

The Cancer Drugs Fund

A consultation

The Cancer Drugs Fund – a consultation

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The Cancer Drugs Fund

A consultation

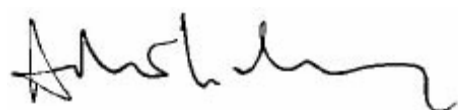
Ministerial foreword

In the White Paper *Liberating the NHS*, published in July, we described our ambition for the NHS to excel in the future. Achieving equity and excellence in the NHS will give the people of this country confidence in the quality of the healthcare they receive, in addition to their confidence in access to healthcare based on need, not ability to pay. The Government is committed to ensuring that the NHS is there for people when they need it most.

We know that patients and clinicians are frustrated and angry that they cannot access some effective cancer medicines on the NHS. This is why we made a commitment in the Coalition's Programme for Government to create a Cancer Drugs Fund to help patients access the cancer drugs their doctors think will help them. Access to cancer drugs is a key priority for the Government, as demonstrated by the extra £50 million we have already made available to the NHS this year for interim funding of additional NHS cancer drugs. This consultation document sets out how we plan to build on this early progress and establish the Cancer Drugs Fund from April 2011.

We want to empower clinicians, and to enable them to use the cancer drugs that they and their patients agree are needed to extend or improve life. In parallel, we are working to change the way the NHS pays for drugs in the longer term, so that patients get better access to treatments that will benefit them, pharmaceutical companies are rewarded for delivering benefits to patients and taxpayers get better value for money. In that context the Cancer Drugs Fund is a key part of our wider plans to improve access to effective medicines, as well as one element of our wider strategy to improve NHS cancer services.

The Government is fulfilling its commitment to establish the Cancer Drugs Fund, committing £200 million a year over the next three years to ensure its success. We need comments and suggestions from patients, clinicians and other interested groups to ensure that the Fund works as well as possible and delivers the greatest benefit to patients. I hope that you will want to respond to this consultation and give us your views.



Secretary of State for Health

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The Cancer Drugs Fund: A Consultation

Section 1 - Introduction

- 1.1 The Government has set out its plans to establish a Cancer Drugs Fund from April 2011. The Fund will provide a means of improving patient access to cancer drugs prior to the anticipated reform of arrangements for branded drug pricing on expiry of the current Pharmaceutical Price Regulation Scheme (PPRS) at the end of 2013.
- 1.2 This document sets out proposals for the establishment of the Cancer Drugs Fund and seeks views on a number of key issues. The consultation will run for 12 weeks from 27 October 2010 to 19 January 2011. Information on the consultation process, including how you can respond to the consultation, is contained in Annex B. Alongside this public consultation, we will actively engage key stakeholders in developing the proposals for implementation.
- 1.3 Decisions on the implementation of the Cancer Drugs Fund will be taken following this consultation.

Section 2 - Context and Case for Change

The Cancer Drugs Fund – A Bridge to Value

- 2.1 The Government believes that there are significant failings within the current system for drug pricing and access. *The Coalition: our programme for government* outlined the Government's commitment to move to a system of value-based medicines pricing to provide NHS patients with better access to effective and innovative treatments at a price that secures value for the NHS. It will take time to implement these changes and the Government has set out its intention to work towards introduction of the new arrangements on expiry of the current PPRS agreement at the end of 2013.
- 2.2 *The Coalition: our programme for government* also confirmed the Government's commitment to the establishment of a Cancer Drugs Fund from April 2011. The Fund will address some of the most pressing access issues, enabling cancer patients to be treated with the cancer drugs their doctors think will help them. It will begin to make the connection to value by putting clinicians and cancer specialists in the driving seat to decide how the funding is best spent for patients. The Fund will bridge the gap until introduction of the new medicines pricing arrangements at the end of 2013, which will formalise the relationship between value and price. Both the Cancer Drugs Fund and value-based medicines pricing reflect our determination to give more power to clinicians to take decisions about treatments in discussion with patients.
- 2.3 As part of the transition to a new medicines pricing approach, consideration will need to be given to the position of drugs that have been funded through the Cancer Drugs Fund following a negative appraisal from the National Institute for Health and Clinical Excellence (NICE). The Government intends to consult shortly on its plans for introducing value-based pricing.

Why Cancer?

