Cancer Research UK response
The Cancer Drugs Fund: a consultation
January 2011

Summary

- We welcome the Government’s commitment through the Cancer Drugs Fund to improve access for patients to cancer drugs. How the Fund works in practice will be crucial to its success.
- Excellence and equity should be at the heart of the Fund; the Government has a responsibility to ensure that all cancer patients have equal access to treatments, regardless of where they live.
- Clinicians should lead on all decisions about which treatments will be provided through the Fund, both at the local and national level.

Operation of the fund:

1. **Money should be held nationally and distributed locally on the basis of need.** We are concerned that the proposed funding arrangements could mean that the Fund is exhausted in certain areas faster than in others.
2. **A national list of ‘priority’ drugs should be established.** These drugs, which have either not been approved by NICE on the basis of cost, or not yet considered by NICE, should then be available on a named-patient basis through the Cancer Drugs Fund.
3. **Clinically-led regional panels should consider all other individual requests for cancer treatments which fall outside the national list.** This would include all cancer treatments currently considered by exceptional case committees. We are already seeing PCTs deferring individual funding requests to the Cancer Drugs Fund panels. Formalising this arrangement would not only reduce confusion, but also increase efficiency and fairness across the country. This would need to be budgeted for accordingly.
4. **Clinically-led regional panels should remain in place during and after the phasing out of PCTs and SHAs.** A commitment to maintaining current arrangements will provide consistency at a time of uncertainty within the health service. Future uncertainty about funding mechanisms for NHS services further strengthens the case for a centrally-held pot.

At a national level:

- Given the complexity of the decisions facing clinically-led panels, clear guidance for these panels on the principles of operation of the Fund from the Department of Health will be crucial.
- The Department should also take responsibility for actively monitoring distribution of the Fund. This will not only show where variations in decision-making exist, but also ensure that money is reaching the patients who need it most.
- A national scanning process should be in place to provide advice on new cancer drugs. NICE should also continue to provide evidence on clinical effectiveness for all new treatments.
- The Department of Health should closely monitor the impact that the Fund has on funding behaviours of individual PCTs.

At a regional level:

- Regional panels should be clinically-led and include flexibility so decisions can be made quickly.
- Tailored local guidance for clinicians and patients on how to access the Fund is needed.
- A clear, independent, appeals process should be established in all regions; providing detailed feedback to both clinicians and patients within appropriate timelines.
General comments

Cancer Research UK is the world’s largest independent organisation dedicated to cancer research; in 2009/10 we spent £334 million on research. Our vision is that ‘Together we will beat cancer’. We carry out world-class research to improve our understanding of cancer and to find out how to prevent, diagnose and treat different types of the disease. Around 300,000 people are diagnosed with cancer in the UK every year. And every year more than 150,000 people die from the disease.

Cancer Research UK welcomes Government measures to improve access to treatments for cancer patients. However, it should be remembered that cancer treatment is not limited to cancer drugs, but also world-class radiotherapy and the latest surgical techniques. We look forward to seeing commitments in these areas in the forthcoming refresh of the Cancer Reform Strategy.

We also welcome the Government’s moves to find a long-term solution to the current situation by which important new treatments for cancer are not being approved by NICE or the SMC. The introduction of a new system of value based pricing offers an opportunity to address these difficulties. It will be important that this new system reflects the need for an additional £200 million, highlighted by the introduction of the Cancer Drugs Fund, in the cancer drugs budget in England.

It will also be important that the Department of Health takes lessons from the working of the interim Cancer Drugs Fund. To this end, we commend the work of the Department of Health and the National Cancer Action team to date in engaging with clinically-led panels across the country.

Answers to specific questions

1. How can clinically-led panels ensure they are able to respond to the changing nature of available technologies and patient demand over the life of the fund?

Given the burden of decision-making already facing each of the regional panels, we recommend that a national scanning process is put in place for the purpose of identifying new technologies. This could build on the work of the current National Horizon Scanning Committee, but with a greater emphasis on concerted clinical input.

