organisations like NICE use in coming to a decision to recommend a new medicine or not, and how patients are involved in those decisions. We are also keenly awaiting the results of the Accelerated Access Review (AAR) (also known as the Innovative Medicines and Medical Technology Review) which we believe is relevant to how the NHS approaches new cancer drugs.

We have already said in our response to NHSE on investing in specialized services (available here: <http://www.cancer52.org.uk/wp-content/uploads/2014/09/Cancer52-Response-to-Investing-in-Specialised-Services-FINAL.pdf>) that we want companies to ensure that they share data as early as they are able to with NHSE.

**5. Do you agree with, or have any comment on, Proposal A2 - the consistent use of 'significant' rather than 'major' as the standard for improvement/deterioration when scoring QOL?**

**Don't know**

Comments:

Without clarity in what NHSE means with 'significant' versus 'major' it is difficult to assess whether this is a meaningful change or not. Whilst we accept that 'significant' might be taken to mean statistically significant we would urge NHSE to be clear if this is what it means, and if not, define it. In effect, we will only know what NHSE believes is 'significant' following the decisions made.

**6. Do you agree with, or have any comment on, proposal B1 - the amendment of the definition of rarity to be used when scoring a drug's median cost per patient, so that a drug's potential use, rather than its likely actual use, is taken into account?**

**No**

Comments:

We believe that actual use should be the focus simply because that is the relevant decision that NHSE faces; to assess the value and cost of a drug in the actual patients that it will be used for.

We also note that there appears to be a line (as below) that is crossed out in the proposed new SOP which did not appear in the November 2014 SOP that is being revised.

*'but has one or more indications in one or more other settings within or outside of cancer but is not commissioned by and/or used in the NHS in these settings then this definition of rarity does not apply.'*

We are concerned that replacing 'likely to actually receive treatment' with 'likely to be covered by the licensed indication(s) of a particular drug is unhelpful without adding in the 'or not' qualifier. This appears to give considerable scope to disqualify a drug from being considered rare and being able to achieve a high level of reimbursement.

- 7. Do you agree with, or have any comment on, Proposal B2 - the amendment of the definition of rarity to be used when scoring a drug's median cost per patient, so that a drug's use both within and outside the NHS is taken into account?**

**No**

Comments:

We find the suggestion that the drug's use both within and outside the NHS being taken into account when spending NHS funds for NHS patients counterintuitive. We would expect a pharmaceutical company to have already taken into account the total likely patient population when pricing (that even includes pricing in other indications given that few markets enable prices that differ by brand name limiting the opportunity to truly price by indication). In this way, their price, whether reasonable or not, is a function of the wider patient population. It is for NHSE to consider, on behalf of taxpayers, efficiency of their spend on care for NHS patients.

We would also add that patients in England treated outside the NHS would include non-UK nationals traveling to England to be treated as private patients and think it highly inappropriate that they be included in any patient cohort. Doing so could result in the rarity criteria, and with it the triggering of a higher level of reimbursement, never being applicable in a particular case.

We suggest a more appropriate qualifying patient population be less than 500 rather than less than 100. This would enable 'very rare' (9.3 p.77) to align with the existing NICE evaluation process that informally references this particular measure.

**8. Do you agree with, or have any comment on, Proposal C - the creation of a single process for challenging decisions made by the NCDF Panel, as described in paragraphs 10 and 11, of Appendix G, of the proposed Standard Operating Procedures for 2015/16?**

**Yes**

Comments:

This is a pragmatic suggestion. We are also pleased to see that the process for challenging decisions made by the NCDF panel are now open to patient groups.

Cancer52  
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