- 2.4 More than one in three people will develop cancer at some time in their lives and one in four will die of cancer. In England in 2007 (the latest year for which data is available) 245,300 people were diagnosed with cancer and 127,800 people died of cancer. Cancer accounted for 30 per cent of all deaths in males and 25 per cent in females.
- 2.5 The creation of the Cancer Drugs Fund recognises the particular issues around access in the UK to some newer cancer drugs. These issues were highlighted earlier this year in a report from Professor Sir Mike Richards, National Cancer Director, to the Secretary of State for Health. The *Extent and Causes of International Variations in Drug Usage* looked at international variations in the use of a number of medicines across a range of disease areas. The report clearly illustrates the UK's comparatively low usage of cancer drugs, in particular newer cancer drugs, by international standards.
- 2.6 Professor Richards' report concludes that a range of factors appear to influence the UK's level of drug usage, as compared with other countries. These encompass health, economic, organisational and cultural issues and are likely to vary according to the disease area. UK patterns of use are frequently driven by clinical preference, but it is undoubtedly the case that funding restrictions are a factor in some cases.

- 2.7 In 2009 NICE introduced new flexibilities in its appraisal of drugs for less common, end of life conditions. In addition, the 2009 PPRS sets out more flexible pricing options which drug companies can use to improve the value specific drugs offer the NHS. In combination, these measures have already helped to make more drugs for rarer cancers available to NHS patients, including: Sutent for renal cell carcinoma, Revlimid for multiple myeloma and Yondelis for soft tissue sarcoma. However, there remain cancer drugs which NICE has not felt able to recommend even with the application of a more flexible approach to decision-making, and which drug companies have been unwilling or unable to price at a level NICE would regard as cost-effective.
- 2.8 NICE guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and their guardian or carer. Clinicians have to make an independent clinical judgement, taking account of NICE's advice and the strength of evidence which lies behind it. This clinical freedom also applies in relation to those treatments on which no NICE guidance exists. The Cancer Drugs Fund is intended to ease the funding constraints which can prevent patients in such circumstances from accessing drugs which their doctors recommend for them at a time when some extra weeks or months of life may be particularly precious. The Fund should be seen as addressing a particular category of cases where NHS funding is not otherwise available. The role of NICE as an authoritative source of advice to clinicians remains undiminished.
- 2.9 The drugs NICE rejects generally combine high cost with a limited average extension of life and/or improved quality of life. These benefits can of course be of great importance to individual patients and their families, and it may be that current arrangements do not adequately reflect the value society places on ensuring that patients in such circumstances have access to drugs that can help them.
- 2.10 In response to the publication of Professor Richards' report, the Government announced additional funding of £50 million to improve access to cancer drugs in 2010-11. The funding was issued to Strategic Health Authorities (SHA) for allocation through regional clinically-led panels from October 2010.

Why Cancer Drugs?

- 2.11 The Cancer Drugs Fund is an interim measure until we can introduce a new value-based approach to medicines pricing. The purpose of the Fund is to mitigate the current problems of access and value that have been identified in relation to cancer drugs. In the medium-term, the Government plans to introduce value-based medicines pricing and make new medicines available to NHS patients at a price that represents their value.
- 2.12 Whilst the funding will therefore focus primarily on improving access to drugs, there may be other cancer treatments at the margins that clinicians consider it would be appropriate to provide out of the Fund. This issue is explored in paragraph 4.11.
- 2.13 The Cancer Drugs Fund is also an important part of the Government's wider plans to improve cancer services. The Government is currently reviewing the Cancer Reform Strategy (CRS) to set the direction for cancer services for the next 5 years and ensure

we have the right strategy to deliver what is most important to patients and their families – cancer outcomes.

- 2.14 Improving cancer survival rates is key. It is now generally agreed that the most important reasons for lower survival rates in England, compared with other European countries are low public awareness of the signs and symptoms of cancer, delays in people presenting to their GPs, and patients having more advanced disease at diagnosis. By bringing survival rates in England in line with the best performing European nations through earlier diagnosis, as well as improving treatment and after care, it is estimated that up to 10,000 cancer patients' lives could be saved each year. On 21 September, the Government announced that a new campaign to alert people to the early signs of cancer and encourage them to see their doctor quickly will be launched in January next year. The campaign will consist of 59 local initiatives focussing on the three big killers - breast, bowel and lung cancer. At the same time, the Department will be trialling, in two regions, centrally-led campaign activity to raise awareness of bowel cancer symptoms and to encourage early presentation. Subject to evaluation, the campaign will be introduced nationally.

