Report on the implementation of the Cancer Drugs Fund and the development of a value-based pricing system
December 2011
Macmillan Cancer Support has campaigned for a number of years for fairer access to effective drug treatments for people with rarer cancers. For Macmillan the issue is simple. Cancer patients do not choose which cancer they get. We feel passionately that the NHS must provide everyone diagnosed with cancer with the best quality treatment, care and support no matter who they are, where they are from, or which cancer they have. This means making sure people with rarer cancers get access to the best drug treatments available.

We were delighted by the Government’s decision to introduce a Cancer Drugs Fund in England to improve access to cancer medicines. It is a huge achievement that the Fund has already helped thousands of cancer patients. Macmillan truly understands the impact that access to cancer drugs can make to patients. Whether by improving quality of life or by giving someone more time to spend with their family and friends, getting access to clinically effective drug treatments can mean the difference between seeing a son or daughter get married or meeting your grandchild.

We hope the recommendations in this report will help the Government and NHS to improve further the operation of the Cancer Drugs Fund during its lifetime.

In particular, Macmillan wants to see closer monitoring and auditing to ensure it is helping as many cancer patients as possible and that regional variations do not become a postcode lottery.

Macmillan also warmly welcomes the Government’s commitment to introduce a new drug pricing system by 2014 which we hope will more closely reflect the value medicines bring to patients and the NHS.

Macmillan will be looking for assurance that value-based pricing will be designed to support people with rarer cancers and that, crucially, effective drugs that are being made available through the Cancer Drugs Fund continue to be available on the NHS when the new system comes into place.

It is fantastic that the Cancer Drugs Fund has enabled so many people across England, especially those with a rarer cancer, to access vital medicines they may have missed out on receiving in the past.

Much has been achieved in the first year of the Cancer Drugs Fund, but more can still be done. We want to make sure that all cancer patients who need to can access this vital funding, and we will continue to advocate for all cancer patients to receive the best treatments available.

Mike Hobday
Director of Policy and Research
Macmillan Cancer Support
Executive Summary

In 2010 the National Cancer Director’s report *Extent and causes of international variations in drug usage*¹ revealed that the UK has far less take up of the latest cancer medicines than the average across the 14 comparable countries studied. This finding was on top of estimates reported in the 2007 Cancer Reform Strategy that England’s anti-cancer drug usage is only 60% that of other major European countries.

Macmillan is delighted that the Government has created the Cancer Drugs Fund. This money will help those people who have struggled to get hold of the drugs they and their doctors believe will be effective in treating or controlling their cancer.

Six months on from the launch of the full Cancer Drugs Fund, Macmillan wanted to know more about how the Fund has been operating from the perspective of patients and clinicians.

Over the summer we commissioned the research company, RS Consulting, to gather and review publicly available data on the Fund to begin to build a picture of both the benefits of the Cancer Drugs Fund and how the operation of the Fund can be improved further to ensure its full potential is realised.

RS Consulting also held a short series of telephone interviews with healthcare professionals, cancer patients and patient representatives from national charities to understand more about the experiences of people who have had difficulty getting the cancer drugs they need and have turned to the Cancer Drugs Fund as their last resort.

Most significantly, Macmillan has been delighted to learn that the Fund has improved considerably patients’ access to cancer drugs not routinely available on the National Health Service (NHS). According to the most recent Department of Health released figures, since October 2010 more than 7,500² patients in England have benefited from the additional funding. We have also been pleased to learn that people with rarer cancers have often been the beneficiaries of funding decisions and that a number of ‘off-label’ treatments are being approved by funding panels – potentially paving the way for a much better understanding of the clinical effectiveness of drugs for which there is a lack of evidence.

Our research has also identified some key areas where we believe the operation of the Fund can be improved. Macmillan appreciates that the regional management of the Cancer Drugs Fund does help to speed up decision making and ensure decisions are responsive to local populations. However, variations in how Strategic Health Authorities (SHA) choose to administer their allocation of the Fund have produced regional disparities in the number of applications made to the Fund and application approval rates, as well as differences in SHA shortlists of drugs.

