The Cancer Drugs Fund

Government response to consultation

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Document Purpose	For Information
Gateway Reference	15865
Title	The Cancer Drugs Fund: Government response to consutation
Author	DH
Publication Date	01 Apr 2011
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, PCT Chairs, NHS Trust Board Chairs, Special HA CEs, Directors of Finance, Allied Health Professionals, GPs, Communications Leads, Patients, Carers, Cancer Networks, the Pharmaceutical Industry and the general public
Circulation List	PCT PEC Chairs
Description	The Government's response to the consultation on the Cancer Drugs Fund. The consultation took place between 27 October 2010 and 19 January 2011. This document contains a summary of the responses received to the consultation and actions taken as a result.
Cross Ref	The Cancer Drugs Fund: A consultation (Gateway: 14909)
Superseded Docs	N/A
Action Required	N/A
Timing	**N/A**
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For Recipient's Use	

First published 1 April 2011
Published to DH website, in electronic PDF format only.
http://www.dh.gov.uk/publications

The Cancer Drugs Fund

Government response to consultation

Prepared by the Department of Health

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1. Introduction

The Coalition: our programme for government[1] confirmed the Coalition Government's commitment to the establishment of a Cancer Drugs Fund from April 2011 to enable cancer patients to access the additional cancer drugs their doctors think will help them. This was reaffirmed in the White Paper, Equity and Excellence – Liberating the NHS.[2]

The Cancer Drugs Fund provides 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. The Government has separately consulted on principles to underpin a move to value-based medicines pricing and this consultation closed on 17 March 2011.[3]

Both the Cancer Drugs Fund and value-based medicines pricing reflect the Government's determination to give more power to clinicians to take decisions about treatments in discussion with patients.

We will ensure that £200 million is available for each of the three years of the Cancer Drugs Fund's operation, beginning in 2011/12.

Analysis of a report by Professor Sir Mike Richards, National Cancer Director, on the Extent and Causes of International Variations in Drug Usage[4] 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 a little under £200m. We are not aiming to match an international average level of spend, but this demonstrates that the funding injection we are making will enable cancer specialists to make decisions on the same kind of footing as their counterparts in other European countries.

The Rarer Cancers Foundation has estimated the costs of taking a less restrictive attitude towards funding cancer treatments and concluded that this would require additional funding of up to £175m a year.[5]

Although these estimates have been arrived at in different ways, they both lend support to a figure of around £200m a year.

Arrangements in 2010-11

In July 2010 in response to the publication of the report by Professor Sir Mike Richards on the Extent and Causes of International Variations in Drug Usage,[6] the Government announced that £50 million additional funding had been identified in-year to support improved access to cancer drugs. SHAs were tasked with working with their Cancer Networks and PCTs to ensure that appropriate arrangements were in place by October 2010 to manage this funding. These arrangements included the establishment of clinically-led panels to make decisions on the

[1] The Coalition: our programme for government, May 2010
[2] Equity and excellence – Liberating the NHS, July 2010
[3] Pharmaceutical Price Regulation Scheme (PPRS) 2009, December 2008
[4] IMS Health, Issues Bulletin: New insights into the extent and causes of international variations in drug usage, October 2010
[5] Exceptional England?, Rarer Cancers Foundation, October 2008
[6] Extent and Causes of International Variations in Drug Usage, July 2010

most appropriate use of resources and to approve funding requests. Over 2,000 people have already benefitted from access to life-extending drugs through these arrangements.

Implementation of the arrangements in 2010-11 has provided useful experience we are able to build on in 2011-12, complementing the consultation on the Cancer Drugs Fund proposals.

Arrangements for 2011-12

The Department of Health published The Cancer Drugs Fund – A Consultation[7] on its website on 27 October 2010. The consultation closed on 19 January 2011. The consultation set out proposals for the establishment of the Cancer Drugs Fund from 1 April 2011 and sought views on a number of key issues. The Department has used the responses to this consultation to inform the development of the Cancer Drugs Fund.

Alongside the development of the Government's response to the consultation, the Department has worked with NHS colleagues to develop best practice guidance to support the operation of the Cancer Drugs Fund in 2011-12. The guidance builds on experience in 2010-11 of operating the regional arrangements for providing additional cancer drugs and feedback to the consultation. The guidance was published on the 23 March 2011 and will come into operation on 1 April 2011.

2. How we consulted

The Department of Health managed the consultation exercise and fully complied with the Government's Code of Practice on Consultation. We published the consultation document, accompanying consultation stage Impact Assessment and Equality Impact Assessment screening agreed by Ministers on the Department of Health's website.

We also raised awareness of the consultation using a number of additional mechanisms

- Notifications in NHS e-bulletins
- Press release
- Cited consultation information in official correspondence, ministerial presentations and parliamentary business – including through Parliamentary Questions - and invited interested parties to respond
- Encouraged chairs of the clinically-led panels at meetings to respond to the consultation and to ask their colleagues to do so

In addition, some respondents held workshops to discuss the consultation and sent detailed responses containing the outcome of their discussions about the consultation. We also received collated responses from patient groups, trade organisations, colleges, trade unions and NHS organisations encompassing their members' opinions.

[7] The Cancer Drugs Fund – A consultation, 27 October 201, Gateway 14909

3. Breakdown of consultation responses

We received 160 responses to the consultation online, by email and by letter.