Innovation Pass and the Cancer Drugs Fund

- 2.15 The Innovation Pass was an initiative announced in the previous Government's Office for Life Sciences (OLS) blueprint. The Innovation Pass was intended to provide funding to innovative new medicines for small patient populations that had the potential to offer valuable benefits, but which would be unlikely to receive a positive NICE appraisal. In developing proposals for the Cancer Drugs Fund, it became apparent that there is a high degree of potential overlap between drugs potentially covered by the Fund and possible candidates for the Innovation Pass. It is important that we are able to look at our plans to improve patient access to innovative medicines as a whole, avoiding duplication between the Pass and the Fund, and, in view of this, the Innovation Pass was suspended in July. We have no plans to reinstate the Pass at this time, but our plans for the Cancer Drugs Fund recognise the vital role the pharmaceutical industry plays in developing new drugs that deliver benefit to patients.

Section 3 - Cancer Drugs Fund – Outline for Implementation

Objectives for the Fund

- 3.1 There are a number of objectives that the Cancer Drugs Fund should address. We consider the most important of these are that the Fund should:
- provide maximum support to NHS patients;
 - put clinicians and cancer specialists at the heart of decision-making, consistent with the Government's wider policy of empowering health professionals and enabling them to use their professional judgement about what is right for patients; and
 - act as an effective bridge to the Government's aim of introducing a value-based pricing system for branded drugs in 2014.

Implications for the Structure of the Fund

- 3.2 A range of options for structuring the Fund has been considered, from complete devolution to complete central control, with each offering a different balance of risks and benefits:
- **Complete devolution of decision-making:** this is immediately attractive as it places decisions on use of the funding firmly in the hands of the doctors treating patients. However, if clinicians take decisions in isolation this may lead to greater variations in patient access with decision-making lacking structure and investment lacking focus. It would be very difficult to guarantee that resources allocated for the Fund were used for the intended purposes;
 - **Central control:** this should lead to greater consistency in decision-making but there is a danger that a national approach may be unresponsive to particular patient needs and to the experience of treating clinicians. The NHS White Paper sets out our wider plan to empower NHS clinicians to do the best for their patients. We want decisions about the use of drugs to be taken by the clinicians who treat cancer patients, and not by politicians in Whitehall;
 - **Regionally based coordination:** this would build on the approach taken to managing the additional £50 million funding for cancer drugs in 2010-11. Organising the Fund regionally would provide a clear structure for decision-making and should prevent funding running into the sand. A regionally based approach would provide good opportunities for co-operation and information sharing between relevant parties, including clinicians, NHS commissioners, patient groups and industry, and should help to guard against unjustified variations in patient access to drugs.
- 3.3 A key objective for the Cancer Drugs Fund is that it should put clinicians at the heart of decision-making. There is of course a potential conflict between ensuring clinical ownership of decision-making and providing uniformity of decisions. A national model would in theory allow a high degree of consistency, but decision-making would be less likely to have local clinical ownership and would be less able to respond to particular patient needs. While a regional model could introduce greater scope for variation, it would deliver much stronger clinical ownership and be significantly more responsive to

the needs of patients. We believe that there are ways in which the risks associated with a regional model could be mitigated, and these are described further.