Central to our recommendations is a call for closer monitoring of approval rates and expenditure to ensure that as many people as possible can benefit from the funding available in each SHA.

We also welcome the Government’s commitment to develop a new pricing model that better reflects the value of drugs for both patients and the NHS. We are keen to ensure that this change helps those cancer patients who currently cannot get hold of vital life enhancing and life extending medicines on the NHS.

We want all treatments that are made available through the Cancer Drugs Fund to be automatically available on the NHS when a new system of value-based pricing comes into place in 2014.

¹ Department of Health (2010) Extent and causes of international variations in drug usage: a report for the Secretary of State for Health
² Hansard HL, 14 Nov 2011: Column 447
Introduction

Barriers to access
It is clear that cancer patients in England have for some time been losing out on what are deemed ‘gold standard’ treatments. There are three significant factors that have encouraged this disparity: the current drug pricing system, the Pharmaceutical Price Regulation Scheme (PPRS) can result in the NHS paying arguably unjustifiably high prices; the National Institute for Health and Clinical Excellence (NICE) drug appraisal process, which can be inflexible and unresponsive, especially where treatments for rarer cancers are concerned; and a great deal of strain on the cancer drugs budget over the last twenty years – expenditure on cancer treatment increased considerably, rising from £3 billion in 2002 to £5 billion a year in 2011.

NICE has itself acknowledged that the standard appraisal process is not suitable for evaluating drugs for a number of rarer cancers. NICE has also introduced end of life flexibilities to address some concerns about access to cancer medicines. Pharmaceutical companies cite the high cost of developing new drugs and technologies, as well as the low success rate for new drug developments, as resulting in higher fixed costs for the industry that must be recouped. What all parties agree on is that as new technologies and drugs come online and incidents of cancer continue to increase, the current expenditure, pricing model and system of appraisal will all become unsustainable.

Beginning to find solutions
In July 2010 the Government announced formally that it would launch in April 2011 a Cancer Drugs Fund. The Fund makes available £600 million over the next three years to improve access to clinically effective cancer medicines. In recognition of the urgent need to address the situation the Government also announced that it would make available a £50 million Interim Cancer Drugs Fund from October 2010 until March 2011 while it consulted on how the full fund should operate. The Fund gives SHAs additional funding for cancer drug treatments that are not available on the NHS, through Exceptional Funding or via Primary Care Trusts’ (PCTs) local cancer drug funding policies. It functions as a regional model, with SHA-established clinical panels making decisions on funding requests.

To speed up the decision-making process, many panels have put some drugs on a priority list, meaning the Cancer Drugs Fund finances them automatically. The Department of Health (DH) has asked any panels that do this to keep their priority list under review to ensure they are responsive to any new decisions made by NICE and that they most accurately reflect the needs of their local population.

For many, the Cancer Drugs Fund represents a short-term solution. The Government described the Fund as a ‘bridge to value’ when it launched its consultation in October 2010, and in January 2011 it set out its plans to develop a new value-based pricing model for funding to ‘improve NHS patients’ access to effective and innovative drugs by ensuring they are available at a price that reflects the value they bring’. Value-based pricing will come into effect in 2014 when the current PPRS comes to an end.

The Lancet Oncology, Volume 12, Issue 10, Pages 933–980, September 2011
Improved access for people with rarer cancers

The UK spends less on cancer treatments than other European countries and is slower to provide access through the NHS. Historically, individual PCTs decide whether to provide funding for treatments not routinely available on the NHS through mechanisms such as Exceptional Funding Requests. However, there is wide variation in how these processes work and many patients have their requests for funding denied.

The ten most commonly requested drugs during the Interim Cancer Drugs Fund period are listed in Table 1 on the next page. The most requested drugs were used to treat a number of rarer cancers, indicating a relatively high level of unmet need for treatment of these types of cancer on the NHS. These cancer drugs are typically – although not always – included in SHAs shortlists.