We received a wide range of responses from individuals and organisations. From other government departments, the NHS including - special health authorities, strategic health authorities (SHAs), cancer networks, specialised commissioning groups, primary care trusts (PCTs), acute and foundation trusts, specialist cancer centres and cancer drugs advisory groups. Other organisations included pharmaceutical companies, pharmaceutical trade organisations, Royal Colleges, research organisations, trade unions, charities, patient groups and a Town Council. Individual responses included patients, health professionals, academics, members of the public and others.

Tables showing the breakdown of responses are below.

The Cancer Drugs Fund applies in England only. In responding to the consultation, respondents indicated the countries to which their comments related.

Of the 160 responses received

- 46 related to England
- 1 related to England and Wales
- 48 related to the UK
- 65 were from respondents who did not indicate which countries the comments related to

Figure 1 - The breakdown of responses by country

	England	England and Wales	UK coverage	Country not given	Total
Health & Social Care Professional	7	0	13	1	**21**
Health & Social Care Prof & on behalf of an organisation	5	0	1	0	**6**
Member of the public	4	0	5	5	**14**
Member of the public & on behalf of an organisation	1	0	1	0	**2**
On behalf of an organisation	28	1	26	11	**66**
Not given	1	0	2	48	**51**
Total	**46**	**1**	**48**	**65**	**160**

Figure 2 - The breakdown of responses by area of work:

	England	England & Wales	UK coverage	Country not given	Total
Education	1	0	0	0	**1**
Independent Contractor to the NHS	1	0	0	0	**1**
Manufacture / Pharma Company	3	0	12	0	**15**
NHS	32	1	18	4	**55**
NHS & Education	1	0	1	0	**2**
NHS & Professional Body	0	0	1	0	**1**
NHS / Social Care & Third Sector	1	0	0	0	**1**
NHS & Private Health	0	0	1	0	**1**
NHS / Private Health & Professional Body	1	0	0	0	**1**
Private Health	0	0	1	0	**1**
Professional Body	0	0	2	0	**2**
Third Sector	2	0	3	1	**6**
Trade Body	0	0	2	0	**2**
Trade Body / Manufacturer & Supplier	0	0	1	0	**1**
Not known	2	0	5	59	**66**
Other	2	0	1	1	**4**
Total	**46**	**1**	**48**	**65**	**160**

4. Key findings

Responses to the consultation were varied in their content and focus, but a clear majority were supportive of the principles behind the Cancer Drugs Fund and focused on issues that needed to be considered in implementation of the Fund.

Responses to the consultation addressed the key issues we had identified in the consultation. These included matters relating to the scope of the Cancer Drugs Fund, the decision-making processes, prioritisation of drugs available under the Cancer Drugs Fund, the role of the Department of Health, the role of the National Institute for Health and Clinical Excellence (NICE), provision of information for patients and the approach to audit. A summary of the responses to our consultation questions and actions taken as a result are covered later in this document. A list of key findings along with a selection of comments from consultation follows:

> "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. "(Cancer Research UK)

> "We are pleased that the Government has prioritised improving patient access to cancer drugs and acknowledge that there are significant failings within the current system for drug pricing and access. We also welcome the recognition that clinicians and cancer specialists should be given more power to take decisions about treatments – in discussion with their patients." (Breast Cancer Care)

Consultees were widely supportive of empowering local clinicians to take decisions on behalf of their patients, and many acknowledged the benefits of keeping decision-making close to patients and clinicians through the regional model adopted. Some respondents advocated a single national approach to the Cancer Drugs Fund and, in the absence of this, most supported collaborative working across the SHAs supported by clear national guidance. Most respondents stressed that under any collaborative arrangements decision-making should still rest with the respective SHA clinically-led panels to ensure that decisions remained responsive to local needs.

> "We fully support the over-arching principle behind the introduction of the Cancer Drugs Fund (CDF), namely to enable clinicians to give their patients the treatments that are right for them and at the right time, to maximise their chances of benefitting from them. Clinicians are best placed to determine which treatments are right for their patients, and they should be able to make their decisions either individually or as part of clinically led panels. They are the cancer experts and know more about their patients' health than anyone else. They are also best placed to discuss treatment options with their patients and their families and agree the right course of action with them." (Bowel Cancer UK)

> "The NHS clinicians should have complete control over assessing all new treatment, based on local clinical specialist response to the latest information on that treatment." (Member of the public)

> "a regional level approach could lead to greater responsiveness however there needs to be transparency in the operation of the fund to ensure there is not significant variation in access between regions. Best practice and knowledge should also be shared between different regions, so that people with rarer cancers don't lose out if there is no specialist expertise on their cancer in a particular region." (Macmillan Cancer Support)

Respondents to the consultation stressed the pivotal role of treating clinicians, nurses and those working in palliative care in helping patients to make decisions about their treatment. Many respondents also suggested that patient groups, charities and the pharmaceutical industry could have a key role to play in supporting patients with information to enable them to make informed decisions.