- 3.4 There will be a need to manage priorities to ensure the greatest benefit within the funding available. A regional model offers obvious attractions if it properly engages clinicians in the decision-making process. A national approach would inevitably be more bureaucratic in bringing together the specialisms within cancer treatment. It would also be further removed from knowledge of the local circumstances and individual cases. A national approach would require the introduction of central controls to manage financial risk and comply with legal requirements in Government procurement, such as limiting the funding any one drug could receive and possibly restricting use of the Fund to specific named treatments. We feel such an approach would be inconsistent with our drive to empower front-line clinicians and their patients.
- 3.5 We want to ensure that the Cancer Drugs Fund secures the best possible deal for the NHS. A national approach to the Fund would not appear to add anything to what companies are already able to offer in the context of the NICE appraisal process. A regional approach could open up greater flexibilities than may be available at national level for the NHS to reach agreements with manufacturers for supply of individual drugs, as happens now in some cases.
- 3.6 On the balance of the risks and benefits, we have concluded that by far the best way of delivering our objectives for the Fund would be through a regional fund, balancing local ownership of decision making with sufficient traction to ensure the Fund is deployed to good effect. A regionally based process will allow real clinical engagement with the opinion leaders in local cancer services.
- 3.7 This approach can usefully build on the regional arrangements established for allocation of the additional £50 million funding in 2010-11. In response to the challenge set in 2010-11, SHAs have worked closely with Cancer Networks, and with each other, to develop appropriate arrangements for allocation of the additional funding. As part of the implementation arrangements for the Cancer Drugs Fund, the regional committees will need to consider arrangements for patients who have received drugs through the additional funding provided in 2010-11. The committees will need to determine, on the basis of clinical advice, the appropriate transitional arrangements for such patients.
- 3.8 Over the period of the consultation, we will work with those involved in developing and operating the current arrangements to ensure that any learning is fed into the implementation of the Cancer Drugs Fund.
- 3.9 A regional approach is of course not without its challenges. Section 4 invites views on how we can ensure that the Fund delivers its objectives as well as possible.

Section 4 – Key Issues and Questions for Consultation

Consistency with NHS White Paper

- 4.1 The NHS White Paper: *Equity and Excellence: Liberating the NHS* sets out the Government's plans to delay and simplify the architecture of the health system and liberate the NHS from excessive bureaucratic and political control. It is therefore important that the structure of the Cancer Drugs Fund can be adjusted to enable it to keep pace with the evolution of the NHS.
- 4.2 In the first instance, we envisage implementation being overseen by SHAs. However, given that SHAs will be abolished once the NHS Commissioning Board is fully established as a Non-Departmental Public Body (NDPB) from April 2012, further consideration will need to be given to what adjustments need to be made to the Cancer Drugs Fund to reflect these changes. We would expect the NHS Commissioning Board to be guided by the principles outlined in this document and the outcome of the consultation in taking any decisions on the future format of the Cancer Drugs Fund.

Resourcing

- 4.3 The Spending Review outcome reaffirmed the Government's commitment to protect funding for the NHS, despite the very tough fiscal climate, and to ensure that the NHS is there for patients when they most need it. Therefore, we will ensure that £200 million is available for each of the three years of Fund operation, beginning in 2011/12. Analysis of the "Extent and causes of international variations in drug usage" report¹ makes clear that, if the UK were to provide newer (less than 5 years old) cancer medicines in line with European average levels, this would cost an additional £225m a year. For England, this would represent less than £200m. This accords with work done by the Rarer Cancers Foundation and is in line with expectations, based on estimates of resources available, prior to the election. The Fund will bridge the gap until the introduction of new pricing arrangements for medicines from the start of 2014, which will establish a clear link between the value of a drug and the price the NHS pays for it. The Cancer Drugs Fund will therefore finish at the end of 2013.
- 4.4 The level of annual funding available will remain constant over the three-year life of the Fund, and "underspends" from one year will not be available for carry-forward into the next. Clinically-led panels will need to manage the available funding in a way that enables them to respond to the changing profile of available treatments over that period, and potential fluctuations in the numbers of patients presenting for specific treatments.

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?

- 4.5 Additional in-year funding to support improved access to cancer drugs was issued to SHAs for allocation through regional clinically-led panels from October 2010. The allocations to each SHA were determined on the basis of the weighed capitation formula. We have considered options for resource allocation for the Cancer Drugs Fund

¹ IMS Health, Issues Bulletin: New Insights into the extent and causes of international variations in drug usage, October 2010

and do not believe there are strong arguments for taking a different approach from 2010-11. We therefore propose that SHA shares of the funding are calculated on the basis of the national weighted capitation formula. This formula is used to inform allocations to the NHS and takes account of such factors as the age distribution of the population and additional need in determining the appropriate allocation of funding.

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

Operation of the Fund

4.6 We have set out the Government's rationale for proposing a regional approach to operation of the Cancer Drugs Fund. It will however be useful to set out ground rules for operation of the Fund and there will be areas on which it would be helpful for national guidance to be developed.