We are concerned that if horizon scanning is left to individual panels there may be significant variation in the speed of adoption of new drugs. A national process would remove the need for each region to carry out their own scanning exercise and reduce the likelihood of variations in prescribing of new drugs across the country. It would also avoid duplication of effort and waste of clinical and administrators time.

Care is needed in designing panel membership. While not necessarily limited to practicing oncologists, we believe that these individuals should be at the heart of the process and make up a significant part of panels. This will ensure efficiency and accuracy, ultimately ensuring that the right decision is getting to patients sooner.

Each SHA should decide what the minimum attendance is for meetings at which funding is decided. These panels shouldn’t be too heavily populated otherwise they will be difficult to bring together, which will delay decisions.

2. Do you agree that the national weighted capitation formula is the best way of determining each SHA’s share of the Fund?

While we understand the rationale behind the Department’s decision to distribute funding using the national weighted capitation formula, we are concerned that this does not allow for variations in need across the country. It is already clear that the position varies greatly around the country, with baseline access to new cancer drugs apparently much better in the regions which are favoured by the formula.
The demand on the Cancer Drugs Fund will be led by individual clinical decisions, and patient need. However, the Cancer Drugs Fund is intended to be additional to existing arrangements for non-NICE approved cancer drugs. These arrangements vary hugely across the country, and within SHAs. Therefore it follows that there will be some drugs in some regions made available through the Fund which would elsewhere be routinely funded by the PCT. For this reason it will be difficult to accurately measure demand on a region by region basis.

To guard against a situation whereby the Cancer Drugs Fund will be exhausted in one region and not another, we believe that the money for the Fund should be held nationally, with approvals from clinically-led panels provided for from this Fund.

In this way, we might avoid in-year and regional fluctuations in demand, which could mean that one individual applying for the fund is successful while another with an identical request, but applying at a different time of year, is turned down. This will also ensure best use of resources, avoiding a situation where SHAs are overcautious from fear of running out of money before the year end, and thus do not approve all applications that they perhaps should.

3. What should the national role be in terms of providing guidance? Are there particular issues that national guidance should address?

We would like to see a national ‘priority’ list of those drugs to be semi-automatically available through the Cancer Drugs Fund in each area. This list should be developed with support from NICE and with the agreement of the leads of the regional SHA panels.

In addition other national guidance should be developed on:
- Appropriate handling of requests outside of the approved list of drugs.
- A national scanning process to identify new drugs coming on to the market.
- Appeals processes for decisions not to apply the Fund.
- Monitoring and data collection. A national lead could help to ensure that the data is collected in a timely way in order to feedback into the operation of the fund.

There is also a role for a national body to monitor spend on each cancer type at a national level, including prescribing for rarer cancers. This information should be available in the public domain. We believe this responsibility would most appropriately sit with the Department of Health.

Information should also be collected on outcomes relating to the drugs provided through the Fund. This should be nationally co-ordinated to provide a useful dataset. Not to do so would be a missed opportunity for further research, particularly for rarer cancers.

A national information leaflet with important information that could be adopted by the NHS and other patient organisations is needed. It is important that patients have access to accurate, high quality information about the Cancer Drugs Fund (CDF) including the process for appeal.

4. Do you agree that it would make sense for different regions to take the lead in considering the evidence on drugs for different cancers, to minimise variation, reduce duplication and make the best use of scarce expertise?

No. We believe that a national priority list, which includes those drugs which should be routinely funded for rarer cancers, should be introduced to minimise variations and duplication of effort. National guidance for panels on how they should consider treatments for rarer cancers more broadly than this would also be useful, and made available to all clinically led panels.

We believe that national guidance, a national scanning process and robust data collection, would remove the need for different regions to take the lead on drugs for particular cancers. The priority for regional panels should be in ensuring that patients within their local areas who have a good case
for applying for treatments outside of a nationally approved list have access to these drugs as quickly and efficiently as possible.

5. Is there anything further that could be done to ensure the Fund operates in a way that encourages drug companies to put forward improved value propositions to the NHS?