During our interviews, one clinician commented that before the Fund was launched, nobody in his region was able to obtain Avastin (bevacizumab, the drug most commonly requested via the Fund) from the PCT, leaving some patients to self-fund the treatment.

Macmillan is delighted that data emerging from the Interim and full Cancer Drugs Fund has shown that over 7,500\(^5\) patients received cancer drugs as a result of the Fund. It was also interesting that a patient representative in a national charity who was interviewed noted a reduction in the number of patients contacting them to ask for their help to get hold of medicines they need. This would suggest that fewer patients need to seek the support of charities in getting hold of effective cancer drugs.

‘The one thing that I’ve noticed in particular is that we’re not getting patients coming through saying, ‘Can you help me?’ It’s given clinicians, generally speaking, a very positive route forward.’

Sarcoma Patient Representative

\(^5\) Hansard HL, 14 Nov 2011: Column 447
Improved access to drugs for people with rarer cancers

Table 1: Ten drugs most commonly requested through the Cancer Drugs Fund at June 2011

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Cancers approved for</th>
<th>Total applications</th>
<th>Percentage approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bevacizumab</td>
<td>Bowel; kidney; breast</td>
<td>579</td>
<td>90%</td>
</tr>
<tr>
<td>Cetuximab</td>
<td>Bowel; head &amp; neck</td>
<td>250</td>
<td>92%</td>
</tr>
<tr>
<td>Everolimus</td>
<td>Kidney; pancreatic</td>
<td>187</td>
<td>98%</td>
</tr>
<tr>
<td>Lapatinib</td>
<td>Breast</td>
<td>150</td>
<td>94%</td>
</tr>
<tr>
<td>Rituximab</td>
<td>Lymphoma</td>
<td>127</td>
<td>89%</td>
</tr>
<tr>
<td>Sorafenib</td>
<td>Liver; thyroid</td>
<td>110</td>
<td>89%</td>
</tr>
<tr>
<td>Azacitidine</td>
<td>Leukaemia</td>
<td>95</td>
<td>92%</td>
</tr>
<tr>
<td>Bendamustine</td>
<td>Leukaemia; non-Hodgkin’s lymphoma</td>
<td>73</td>
<td>78%</td>
</tr>
<tr>
<td>Sunitinib</td>
<td>Pancreatic</td>
<td>35</td>
<td>71%</td>
</tr>
<tr>
<td>Alemtuzumab</td>
<td>Leukaemia</td>
<td>30</td>
<td>100%</td>
</tr>
</tbody>
</table>

Support for people with very rare cancers
Macmillan is very pleased to see from the data available to date that patients with rarer cancers are being supported by the Fund. We were also pleased to hear from interviewees that the Fund would appear to be supporting the use of ‘off-label’ drug treatments. This means that many more patients living with very rare forms of the disease are at last able to take drugs that can control their condition.

Healthcare professionals we spoke to identified that a key benefit of the Fund could also come from the data generated by the use of ‘off-label’ treatments. Clinicians are expected to complete clinical audits for all the Fund patients which have the potential to strengthen the evidence base on the clinical effectiveness for a number of drugs. This could be of particular benefit in advancing treatments for rarer cancers.

6 Rarer Cancers Foundation (2011). Funding Cancer Drugs: An evaluation of the impact of policies to improve access to cancer treatments
Case Study: NHS London

The London Cancer New Drugs Group has developed a list of near off-label indications. This is included in the shortlist of all drugs and indications funded by the Cancer Drugs Fund in London. At the present time, it primarily addresses the use of Rituximab to treat off-label indications. Applications for drugs on the off-label list are processed differently to other applications, as they must be reviewed by the London Cancer Drugs Fund Panel prior to approval.
Take-up of the Cancer Drugs Fund

**Increasing number of applications**
Clinicians are central to take-up from the Fund, as they have responsibility for making applications to the Fund on behalf of patients. Approximately 2,000 applications were made to the Interim Cancer Drugs Fund, which ran between October 2010 and March 2011. Pleasingly, in the three-month period following the introduction of the full Cancer Drugs Fund, the number of applications exceeded that of the interim period and continues to rise.