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

4.7 We believe that regional variations could be minimised by encouraging regional bodies to work collaboratively in assessing individual drugs, pooling expertise and avoiding unnecessary duplication of effort. For example, we could encourage individual regional panels to take the lead in evidence assessment for specific cancers.

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?

4.8 As part of the NICE technology appraisal process, Patient Access Schemes can be put forward by a manufacturer to increase the value offered by specific drugs, but there is no scope for national price negotiation. The Cancer Drugs Fund will operate within the framework of the existing PPRS, but a regional approach could open up greater flexibilities than may be available at national level for the NHS to reach agreements with manufacturers for supply of individual drugs which enhance patient access and reflect value.

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?

Scope

4.9 The Fund is intended to give patients access to cancer drugs that would not otherwise be available on the NHS. This may include:

- drugs appraised by NICE and not recommended on the basis of cost effectiveness, or where the recommendations materially restrict access to the treatment beyond the specifications set out in the marketing authorisation (an 'optimised' recommendation); and
- drugs not, or not yet, appraised by NICE.

- 4.10 Where NICE has not carried out an appraisal, the available evidence may make it hard for PCTs to agree funding, for example use of cancer drugs outside their licensed indications (so called “off-label” use). In some individual cases, clinicians may judge that the use of an “off-label” drug is in the patient’s best interest and local management of the fund would allow clinicians greater flexibility in deciding whether to use such treatments in the best interests of patients.
- 4.11 The funding is intended to be additional to that already included in PCT allocations and to be used to provide treatments where there is no appropriate alternative that the NHS would otherwise fund. It is therefore important that existing PCT processes are adequately explored before a call is made on the Fund. This includes PCT consideration of Individual Funding Requests (IFR), where appropriate. It will be important to ensure that PCT level considerations are timely and do not result in delays to patients accessing drugs from the Fund. The regionally based panel should monitor these arrangements to ensure that cases are being handled appropriately.

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?

- 4.12 We have set out the reasons why the Fund is focussed on access to cancer drugs. There may however be treatments at the margins that may not be considered to be conventional drugs, but which clinicians feel it would be appropriate to provide from the Fund, particularly where the evidence on a treatment is not yet sufficiently developed for it to be routinely funded in the NHS. The obvious example is of radiopharmaceuticals, drugs combined with radiation therapy, including treatments such as Selective Internal Radiation Therapy (SIRT).

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

- 4.13 We believe that decisions on competing priorities should be managed with the involvement of treating clinicians, and that we should not put central restrictions on the cancer drugs that are eligible for the Fund. It will be important for the composition of the clinical panels to allow for the broadest consideration of cancer drugs, including drugs for rarer cancers, and panels will wish to ensure there is the facility to obtain further expert input where appropriate. This may be particularly important for some rare or very rare cancers where there may be limited published evidence of effectiveness, and a decision taken solely on the strength of such evidence may leave patients with these conditions at a disadvantage. Conversely, there could be a case for issuing guidance to panels on the need to avoid a scenario where just one or two drugs consume a disproportionate share of the Fund.

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?

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?

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?

4.14 To enable the funding to go as far as possible, the Fund will be focussed on the cost of the drug and PCTs will be expected to meet the associated service costs related to provision of these medicines. It may be that molecular diagnostic tests, such as those for KRAS or EGFR mutations, would help target the drugs patients are most likely to benefit from. It could therefore be argued that it would be useful to provide these tests out of the Fund.

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?

4.15 It is of course imperative that patients receive the drugs they need in a timely fashion and are not delayed in accessing treatment as a result of overly bureaucratic processes. We would therefore encourage regional panels to develop funding policies for groups of patients wherever possible. This will support timeliness, consistency of decision-making and effective management of the resources available. It will be necessary for the panels to have the facility to consider individual requests where these would not be appropriate for a population-based approach, for example if the drug in question is for treatment of a very rare tumour or if exceptional circumstances apply in particular cases. In cases where the treatment relates to a very rare tumour, the panels will need to ensure that they have access to the appropriate clinical expertise to make an informed decision.

4.16 Panels will need to put in place a mechanism for considering appeals against funding decisions and should ensure that these processes support timely consideration.

Evidence, Information and the Role of NICE

4.17 NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. As set out in the NHS White Paper, NICE remains at the heart of the Government's plans for the NHS. It will continue to play a vital role in offering advice to the NHS on the clinical and cost effectiveness of new medicines.