> "we strongly recommend that national guidance explicitly requires professionals to hold open discussions with the person about the relative merits of end of life care in addition to the curative or life-extending drugs available through the fund." (Joint response from Help the Hospices, The National Council for Palliative Care, Sue Ryder and Marie Curie Cancer Care)

> "patients must be supported to understand the information they are given on different treatment options through face-to-face communication with a healthcare professional. The fund also should not be an excuse to avoid difficult conversations at the end of life." (Macmillan Cancer Support)

> "We support the Government's policy of 'no decision about me without me' which is an essential aspect of a modern health system. Information is key to people being able to exercise choice and make decisions, with information on treatment options an important aspect of this. Information on the Fund should be transparently available to patients, the public and other stakeholders and SHAs should proactively implement measures to ensure awareness of the Fund. That information should not only be about its existence but also about how and what decisions are made. The options for patients should be made transparent so they are equipped to have informed conversations with their clinicians." (European Medicines Group, EMG)

There was strong support for national guidance to promote good practice across SHAs and encourage transparency, consistency and timeliness of decision-making.

The use of "priority lists" of drugs that would routinely be funded through the Cancer Drugs Fund was generally supported, providing these lists were not restrictive and were managed in a dynamic way that allowed changes to be made during the year.

> "Experience gained from implementing the Interim Cancer Drugs Fund has highlighted the benefits of a population based approach with strong clinical involvement and leadership in identifying the priority list of drugs to be funded." (Specialised Commissioning Groups combined response)

> "wherever possible, policies should be developed for specific diagnostic patient groups." (Clinician)

> "Over the life of the fund there will be a number of additional issues which will mean that any dynamic process may need to review decisions more regularly than once a year. The level of evidence for cancer drugs changes rapidly, demand for new cancer drugs can arrive more rapidly then predicted and price is often not known until close to launch. This makes predicting the costs for the regions covered by the CLPs (clinically-led panels)12-18 months before some treatments become available impossible and we would argue means that the CLPs will have to have lists that are constantly changing." (British Oncological Pharmacists Association, BOPA)

The importance of NICE's continuing role as an authoritative source of information on the clinical and cost effectiveness of medicines through its technology appraisal process was widely recognised. NICE guidance was considered to be a leading source of information to inform the decisions of the clinically-led panels. The majority of responses agreed with the suggestion 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.

> "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." (Cancer Research UK)

> "ABPI recommends the CDF is not used to fund treatments where NICE has informed those responsible for administering the CDF that a company has unreasonably not cooperated with the NICE appraisal process." (Association of the British Pharmaceutical Industry, ABPI)

There was wide support for the collection of clinical audit data and a strong sense that this information would prove extremely valuable, in particular in improving the available evidence on how the drugs funded from the Cancer Drugs Fund perform in real-world clinical practice.

> "It is vital that clinical audit is undertaken to ensure that there is an increased evidence base on drugs that are made available through the Fund and to ensure that resources are used most effectively." (Cancer Campaigning Group)

5. Summary of responses to each consultation question and the Government's response

This section contains a summary of responses to each of the consultation questions and the Government's response. Where respondents answered a closed question, we have included a breakdown of responses and comments where possible. To avoid possible identification through small numbers we have not broken down responses further by organisational or individual type.

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?

A large number of respondents stressed the importance of the clinically-led panels managing the funding in a dynamic way that allowed them to respond to the changing nature of available technologies and patterns of patient demand. Where clinically-led panels identified lists of drugs that would be made routinely available through the Fund (a "priority list"), responses suggested that these lists would need to be regularly reviewed in-year to take account of new evidence, new drugs coming on to the market and other drugs moving into PCT mainstream commissioning arrangements (for example, following a positive appraisal from NICE). It was suggested that SHAs share these lists and the reasons for their prioritisations with each other to promote consistency of approach.

It was suggested that the clinically-led panels should ensure they had access to information sources that would support them in horizon scanning for new drugs. This would help the panels anticipate the potential demand on the Fund and plan use of resources. For example, respondents suggested drawing on information from the National Horizon Scanning Centre, UK PharmaScan, the Cancer Commissioning Toolkit, London Cancer New Drugs Group and NICE. It was suggested that the clinically-led panels would need to keep abreast of the progress of relevant NICE guidance in development, and plan for the potential impact of NICE appraisal decisions on demand against the Fund.

Government response

It is important that clinically-led panels are able to respond to the changing nature of available technologies and potential fluctuations in the numbers of patients presenting for specific treatments over the life of the Fund. Developing funding policies for defined groups of patients should support this through enabling the clinically-led panels to better forward plan the use of resources. In addition such an approach should provide transparency, equity and speed of decision-making and reduce the burden on clinicians and managers.

This approach generates lists of drugs (a "priority list") that will routinely be made available through the Fund. For the Fund to remain responsive to the availability of new technologies and changes in patient demand, it is important that the clinically-led panels keep such lists under regular review and update them in response to new developments and new evidence. Where a clinically-led panel decides not to prioritise a drug for routine funding from the Cancer Drugs Fund or to remove a drug from a priority list, it should be clear that these decisions will be kept under review.

This position is reflected in guidance the Department of Health has developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12. The guidance stresses the importance of keeping "priority lists" dynamic and recommends review of such lists on at least a quarterly basis, with the facility for consideration of applications for additional candidate drugs in between scheduled review points.

Clinically-led panels should consider the sources of information they can draw on, such as horizon scanning, to support them in predicting the potential future demand against the Fund and planning the effective use of resources.

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

43% (68) said yes
13% (20) said no
45% (72) did not answer this question

Overall, respondents were supportive of the national weighted capitation formula as the most appropriate way of determining each SHA's share of the funding for 2011-12. Those that disagreed with this approach suggested linking allocation of funding to some form of targeted needs-led assessment.