Interviewees suggested that rising applications could be down to growing awareness of and familiarity with the Fund process among clinicians. We imagine the rise in applications could also be occurring because of the growing number of cancer drugs included in SHA shortlists of drugs, which fast-tracks certain treatments so that they do not need to be considered by a panel on a case-by-case basis.

However, we were interested to note from data available on the Fund that NHS South Central clinicians from Hampshire PCT had made 107 applications to the Fund as of 30th June 2011, compared to only eight applications made by clinicians from Portsmouth PCT. This may suggest further action is required in some areas of the country to continue to raise awareness amongst clinicians about how the Fund could benefit their patients.

**Spending of the Interim Cancer Drugs Fund**
Based on the most recent publicly available figures, in total, only 56% of the £50 million Interim Cancer Drugs Fund was spent from October 2010 to March 2011 inclusive. If the anticipated future costs are included for patients whose treatment was initiated before April 2011, this spending rises to just over 65%.

The extent of underspend varied a great deal across SHAs during the period of the Interim Cancer Drugs Fund. At the extreme end of the scale, NHS South West used less than 25% of its allocated funds. The clinicians we spoke to stressed that it is important to recognise that panels are tasked with making very difficult decisions on future commitments. By approving a drug for a patient the panel is potentially committing funds from next year’s allocation of the Fund as well as the current year’s allocation.

7 Applications to the Cancer Drugs Fund, NHS South Central June 2011.
8 Rarer Cancers Foundation (2011). Funding Cancer Drugs: An evaluation of the impact of policies to improve access to cancer treatments
Administering the Fund

The Cancer Drugs Fund is administered on a regional basis which can help ensure it is responsive to the need of the local population. It is to be expected that variations will develop in approaches to managing the Fund but we are concerned that there are significant differences in the criteria used by each panel to approve or reject applications; the time in which it takes them to make decisions on applications; and the drugs which SHAs choose to include on their shortlist of drugs.

Application approval rates
There was a considerable degree of variation amongst SHAs in terms of application approval rates during the period of the Interim Cancer Drugs Fund. The national approval rate for applications to the Interim Cancer Drugs Fund was 87%, but NHS South Central only approved 70% of all funding requests during this period, in contrast to the 100% approval rate of NHS North East.

In total 187 applicants to the Interim Fund were denied treatment. Macmillan is keen to gain clarity on the reason for these applications being rejected. One health professional interviewed felt that many clinicians do not understand why applications for certain cancer drugs have not been approved, especially when funding was requested for a relatively inexpensive medicine. While another clinician explained that they were not given an explanation as to why an application had been rejected suggesting the transparency of the Fund’s decision-making process could be improved.

Shortlisting drugs
We are pleased that all SHAs have attempted to speed up the application and approval processes by creating shortlists of drugs that are routinely funded through the SHA’s allocated share of the Fund.

There are two broad routes through which clinicians can apply for these ‘priority’ drugs: some SHAs have created an application form for each priority drug, while others have a single application form and a box to check for each priority drug. These application forms simplify the process for both clinicians and the clinical panel, by requiring and specifying the minimal level of detail needed for panel members to make a decision.

Although Macmillan supports the use of shortlists, there is the potential for inequalities in access to cancer treatments, as each SHA is responsible for developing its own list of ‘priority’ drugs. Cancer patients are already weary of the postcode lottery of accessing certain treatments on the NHS that pre-dates the Fund.

Both patients and healthcare professionals we spoke to perceive a need for greater national advice to standardise the shortlisting of drugs available through the Fund, to ensure a minimum level of consistency in access to treatment. While we acknowledge the Fund is regionally based, the DH should consider closer monitoring of drugs being approved by the clinical panels. A number of clinicians who were interviewed for this research felt that some region-specific Fund policies are to their patients’ detriment.
Response times
Timely decision-making on applications to the Fund is crucial, given the time sensitivity of treating cancer patients, and particularly those with advanced cancer. The application process should adhere to the cancer waiting time standards outlined in the NHS Cancer Plan 2000 and the Cancer Reform Strategy 2007 – particularly the 31-day treatment standard.