We are concerned that clinically led panels lack the appropriate expertise to handle negotiations with drug companies. Agreements on pricing, other than those currently made at the local hospital level, should if possible be made between the Department of Health and drug companies at a national level.

We know that a consortium of SHAs has already had discussions with several of the major drug companies about their role in drug pricing. There may be merit in an extension of this process to all SHAs.

6. How else can we ensure the Fund is focused on providing new drug treatments, and does not subsidise treatments that would otherwise have been funded by PCTs?

We believe that there is a real challenge within the proposed approach in ensuring that PCTs do not choose to simply defer all decisions about non-NICE approved cancer drugs to the Cancer Drugs Fund. We suspect that the rate of approvals of exceptional case panels for cancer treatments has already declined since October 2010. There are therefore real challenges in requiring all funding to have failed as an individual funding request in order to qualify for the Fund, and in completing both an exceptional case and a Cancer Drugs Fund application within the recommended 31 days to treatment.

Therefore recommend that the new process acknowledges the impact that the Cancer Drugs Fund is likely to have on exceptional prescribing for cancer, and propose that all decisions on individual requests for cancer drugs be referred to the clinically-led panels within each region.

This would also ensure that cases aren’t repeatedly sent back and forth between PCTs and SHAs for individual funding requests and Cancer Drugs Fund funding. Appropriate adjustment to local and Cancer Drugs Fund budgets will need to be made to account for this.

The Department of Health should also keep of close eye on the impact that the Cancer Drugs Fund is having on local funding decisions about non-NICE approved cancer drugs. We already know that some drugs which are routinely available in one area are not in others. The Cancer Drugs Fund should not undermine important work in terms of local negotiations with drug companies and this should be closely monitored.

The Department of Health should take an overview of arrangements in each local area. This will be important to ensure that existing arrangements are not undermined by the introduction of the Fund.

A national priority list for those treatments which will be routinely prescribed under the Cancer Drugs Fund should be made available. In addition, in each local area those drugs which are not NICE approved but are routinely available without the need to apply to the fund should also be published. This will enable comparisons to be made between regions and provide a clear and navigable process for clinicians and patients alike.

7. Should the NHS have some flexibility in application of the Fund to cover, for example, the funding of radiopharmaceuticals for Cancer?

Yes. Where a treatment is deemed to be safe and effective and would benefit a particular patient we would support flexibility in application of the Fund. However, the Cancer Drugs Fund is intended to address the shortcomings in the current system in advance of the introduction of value-based pricing. Treatments which would not be covered by value based pricing should therefore not be covered by the Fund.
We believe that it is vitally important to monitor the use of the fund in order to assess the impact of prescribing highly specialised treatments. This needs to be a national process.

8. Do you agree that the Fund should be available for use on any cancer drugs that would not otherwise be funded by the NHS, and not be restricted to a national list of eligible drugs?

We agree that there should be flexibility in the use of the fund. This is particularly important for rarer cancers where prescribing is often “off” or “near label”. A national priority list would introduce efficiency into the system, giving local panels the freedom to consider unusual cases and act with flexibility in these cases.

9. Should guidance be issued on prioritising the Fund application, for example to rarer cancers, or should these be issues left for local resolution within the available funds?

We believe that a national priority list, and a level of flexibility in the use of the Fund, should remove the need to prioritise applications. It will be important to monitor the use of the Fund in the case of rarer cancers by nationally collecting and reviewing data on prescribing across the country.

10. What advice can we give the panels on the specific challenge posed by rarity, or single drugs that have the potential to consume a large proportion of the Fund?

National guidance on funding for these treatments is needed. A national scanning process should ensure that regional panels are adequately prepared for the introduction of these new treatments. National-level negotiations with drug companies would also be useful in managing the impact of these treatments. The Cancer Drugs Fund is not designed to make treatments available, or not, on the basis of cost.

11. Should the Fund be restricted to treatments or should the NHS be able to spend some of the Fund on molecular diagnostic tests to help target the drugs patients are most likely to benefit from?