Government response

SHA shares of the £200 million Cancer Drugs Fund for 2011-12 have been calculated using the national weighted capitation formula. This model is familiar to the NHS and avoids the need to develop bespoke, untested allocation mechanisms. It is expected that each SHA Cancer Drugs Fund will put in place a plan to fund cancer treatments using their appropriate weighted capitation share of the £200m Fund. £60 million of the funding is being held centrally and an assessment of demand against the SHA level Cancer Drugs Fund budgets will be made before any allocation of this element of the funding.

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

Nearly all of the consultees who responded to this question considered that DH had an important national role to play in providing guidance to the NHS to support the operation of the Cancer Drugs Fund. It was suggested that guidance would help ensure consistency of approach among the clinically-led panels. Many of the responses suggested that this guidance should focus on broad principles and allow the NHS freedom in approach. Some responses suggested a much stronger national role, in some cases advocating a single national approach to managing the Cancer Drugs Fund as a whole. Acknowledging that a national approach to management of the Fund was not an option under consideration for 2011-12, most of these responses supported collaborative working across the SHAs.

Respondents from a variety of organisational and individual origin identified a number of key issues for national guidance as below:

- It should set out the scope of the Cancer Drugs Fund
- It should encourage consistency of decision-making
- It should encourage transparency of decision-making
- It should encourage timeliness of decision-making
- It should support provision of information to patients and clinicians
- It should require clinically-led panels to have appropriate processes in place for reviewing decisions and a robust appeals process
- It should encourage open discussions between patients and clinicians on the relative merits of treatment options
- It should encourage the involvement of a patient or lay perspective in the Cancer Drugs Fund process
- It should take into account feedback based on the experience of the clinically-led panels operating the £50million additional in-year funding for cancer drugs

In relation to the scope of the Fund, a number of respondents commented that national guidance should include clarification on whether radiopharmaceuticals and molecular diagnostic tests are within scope (see Government responses to Questions 7 and 11) and advice on the treatment of rarer cancers (see Government response to Question 9). Others suggested that it would be helpful for the national guidance to clarify the relationship between the Cancer Drugs Fund and existing drug funding processes, including PCT Individual Funding Request (IFR) processes.

Respondents were supportive overall of clinically-led panels developing funding policies for groups of patients and using these to generate lists of drugs that would routinely be funded through the Cancer Drugs Fund. It was suggested that the national guidance should provide national advice or principles on the use of these “priority lists”. There was much commentary in response to this question about how the lists should operate (which is covered at Question 8).

Government response

Guidance has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12. This guidance takes into account the suggestions for national guidance put forward in the responses to the consultation and experience gained in 2010-11 through operation of the regional arrangements for providing additional cancer drugs.

Arrangements for 2012 and beyond will be subject to discussions between the Department of Health and the shadow NHS Commissioning Board.

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?

30% (48) said yes
31% (50) said no
39% (62) did not answer this question

A majority of responses to this question supported the spirit of collaborative working and felt the clinically-led panels should be encouraged to share expertise and information. Some respondents were resistant to the proposal that individual regions take the lead in considering the evidence on drugs for different cancers as they had interpreted this as meaning the lead region would also take the decision on funding. Providing decision-making remained with the respective SHA clinically-led panels there was support for sharing assessments of evidence across the SHAs, drawing on the different expertise in particular cancers across the regions.

Government response

SHA clinically-led panels may wish to collaborate on evidence assessment and share expertise, particularly in cases where the published evidence may be limited. This is set out in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12. The guidance makes clear that the responsibility for decision-making in such cases will remain with individual SHA clinically-led panels.

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?

A great number of replies to this question stressed the importance of the Cancer Drugs Fund arrangements remaining consistent with arrangements set out in the 2009 Pharmaceutical Price Regulation Scheme (PPRS), which will not expire until the end of 2013. There was a strong commitment from all parties for the clinically-led panels, NHS and pharmaceutical companies to continue to work together to deliver value for money.

Many responses commented that the panels should take account of cost effectiveness in deciding which drugs should be made available through the Cancer Drugs Fund. It was considered that this, combined with the fixed size of the funding pot being made available, might be effective in stimulating drug companies to put forward improved value propositions.

A number of responses suggested that the potential for negotiation with pharmaceutical companies on the price of individual drugs should be explored. Many respondents asked that the Department of Health consider how procurement might be taken forward at a national level. It was suggested that this would bring the required specialist expertise to the procurement process, reduce the burden on individual SHAs, remove duplication of effort and ensure consistency in the offers made to the NHS.

Government response

The criteria for access to the Cancer Drugs Fund should be based primarily on evidence of clinical effectiveness and anticipated delivery of measurable outcomes such as improved overall survival, progression-free survival or improved quality of life. We agree, however, that panels should also consider cost effectiveness if there is robust data to support decision-making. This should maximise the number of patients that can be treated from the available funding, and encourage pharmaceutical companies to further consider the value propositions offered by their drugs. We welcome the strong

commitment expressed by many consultees, including those from the pharmaceutical industry, to delivering value for money.

In response to the consultation and representations from SHAs, the Commercial Medicines Unit (CMU) will undertake a procurement exercise to establish a framework agreement for drugs purchased within the scope of the fund. The framework will allow regional NHS decision-making in terms of which products will be purchased.

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?