Professionals interviewed for this research indicated that response times for shortlist applications tend to be between one and two days. Among the SHAs that have made timescale-related information readily available on their websites, average times taken to process each application to the Fund have fallen steadily since October 2010. This development brings the NHS closer to meeting its objectives for timely decision-making; yet we believe the time taken for all existing NHS drug application processes to be explored before applying to the Fund should also be considered when assessing adherence to the 31-day cancer standard.

Monitoring and auditing
The Department of Health guidance for the Cancer Drugs Fund advises SHAs to audit and monitor use of the funding they have been allocated and make available periodically on their website information about expenditure against the Fund and “appropriate Cancer Drugs Fund activity data”.

It is important to note the significant variation in the level of detail given as well as the number of information documents: some SHAs publish quarterly monitoring reports while others publish monthly ones; some give expenditure data for each drug requested, whereas others only provide a sum total. Another issue is the extent to which information is up-to-date. At the time of writing, a number of SHAs had published primarily documents and reports relating to the Interim Cancer Drugs Fund and little new information since March 2011.

It is questionable whether all SHAs are operating in compliance with the letter and spirit of the DH guidelines on the operation of the Fund, which states monitoring of its allocation should be a transparent process and up-to-date figures should be easily accessible online.

‘There should have been national guidance on the Cancer Drugs Fund about which drugs would be funded and in what situation. I do not think that should have been devolved to the Strategic Health Authorities because what has happened is that each Strategic Health Authority has come up with a slightly different list of drugs.’

Clinician, NHS East Midlands

Improving Access?

Awareness of the Fund and how it works

**Awareness of the Fund amongst healthcare professionals**
Unsurprisingly, Fund awareness is typically much stronger amongst healthcare professionals than patients. Yet from our interviews we have heard anecdotal evidence that clinicians’ awareness of how the Fund works in their region varies significantly depending on their level of involvement in its set-up or continuing operation. One patient interviewed reported that his clinician, who had recently moved from abroad, was not aware the Fund existed. As such, the patient was left to discover and research it on his own.

However, we were pleased to hear from interviewees that on the whole the establishment of initial drug shortlists was a collaborative process, with healthcare professionals being consulted on the list or asked to nominate a representative for this task.

We were interested to learn from the interviews that when Cancer Drugs Fund panels make funding decisions they may not be sufficiently familiar with particular cancers or their treatment, especially if it is a rarer cancer. It is important that any clinical panel assessing the merits of funding a treatment makes every attempt to draw upon the knowledge of the specialist clinician making the application. This process would also ensure that specialists have a better understanding of how the Cancer Drugs Fund works.

**Awareness and understanding of the Fund amongst patients**
Patients, on the other hand, are not always told about the Fund by their clinician. During the interviews we heard that there have been occasions when patients are left to research funding options themselves. One patient interviewed for this research found out about the Cancer Drugs Fund on the Macmillan website.

‘I had to search the internet to find out about it. I was 64 at the time, not feeling very well, feeling a little depressed because my funding application had been turned down and I really had to clear my head, sit down and go through on the internet and find it. If you haven’t got somebody who can do that for you, or you can’t do it yourself, where would that leave you?’

*Patient, NHS South Central*
Even when patients are made aware of the Fund, their understanding of how it works appears to be quite limited. They may lack clarity on how the funding request differs to ones made previously on their behalf, or on the decision-making process.

Worryingly, a patient representative interviewed believes that some patients assume that funding via the Cancer Drugs Fund is guaranteed rather than subject to meeting a set of criteria or a panel decision.

**Process of applying to the Cancer Drugs Fund**

Beyond being made aware of the funding request, patients appear to have little involvement in the application process to the Cancer Drugs Fund. From discussions with patient representatives from national charities, there appears to be very little awareness among patients of what criteria Cancer Drugs Fund panels use to make their decisions. Interviewees raised concerns that the process potentially marginalises patients and therefore could engender a feeling of hopelessness in them. It is important there is consideration of patients when waiting for a decision on their application, many of whom have already experienced one or even multiple funding rejections by their PCT.