No. Where drugs require specific tests in order for their effective safe prescribing, this cost should be covered from the general health budget. While better arrangements are needed for the funding of companion diagnostic services for increasing numbers of cancer drugs, we do not believe it would be appropriate to redirect money which should be spent on enabling better access to cancer drugs. Longer term solutions to this problem are needed and we look forward to seeing recommendations for this in the refresh of the Cancer Reform Strategy.

12. Is there a role for NICE, in the context of the Fund, in signalling the technologies that are potentially of significant clinical value (albeit they were unable to recommend them as cost effective)?

NICE has an important role to play in this process. NICE appraisals will continue to provide detail on both the clinical and cost effectiveness of the drugs. A national priority list should be developed with input from NICE.

Clinicians in regionally based panels, and individuals considering the best treatment options for their patients, should continue to use NICE guidance considering individual requests outside of this list.

13. Do you agree that it would be appropriate for the regional panels to decide not to fund drugs where a manufacturer has refused to cooperate with the NICE appraisal process?

Yes. In order for drugs to be prescribed safely and in the interests of the patient, it is essential that pharmaceutical companies continue to cooperate with NICE despite the existence of the CDF.
NICE’s future role in new value-based pricing arrangements should be clarified as soon as possible, to ensure that the current benefit for drug companies of a positive NICE appraisal is not undermined.

14. What more could be done to deter pharmaceutical companies from charging higher prices for new drugs in expectation these will be met by the Cancer Drugs Fund?

A continued dialogue between the Department of Health and pharmaceutical companies is needed to ensure that the NHS is getting value for money from the drugs it is purchasing. These negotiations not only have a role in NICE’s appraisal process, but could be included in discussions about a national priority list. We do not believe it is appropriate for clinically-led regional panels to be asked to negotiate with pharmaceutical companies. Local decisions about the availability of individual drugs should be made on a clinical, rather than cost, basis.

15. How can we support patients with appropriate information on the options available to them?

There is a need for high quality national guidance for patients on the process of applying to the Cancer Drugs Fund. This should be tailored to each of the different regional panels and include information about local application and appeal processes.

Information on those drugs which are routinely available through the Fund should be made available. Previous decisions by each of the panels should be routinely reported and available in the public domain.

The Department of Health should take responsibility for developing and accrediting this information.

16. Should there be a national specification for standards for data collection, to promote consistency?

Yes. National standards are essential in order to collect high quality data in a timely way. The Cancer Drugs Fund is a relatively short-lived project. It is therefore vital that data collection gets underway early and collection is guided and monitored nationally.

17. What audit data would it be most valuable to collect and at what level (local or national) should the collection be done?

We believe that the following data should be collected:

- Prescribing data – this should be collected across regions, held nationally, and made easily accessible to professionals and patients.
- Outcomes data – particularly where a drug is relatively new or is not often used for a particular cancer, this information, if collected systematically, could contribute significantly to the current evidence base. These data should include information on disease progression, and patient reported outcomes.

18. Should the clinical panels be able to decide to use a small proportion of the funding (say 0.5-1%) to audit medicines use at a regional level?

Audit is an essential component of the Fund. We agree that some money should be made available from the Fund to support this. However, regional panels must be able to fully account for how this money is spent, to keep administration costs for implementing the Fund to a minimum.

19. Are there any other comments or information you wish to share?

We would like to see more patients offered the opportunity to be involved in clinical trials. National guidance on administering the Fund should include a recommendation that, where appropriate, patients should be entered into a clinical trial, rather than receive funding through the Cancer Drugs
Fund. These discussions could either take place as part of discussions by the regional panel, or form a requirement for clinicians wishing to apply for the Fund.

Variations in access to treatment could have a devastating effect on our ability to carry out clinical research in the UK. If certain drugs are routinely available in one area and not others, this could mean that we struggle to find a control arm for national phase III trials. These trials are vital in testing the clinical effectiveness and safety of new drugs. This would not only reduce the UK’s attractiveness as a place to carry out research, but also mean that British patients are missing out on the opportunity to access innovative and potentially effective new medicines as part of their treatment. This could also hamper our ability to fully assess new medicines for future appraisal by NICE or in setting an appropriate price in the new pricing mechanism.

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