Responses to this question suggested that clear national guidance would be particularly helpful in clarifying the relationship between the Cancer Drugs Fund and existing drug funding processes, including the Individual Funding Request (IFR) process. There should be clear information for clinicians and patients on the processes that need to be followed. It was felt important that clinicians should continue to make the case for NHS funding through normal commissioning routes. A number of respondents suggested that robust IFR processes in PCTs should ensure that the Fund was focused on new drug treatments and would not be used to subsidise treatments that would otherwise have been funded by PCTs. It was suggested that SHAs should keep the position under review to see if the profile of PCT IFR funding decisions appear to be changing.

A number of responses highlighted PCTs' existing obligations under the NHS Constitution on funding of NICE-appraised drugs and on local decision-making. The NHS Constitution sets out a right to drugs and treatments that have been recommended by a NICE appraisal, where a doctor says they are clinically appropriate. It also sets out a right for patients to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. PCTs should ensure that they have robust transparent processes in place to make these decisions - including decisions on exceptional funding.

Government response

To ensure the Fund is focused on providing access to new and additional drug treatments, and does not subsidise treatments that would otherwise have been funded by PCTs, it is important that treating clinicians, working with local NHS managers, fully explore all reasonable avenues for securing NHS funding before using the Cancer Drugs Fund. It is important this consideration does not introduce any undue delay; it should after all be normal good practice in the absence of the Fund. Regional policies need to ensure they set out clearly how the Cancer Drugs Fund and local drug funding arrangements interrelate. Patients and their treating clinicians should be supported in seeking funding through the most appropriate mechanism.

This position is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12. The guidance includes a section on the links between the Fund and existing processes which explores this issue in more detail.

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

54% (86) said yes
6% (10) said no
40% (64) did not answer this question

There was strong clinical support for the inclusion of radiopharmaceuticals and most responses from other organisations and individuals agreed that the NHS should be able to use the Cancer Drugs Fund to fund radiopharmaceuticals where it was considered clinically appropriate. A small minority said that the fund should apply to conventional drugs only.

Government response

The clinically-led panels should have some flexibility in application of the Fund to cover the funding of radiopharmaceuticals for Cancer. This position is set out in the guidance that has been developed to support the operation of the Cancer Drugs Fund in 2011-12.

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?

36% (58) said yes
11% (18) said no
53% (84) did not answer this question

A majority of those that responded to this question agreed that the Fund should be available for use on any cancer drugs that would not otherwise be funded by the NHS and should not be restricted to a national list of eligible drugs. Some responses suggested there could be scope for a national core list of eligible drugs, perhaps created through collaboration between the clinically-led panels, but this list should not be restrictive. There were some concerns about the difficulty in agreeing a national list of drugs due to differences in the existing baseline of drug provision and the need to respond to local needs and circumstances. Many responses suggested that any eligible drugs lists would need to be developed regionally by clinically-led panels in order to better reflect local circumstances, including existing patterns of provision and patient need in the areas they represent.

Many responses commented on the use of “priority lists” by clinically-led panels in 2010-11 for allocating the additional £50 million funding for cancer drugs provided in-year. These responses suggested that the use of such lists for the Cancer Drugs Fund would be helpful in ensuring timely consideration of applications and reducing bureaucracy in the process, which in turn should enable patients to gain swifter access to the drugs that their clinicians have recommended for them. A number of replies supported the use of “priority lists” but considered that panels should also have the facility to consider applications on a case-by-case basis.

Responses strongly suggested that if the panels were to use drugs lists they should be enabling rather than restrictive and should be subject to regular in-year reviews. Respondents suggested this would enable the clinically-led panels to be responsive to changes in the availability of treatments and fluctuations in patient demand by allowing drugs to be added to

the lists and removed from the lists at appropriate times. Respondents suggested that the clinically-led panels should be able to review decisions and alter a previous decision in response to new clinical evidence.

Government response:

The Cancer Drugs Fund should be available for use on any cancer drugs that would not otherwise be funded by the NHS, and should not be restricted to a national list of eligible drugs. Clinically-led panels may agree lists of drugs that will be routinely funded through the Cancer Drugs Fund but these lists should not be restricted to a national list of eligible drugs. Clinically-led panels may agree lists of drugs that will be routinely funded through the Cancer Drugs Fund but these lists should not be restrictive or exclusive. Local clinicians should be able to make representations for the inclusion of specific treatments on any such lists and they should be kept under regular review (see also the Government response to Question 1).

This position is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12.

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?

Issues around access to drugs for rarer cancers were, on the whole, considered best left for local resolution, but it was felt important to ensure such treatments are considered with particular care to ensure that patients with rarer cancers are not disadvantaged. In particular, it was acknowledged that the evidence base may be less well-developed for treatments for some rarer cancers. Although some responses suggested national advice on the definition of rarity would be helpful, a number of replies said it would be very difficult to define a “rarer” cancer and proposed that a definition of "rarer cancers" should be a matter for local consideration.

Many responses supported sharing of evidence and expertise across regions in these cases to ensure regional decisions benefit from the advice of relevant experts and to support consistency of decision-making.

A number of responses suggested the importance of using existing processes, such as the Individual Funding Request (IFR) Process and specialised commissioning for rarer cancers in appropriate cases.

Government response

Panels should be aware of rarity when assessing the evidence base and make appropriate allowances for potential limitations in the available evidence base on treatments for rarer cancers, obtaining expert input where appropriate. SHA clinically-led panels may wish to collaborate on evidence assessment and share expertise, particularly in cases where the published evidence may be limited. However, the responsibility for decision-making will remain with the respective SHA clinically-led panels.

This position is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12.

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?