In our response to the Government’s consultation on the Cancer Drugs Fund, Macmillan stressed the importance of ensuring that patients are always offered timely, personalised and supported information to understand their treatment options, including those drugs that are applied for through the Fund. It is also important for patients to be able to understand what they can expect when their clinicians make an application to the Cancer Drugs Fund on their behalf so they are able to make an informed choice about whether they wish to be part of the process.

‘The fact that a patient isn’t allowed to put forward any personal statement or any advocacy statement at all, I think, puts the patient at a huge disadvantage in terms of the process and the procedure. In the situation that some patients are in, which can be a last stage of their journey, I think it’s a very disempowering process and position for them to be put in.’

Kidney Cancer Patient Representative
Defining ‘value’ in relation to cancer drugs

The Government has always made clear that the Cancer Drugs Fund is a short-term ‘fix’ for a problem which requires a longer term solution.

Macmillan welcomes the Government’s commitment to implement a new pricing model that better reflects the value of drugs for both patients and the NHS after the Cancer Drugs Fund comes to an end in 2014.

The new system presents an opportunity to address the inequity in access to cancer drugs that currently exists. Many patients with less common cancers have lost out on receiving the vital medicines they need on the NHS. It is critical that value-based pricing results in more people with rarer cancers getting hold of the drugs their doctor recommends for them.

The Government has not yet set out the detail of how the value-based pricing system will operate, but held an initial consultation between December 2010 and March 2011.

In our response to the consultation we called for cancer patients to be involved meaningfully in developing a definition of ‘value’. We also urge the Government to commit to making drugs that have been made available through the Cancer Drugs Fund automatically available on the NHS when the new system comes into place.

Understanding value-based pricing

The responses to the Government’s consultation on value-based pricing demonstrate there is a lack of clarity about how ‘value’ will be defined. They also posed questions on how best the value of drugs can be reflected in the pricing system and how a system can be developed that will deliver better health outcomes for all patients.

The Department of Health set out four specific categories of value that it believes should be taken into consideration when setting the price of a drug:

- the clinical and cost effectiveness of the drug;
- the burden of illness – reflecting unmet need or the severity of the illness;
- the extent of therapeutic innovation and improvement involved; and
- wider societal benefits.

Clinical and cost effectiveness of cancer drugs and life extension

Creating a definition of value in the context of cancer drugs requires consideration of the particular complexities of ‘cancer’, which is a catch-all name for over 200 different diseases, and its treatment compared with other conditions. Most cancers can be life threatening, and more people are diagnosed with cancer at an advanced stage than other chronic diseases.

Macmillan is beginning to understand from the interviews we conducted that there simply is not a neat definition of what ‘value’ means for a patient, especially with regards to clinical and cost effectiveness. Key themes around ‘value’ that were raised in our conversations with patients and healthcare professionals included pain management and the ability to continue to make both social and financial contributions.

‘How do you do a cost-benefit on somebody’s life?’

Non-Hodgkins Lymphoma Patient, NHS South Central
However, life extension becomes very important for patients living with the late stages of an incurable disease who desperately want to be able to spend more time with their families and loved-ones. We were also interested to hear from one patient representative how important life extension can be in the context of ever advancing cancer treatments; in six months or a year’s time, a new drug may be available to a patient that will significantly benefit them.

**The burden of illness and quality of life**

It is clear from discussions with both healthcare professionals and patients that quality of life is the aspect generally ascribed the highest value. Notably, patients representatives we spoke to said that pain relief and quality of life are inextricably linked.

‘Essentially, it’s relieving the symptoms of their cancer – whatever it is – and if it does that, then that’s the value as far as patients are concerned.’

**Sarcoma Patient Representative**

Side-effects produced by cancer treatments are also an important factor to consider when defining quality of life.

‘The story I hear again and again is that people are starting to demand a right to refuse treatment, simply on the basis that the side-effects of cancer drugs are frequently as bad as the disease.’