4.18 Even if NICE does not recommend a drug through its appraisal process, its thorough assessment of the evidence on clinical effectiveness will be of considerable use to clinicians and patients looking for the best treatment option. We believe it is important that NICE should continue to appraise new cancer drugs by default and that companies should continue to have an incentive to engage with that process. We therefore consider it would be appropriate for the regionally based panels to decide not to fund drugs that have not been subject to NICE appraisal because the manufacturer refused to supply information to NICE.

4.19 In addition, by continuing to appraise the great majority of new cancer drugs NICE will ensure pharmaceutical companies will have an incentive to offer prices that represent value rather than relying on the Cancer Drugs Fund to pick up new drugs.

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)?

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

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?

4.20 We will also need to consider the information needs of patients. Patients will need appropriate information on the available options to support them in making informed decisions. Treating clinicians will remain responsible for helping patients to make informed choices, taking account of their individual circumstances and the likely benefits and risks of the treatment in question.

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

4.21 The Government is also considering what more can be done to provide the NHS with reliable assessments of the available evidence on “off-label” uses of medicines.

4.22 We believe that it will be important for clinicians to provide audit data (including clinical audit data) on their use of drugs paid for from the Fund. At a local level, this information will be valuable in managing allocation and prioritisation of the funding. At a national level, it may be helpful to monitor the arrangements to ensure the Fund is fully and appropriately utilised. And over time it will help to improve the available evidence on how these drugs perform in real-world clinical practice.

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

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

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?

Section 5 - Cancer Drugs Fund – Summary of Questions for Consultation

Following the consultation, we will consider the responses to these questions before publishing final plans for the implementation of the Cancer Drugs Fund from April 2011.

- 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?**
- 2. Do you agree that the national weighted capitation formula is the best way of determining each SHA's share of the Fund?**
- 3. What should the national role be in terms of providing guidance? Are there particular issues that national guidance should address?**
- 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?**
- 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?**
- 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?**
- 7. Should the NHS have some flexibility in application of the Fund to cover, for example, the funding of radiopharmaceuticals for Cancer?**
- 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?**
- 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?**
- 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?**
- 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?**
- 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)?**

- 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?**
- 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?**
- 15. How can we support patients with appropriate information on the options available to them?**
- 16. Should there be a national specification or standards for data collection, to promote consistency?**
- 17. What audit data would it be most valuable to collect and at what level (local or national) should the collection be done?**
- 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?**
- 19. Are there any other comments or information you wish to share?**

Annex A - Glossary

EGFR (epidermal growth factor receptor) - Mutations affecting EGFR expression or activity could result in cancer

KRAS (Kirsten rat sarcoma) – the mutation of a KRAS gene is an essential step in the development of many cancers

Both KRAS and EGFR tests help to define groups of patients who are more or less likely to benefit from drugs (for colorectal and lung cancer respectively). By doing these tests, clinicians can recommend drugs to those who are most likely to benefit from them and can spare others from treatment, which will almost certainly not be active against the cancer but could have unpleasant side effects.

National Institute for Health and Clinical Excellence (NICE) – NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health.

Pharmaceutical Price Regulation Scheme (PPRS) – a voluntary agreement between the Department of Health (on behalf of the UK health departments) and the branded pharmaceutical industry (represented by the Association of the British Pharmaceutical Industry) which aims to ensure that the NHS has access to good quality branded medicines at reasonable prices, and promotes a healthy, competitive pharmaceutical industry.

Annex B- The Consultation Process

Responding to the consultation

You can respond to the consultation by completing the response form available at http://www.dh.gov.uk/en/Consultations/Liveconsultations/DH_120834 and either emailing it to cancerdrugsfund@dh.gsi.gov.uk or posting it to:

**Cancer Drugs Fund,
Gillian Baker - Consultation Coordinator,
Department of Health,
5W12 Quarry House,
Quarry Hill,
Leeds LS2 7UE**

Comments should be received by 19 January 2011.

Criteria for consultation

This consultation follows the 'Government Code of Practice', in particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible;
- be clear about the consultation's process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at:

[Link to consultation Code of Practice](#)

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please

contact Consultations Coordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE

e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's [Information Charter](#).

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website at

<http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm>