In general, it was considered that these issues were best left for local resolution. Responses supported panels being encouraged to collaborate on the approach to these challenges and share information, evidence and expertise.

Responses suggested that panels should be asked to consider the specific challenge posed by rarity and ensure that patients with these conditions are not disadvantaged. It was suggested by some respondents that simply prioritising rarer cancers per se may be inequitable to other cancer sufferers.

It was suggested that negotiations with pharmaceutical companies might be helpful in managing the impact of drugs that have the potential to consume a large proportion of the Fund.

Government response

See the Government response to Question 9. Issues around the specific challenge posed by rarity, or single drugs that have the potential to consume a large proportion of the Fund are considered best left to local resolution. There should however be an emphasis on the need for particular consideration in the case of rarer cancers to ensure that patients with these cancers are not disadvantaged. Clinically-led panels are encouraged to share information on the approaches they take in dealing with these issues.

This position is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12.

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?

On balance, the responses suggested it would be sensible to allow the clinically-led panels some scope to decide to fund molecular diagnostic tests where they consider such a test necessary to target drugs to appropriate patients. Many of the responses from clinicians were clear that they considered these diagnostic tests to be an integral part of drug therapy. Some respondents suggested these tests may well have been undertaken at an earlier stage in the patient pathway and therefore funding from the Cancer Drugs Fund may not be necessary. Other replies suggested that the cost of such tests should be met by PCTs in the short-term while a longer-term solution to the funding of these tests is found. Some of the responses considered that pharmaceutical companies might be encouraged to offer testing as part of any procurement agreements for the relevant drugs.

Government response

To support patients in accessing the drugs their doctors have recommended, the Fund may be used for molecular diagnostic testing which is necessary to help optimally target the use of drugs for patients who are most likely to benefit. It will be for the clinically-led

panels to decide when the funding of such a test is an appropriate use of the Cancer Drugs Fund.

This position is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12.

12. Is there a potential 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)?

44% (71) said yes
11% (17) said no
45% (72) did not answer this question

A majority of those that responded to this question were supportive of a role for NICE in the context of the Cancer Drugs Fund. Most commented that NICE had an important role to play in providing information on the clinical and cost effectiveness of medicines through its technology appraisal process. Responses suggested that clinically-led panels should draw on this guidance to inform decision-making.

Government response

NICE remains at the heart of the Government's plans for the NHS. It will continue to play a vital role in offering authoritative advice to the NHS on the clinical and cost effectiveness of new medicines. Even if NICE does not recommend a drug through its appraisal process, its thorough assessment of the evidence will be of considerable use both to the clinically-led panels and to clinicians and patients looking for the best treatment options. The role of NICE guidance in signalling the technologies that are potentially of significant clinical value is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12.

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?

53% (85) said yes
8% (12) said no
39% (63) did not answer this question

The majority of responses agreed with the suggestion 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. This included some responses from individual pharmaceutical companies and from the Association of the British Pharmaceutical Industry (ABPI). Some of these responses stressed that this approach should apply where a manufacturer has unreasonably refused to cooperate with the NICE appraisal process, rather than in circumstances where it is mutually agreed with NICE that an appraisal should be stopped or suspended for other reasons. Some responses suggested that the clinically-led

panels should have scope to consider the individual circumstances and agree to fund such drugs despite a manufacturer having refused to cooperate with the NICE appraisal process.

Government response

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. Therefore, clinically-led panels may reasonably decide not to fund drugs where there has been no NICE appraisal as a result of the manufacturer refusing to cooperate with the NICE appraisal process.

This position is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12.

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?

Many responses commented that the continued commitment of pharmaceutical companies to the NICE appraisal process would be important and should ensure that clinical and cost effectiveness continue to be considered (see the response to Question 13).

Many of the answers to this question repeated comments made in response to Question 5, e.g. the potential influence of the fixed size of the funding on pricing behaviour, the need for the clinically-led panels to consider cost effectiveness in taking funding decisions, the potential role of national procurement in helping the NHS obtain consistent value for money.

Government response

As outlined in the Government response to question 13, 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. The clinically-led panels may therefore reasonably decide not to fund drugs where there has been no NICE appraisal as a result of the manufacturer refusing to cooperate with the NICE appraisal process.

As outlined in the Government response to question 5, we agree that the clinically-led panels should consider cost effectiveness if there is robust data to support decision-making. This should maximise the number of patients that can be treated from the available funding, and encourage pharmaceutical companies to further consider the value propositions offered by their drugs. We welcome the strong commitment expressed by many consultees, including those from the pharmaceutical industry, to delivering value for money.

In response to the consultation and representations from SHAs, the Commercial Medicines Unit (CMU) will undertake a procurement exercise to establish a framework agreement for drugs purchased within the scope of the fund. The framework will allow regional NHS decision-making in terms of which products will be purchased.

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

A great majority of the responses to the consultation commented that provision of appropriate information for patients on the options available to them was very important, with some responses citing the "nothing about me, without me" philosophy set out in the NHS White Paper, Equity and Excellence: Liberating the NHS[8].

Responses highlighted the key role for clinicians and other health professionals involved in patients' care in supporting patients to make informed decisions about their treatment options. Many responses stressed the importance of conversations between patients and health professionals about the options available. It was suggested that such conversations should include 'open' and 'honest' discussions with patients about the relative benefits of drug treatments, palliative care and end of life care and the potential impact on quality of life of different options.