**Patient, NHS West Midlands**

When asked about value in relation to cancer treatment, those interviewed for this research commonly drew links between patients’ quality of life and societal benefits. It was generally perceived that patients who feel well are more able to contribute to family life, the community or the workplace.

For those of working age, quality of life can be assessed in terms of ability to continue working and supporting their family. There could be significant associated societal benefits to assisting someone to remain in or return to work – an ability to work means an ability to contribute income tax and avoid claiming from the benefits system.

‘I support my wife and my two children financially – and I might feel differently if I was in a different position, but I do think that that should carry some weight in the decision.’

**Patient, NHS London**

Measuring ‘wider societal benefits’ is perhaps the biggest challenge for the Government, and the new pricing model must also consider what contribution people are able to make to their communities, their families, and to the ‘big society’ more broadly. A new pricing model must also reflect the personal benefits to patients of receiving effective cancer medicines.

‘One person’s burden of illness can be very different to the next individual. If you’re measuring it by what you’ve got proof of on imaging, surgical proof, as opposed to the emotional proof of a burden of illness – how people are managing and coping with a burden of illness, so it’s very complex.’

**Cancer Nurse, NHS South Central**
Unmet need and therapeutic innovation

Although there was no consensus from the interviewees about whether cancer drugs that address ‘unmet need’ should be considered more valuable than other drugs, from the perspective of the cancer care community there could be specific advantages for people with rarer cancers if a new system paid more for drugs for cancers that currently have very few effective treatments.

Some believe that there is a stronger case for developing and providing access to drugs for cancer types where there is no alternative, as opposed to drugs where similar but inferior alternatives exist. However, most of the interviewees believe that drugs demonstrating ‘therapeutic innovation’ should be valued more highly. Patients with rarer cancers and their representatives place greater weight on the importance of innovation.

Measuring aspects of value

Importantly, across all these categories, the response to the consultation noted that there are some concerns about how these different components of value can be disentangled and ‘double-counting’ avoided. For example, if a therapeutic innovation leads to significantly improved outcomes, how is it possible to avoid double-counting the benefit through both the ‘clinical effectiveness’ and ‘therapeutic innovation’ criteria?

Some of the closest examples of attempts to introduce value-based pricing have been in Australia, Germany and Canada but fundamentally all these systems are still focused on clinical and cost-effectiveness, with no consideration of aspects such as wider societal benefits or the extent of therapeutic innovation. There is, however, a component of assessing burden of illness/unmet need to a limited extent.

‘When we fought for the drug Sutent, we were told it only gave a few months of extra life, whereas in fact we still have patients on the drug five years later, and in that time, four/five other drugs have been clinically trialled and have also been licensed. So it becomes not only an extension of life for the one drug, but the possibility of additional life through additional licensed drugs becoming available.’

Kidney Cancer Patient Representative
Conclusion and recommendations

Macmillan will continue to campaign for people with all cancers to have fair access to clinically effective drug treatments, especially those with rarer cancers.

We are delighted that the Cancer Drugs Fund has been established and we are pleased that it is set to improve access to effective cancer drugs for many thousands of people. However, we are keen to ensure that the Fund is as effective as possible in its lifetime. As such we call for greater auditing and monitoring of funding activity and decisions to provide a clearer picture of whether people with rarer cancers are getting hold of the drugs they need no matter where they live in England.

By the beginning of 2014, when the Cancer Drugs Fund ends, the Government wants all new branded medicines to be priced according to the ‘value’ they bring to patients and the NHS. There must be assurance from the Government that when this system comes into place the improvements in access achieved through the Cancer Drugs Fund are not lost. To ensure this, Macmillan calls for all drugs made available via the Fund to be automatically available on the NHS when value-based pricing is introduced.

**Recommendation 1**
The Department of Health must ensure that all SHAs are undertaking and regularly publishing robust clinical audits to make sure that the effectiveness of drugs for rarer cancers is being monitored.