Many responses suggested that patient groups, charities and pharmaceutical companies all had an important role to play in providing patients with good quality information to enable them to make informed choices about their treatment.

Responses stressed the importance of making information on the SHAs Cancer Drugs Fund policies accessible for patients and clinicians. Many responses suggested the provision of information leaflets for patients. Responses suggested that any available patient information should be clear, written in plain language and available in a variety of formats.

A majority of responses suggested that there should be web-based information on the processes in place for the Cancer Drugs Fund in each region. This might include details of any "priority lists", information for clinicians applying to the Cancer Drugs Fund and information for patients.

Government response

Patients will need appropriate information on the available options to support them in making informed decisions. Clinicians and other treating health professionals should have open discussions with patients about the relative merits of drug treatment options, palliative care and end of life care. Written information on the likely benefits and possible side effects of treatments should be made available to the patient. The clinician should confirm that this has happened, and that informed patient consent to treatment has been obtained.

Improving Outcomes: A Strategy for Cancer[9] outlines that one of our priorities moving forward will be to enhance the information available to patients on the benefits and toxicities of treatment. The National Cancer Director will work with cancer charities and the pharmaceutical industry to support the availability of such information. Work is also continuing to develop the use of information prescriptions throughout the cancer pathway.

[8] Equity and excellence – Liberating the NHS, July 2010
[9] Improving Outcomes: A Strategy for Cancer, Department of Health, January 2011, Gateway 15109

Appropriate mechanisms should be put in place by SHAs to ensure patients and clinicians can access up-to-date information on the operation of the Cancer Drugs Fund in their area. This should include activity and financial information. Detailed information on the arrangements that have been put in place should be readily available and accessible via the internet, and clinicians should help to support patients who are unable to access this information themselves. Where panels use a prioritisation process to identify drugs that will be funded routinely from the Cancer Drugs Fund then details of these drugs should be readily available.

This position is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12. The guidance includes a section on information provision. This explores in more detail the information that should be made available to patients, clinicians and others on the Cancer Drugs Fund.

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

66% (106) said yes
3% (4) said no
31% (50) did not answer this question

A large majority of responses agreed that there should be a national specification or standards for data collection to promote consistency. A number of responses commented that clinical audit should be a vital part of the Cancer Drugs Fund and it would be important that data gathered are comparable at a national level. Responses suggested that there should be a national minimum data set for the Cancer Drugs Fund, although a number of these responses commented that this should be consistent with the National Systemic Anti-Cancer Therapy Dataset[10] that is currently being piloted.

Government response

SHAs should audit and monitor use of the funding that has been made available for the Cancer Drugs Fund and ensure that appropriate clinical audit arrangements are in place. This will:

- support SHAs in managing allocation of the funding
- provide assurance that the funding is being used in accordance with agreed regional arrangements
- help improve the available evidence on how these drugs perform in real-world clinical practice

The guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12 sets out suggested basic minimum audit requirements for the Fund, consistent with the National Systemic Anti-Cancer Therapy Dataset.

[10] http://www.ncin.org.uk/collecting_and_using_data/data_collection/chemotherapy.aspx

SHAs will be required to provide basic financial monitoring information to the Department of Health on a monthly basis to support effective management of the total resource available.

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

There was strong support for the collection of audit data, including clinical audit data. There were a number of suggestions of potential data items that could be included in any collection, such as:

- NHS Number
- Patient demographic details (e.g. age, gender, ethnicity, postcode)
- Cancer diagnosis
- Drug name
- Treatment regimen
- Line of treatment
- Number of cycles of treatment funded
- Progression rate
- Date treatment started
- Date treatment stopped
- Side effects observed
- 30 day mortality
- Date of death/next relapse

A majority of responses supported the collection of audit data at a regional level. In general, responses suggested this information should be kept relatively simple, to minimise the burden on clinicians and enable information to be supplied easily and quickly, but of sufficient detail to enable quantification of patient benefit. Some responses suggested that continuation of funding should be dependent on the timely submission of audit data.

A number of responses suggested there should be collation of regional audit data at a national level with local feedback of information to the clinically-led panels.

Government response

See also the Government response to Question 16. The guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12 sets out that SHAs might consider setting a clear expectation that clinicians should provide some basic clinical audit data on patients whose treatment is supported by the Fund. The guidance states that this should be made clear to treating clinicians as part of the application process for the Cancer Drugs Fund.

We will work with SHAs to promote the collection of appropriate audit information and to determine how information can best be shared nationally and used at both a regional and national level.

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

31% (49) said yes
26% (42) said no
43% (69) did not answer this question

A small majority of those that responded to this question supported the collection of audit information, indeed many suggested it would be vital. Some respondents considered that all of the funding available should be reserved for drug treatments but many supported allowing the clinically-led panels to use some of the funding to audit medicines use. Most suggested that this should be kept to the minimum amount of funding required.

Government response

See also the Government response to Question 16 and Question 17. It is in patients' interests that the Fund operates effectively and that it contributes to clinical audit. Feedback from the operation of the clinically-led panels in 2010-11 supported not only that funding should be available for medicines audit but that a small amount of funding should be available to support the management of the arrangements, to ensure they are sustainable through 2011-12. SHAs may therefore use up to 1% of the funding on audit and management costs but this will need to be managed within the SHA's overall administration cost limits.

This position is outlined in the guidance that has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12.