**Recommendation 2**
We urge the Department of Health to monitor Cancer Drugs Fund expenditure much more closely and explore any significant regional disparity in the numbers of applications made to the Cancer Drugs Fund.

**Recommendation 3**
The Department of Health should monitor which drugs SHAs are choosing to include on their priority lists, advise SHAs to share shortlists frequently to encourage greater consistency and investigate SHAs that are regularly turning down applications for drugs that are available in most other regions.

**Recommendation 4**
We urge the Department of Health to issue stronger and more detailed guidance to SHAs around routinely publishing timely and accurate data on the Cancer Drugs Fund, including on funding allocation expenditure and activity.

**Recommendation 5**
Cancer patients must be offered personalised and supported information about their treatment options, including those drugs that can only be applied for via the Cancer Drugs Fund. Patients should also be made aware of what they can expect from the Cancer Drugs Fund process.

**Recommendation 6**
We ask the Department of Health to ensure that drugs for rarer cancers are evaluated fairly in the new system of value-based pricing, to ensure that patients can access the most effective treatments.

**Recommendation 7**
The Department of Health must ensure that cancer patients are involved meaningfully in the development of a definition of ‘value’ and in how the new value-based pricing system operates.

**Recommendation 8**
The Department of Health must ensure that access to cancer drugs continues to improve when value-based pricing is implemented. We want all treatments that are made available through the Cancer Drugs Fund to be automatically available on the NHS when a new system of value-based pricing comes into place in 2014.
Appendix 1: Research methodology

This section outlines the methodology used for the research into the experiences and perceptions of the Cancer Drugs Fund and value-based pricing.

Desk Research
The initial phase of research for this study involved a literature and data review which focused on the role and application of the Fund and value-based pricing. As a starting point, SHA websites were searched for information pertaining to the Fund, particularly information by region on:

- application figures;
- approval rates;
- drugs applied for;
- decision-making criteria used by the Fund panel; and
- Fund expenditure.

DH guidelines for the operation of the Fund in 2011-12 were used in conjunction with the SHA-published materials, to assess whether regional Funds were adhering to national guidance. This review was supplemented with a report completed by the Rarer Cancers Foundation on the Cancer Drugs Fund, released in 2011.

Qualitative Interviews with Cancer Patients and Healthcare Professionals
As a follow-up to the desk research, a programme of qualitative in-depth interviews was planned. The intention was to interview a total of 16 individuals (8 patients and 8 clinicians). However, the small number of patients and clinicians who comprise the target audience for this research, along with the additional challenges posed by the summer timing, meant that it was ultimately not possible to complete this number. 12 interviews in total were completed:

- 5 with healthcare professionals
- 4 with cancer patients
- 3 with patient representatives

The interviews took place between 18th August and 6th October, moderated by RS Consulting researchers. Interviews were conducted via telephone and lasted around 45 minutes. All research was conducted in compliance with ISO20252.

The participants were recruited through all available channels, including Macmillan Cancer Voices and online community, the Macmillan professional’s network who work within the NHS across the UK and wider advertising of this research project through media channels.
References

• Department of Health. (2010). Extent and causes of international variations in drug usage: a report for the Secretary of State for Health by Professor Sir Mike Richards CBE.


• Hansard HL, 14 Nov 2011: Column 447


• The Lancet Oncology, Volume 12, Issue 10, Pages 933–980, September 2011
Cancer is the toughest fight most of us will ever face. But you and your loved ones don’t have to go through it alone. The Macmillan team is with you every step of the way.

We are the nurses and therapists helping you through treatment. The experts on the end of the phone. The advisers telling you which benefits you’re entitled to. The volunteers giving you a hand with the everyday things. The campaigners improving cancer care. The fundraisers who make it all possible.

Together, we are Macmillan Cancer Support.

Questions about living with cancer?
Call the Macmillan Support Line free on 0808 808 00 00 (Mon–Fri 9am–8pm)

Alternatively, visit macmillan.org.uk
Hard of hearing? Use textphone 0808 808 0121, or Text Relay.
Non-English speaker? Interpreters available