6. Conclusion

We are extremely grateful to those who responded to the consultation on our proposals for the Cancer Drugs Fund. We have been able to use this feedback to shape our plans for implementation of the Cancer Drugs Fund from 1 April 2011.

We are also grateful to the SHA clinically-led panels and those involved in the arrangements for the £50 million additional funding provided in 2010-11. Their hard work and the experience they have shared with us has been invaluable in taking work on the Cancer Drugs Fund forward. Through their commitment, we have helped many hundreds of patients to access cancer drugs that would otherwise not have been available to them.

Best practice guidance has been developed for the NHS to support the operation of the Cancer Drugs Fund in 2011-12. This guidance takes account of feedback to the consultation, alongside experience of operating the arrangements for providing additional cancer drugs in 2010-11. The guidance was published on 23 March 2011 and is available on the Department of Health website at:

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_125445

The guidance comes into operation on 1 April 2011 and will be kept under review.

Arrangements for 2012 and beyond will be subject to discussions between the Department of Health and the shadow NHS Commissioning Board. We anticipate the NHS Commissioning Board will be guided by the outcome of this consultation in taking decisions on the future format of the Cancer Drugs Fund.

Annex A – List of organizations that responded

We are very grateful to all those who responded to the consultation exercise.

Three Counties Cancer Network Partnership Group

Association of the British Pharmaceutical Industry

Anglia Cancer Network Haematology Site Specific Group

Anglia Cancer Network Interim Cancer Drugs Fund panel, Cambridge University Hospitals NHS Foundation trust

Association Upper Gastrointestinal Surgeons Great Britain and Ireland

AstraZeneca UK

Bayer Plc

BioIndustry Association

Boehringer Ingelheim

Bowel Cancer UK

Breakthrough Breast Cancer

Breast Cancer Campaign

Breast Cancer Care

Bristol Haematology and Oncology Centre

Bristol-Myers Squibb

British Neuro-oncology Society

British Oncology Pharmacy Association and Royal Pharmaceutical Society

Cancer Campaigning Group

Cancer Partnership Group at Mid Yorkshire Hospitals NHS Trust

Cancer Research UK

Celgene

Central South Coast Cancer Network

Defence Medical Services

Dorset Cancer Network

Eisai Limited

East of England Specialised Commissioning Group

Eli Lilly and Company Ltd

Essex Cancer Network

Ethical Medicines Industry Group

European Medicines Group

Foundation Trust Network

Genetic Alliance UK

Genzyme Therapeutics

GlaxoSmithKline

Gloucestershire Primary Care Trust

Greater Manchester and Cheshire Cancer Commissioning Group

Greater Midlands Cancer Network

Guild of Healthcare Pharmacists

Haematology and Oncology Consultants, Taunton and Somerset NHS Trust

Haltwhistle Town Council

Help the Hospices, Sue Ryder, Marie Curie Cancer Care and the National Council for Palliative Care

James Whale Fund for Kidney Cancer

Janssen-Cilag Ltd

Kent and Medway Cancer Network

King's Health Partners Integrated Cancer Centre

Leeds Teaching Hospitals NHS Trust

Leukaemia CARE, Leukaemia & Leukaemia Research and the MDS UK Patient Support Group

London Cancer New Drugs Group

London Specialised Commissioning Group

MDS UK Patient Support Group

Merseyside and Cheshire Cancer Network

Mills & Reeve LLP

MSD

Myeloma UK

Napp Pharmaceuticals Ltd

National Specialised Commissioning Team

Neuroblastoma Parents Group

NHS Barnsley Cancer Strategy Group

NHS Confederation

NHS Counter Fraud and Security Management Service

NHS East Midlands

NHS East of England

NHS Great Yarmouth and Waveney

NHS Halton & St Helens Primary Care Trust

NHS Hertfordshire

NHS Heywood, Middleton and Rochdale
NHS Norfolk
NHS South Central
NHS South East Coast Special Health Authority and Primary Care Trust
NHS Stockport
NHS West Essex
NHS West Kent Primary Care Trust
NICE
Norfolk & Norwich University Hospital
North of England Cancer Drugs Advisory Group
North Tyneside Local Involvement Network (LINk)
North West Specialised Commissioning Team
Novartis Pharmaceuticals UK Ltd
Nuclear Medicine Specialist Advisory
North West Primary Care Trust Cancer Drugs Fund
Oxford Liver Multidisciplinary Team
Pan Birmingham Cancer Network Board
Patient Assembly – Croydon Health Services NHS Trust
Macmillan Cancer Support
Pfizer UK
PharmaMar
Prostate Cancer Charity
Rarer Cancers Foundation
Roche Products Ltd
Royal College of General Practitioners
Royal College of Nursing
Royal College of Radiologists
Royal Marsden NHS Foundation Trust
Sandwell Primary Care Trust
Sanofi-aventis
Sirtex Medical
South Central Specialised Commissioning Group
South East London Cancer Network
South West Strategic Health Authority
Specialised Commissioning

Sussex Cancer Network team and Partnership Group.
Takeda UK
Target Ovarian Cancer
Teenage Cancer Trust
Thames Valley Cancer Network
The British In Vitro Diagnostics Association
The Christie NHS Foundation Trust
The Faculty of Pharmaceutical Medicine
Three Counties Cancer Network
Tom Prince Cancer Trust
UK Medicines Information
UNISON
West Midlands Specialised Commissioning Team &Specialised Commissioning Group
Yorkshire and the Humber Specialised Commissioning Team