

# **Improving access to medicines for NHS patients**

**A report for the Secretary of State for  
Health by Professor Mike Richards CBE**  
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## Letter to the Secretary of State



Professor Mike Richards CBE  
National Cancer Director

### Dear Secretary of State

I feel very privileged to have been invited by you in June of this year to lead a review to examine if, when and in what circumstances patients should be able to purchase additional drugs that are not funded by the NHS.

Developments in drug treatments have helped to transform the prospects of many patients with life-threatening or debilitating illnesses. Although the majority of these drugs are available to all NHS patients who need them, some are not. Since the creation of the National Institute for Health and Clinical Excellence (NICE), more drugs have been made available to more patients and we have seen equity of access to these drugs improve across the NHS. However, there are some circumstances in which NHS funding will not be available. When a clinician wishes to prescribe an unfunded drug, a patient may opt to purchase the treatment themselves. How the NHS handles such situations has proved to be controversial, arousing strongly held views on all sides.

At the heart of the issue is the tension that exists between the principles of equity – that every person should have access to health services based on their need and not on their ability to pay – and personal autonomy – that people should be free to spend their money as they choose. This tension has existed since the NHS was founded 60 years ago, and the issue of unfunded drugs is simply its latest iteration.

You set a deliberately challenging timescale for the Review so that the problems which are causing concern and distress to patients and their families could be resolved as soon as possible. Since June, I have sought to understand current law and practice relating to purchasing unfunded drugs, investigate the situation in other countries and seek the views of as many stakeholders as possible, including the public, patients, clinicians, NHS managers and the pharmaceutical industry, among others. Most importantly, I have also sought to understand the reasons why people have been placed in a position where they feel they need to purchase additional drugs.

It is clear that views are polarised. There is no easy answer to this difficult issue. I am now, however, in a position to make recommendations about how the government should proceed.

During the course of my Review, a small minority of stakeholders argued that clarifying the circumstances in which patients can purchase additional drugs without losing their entitlement to NHS care should be a precursor to moving towards an insurance-based system. I want to make clear from the outset that I do not accept this premise. My recommendations are intended to set out a clear framework for how the NHS should handle situations where patients might wish to purchase

additional drugs, but also to keep to an absolute minimum the number of patients who will be placed in this position in the future by ensuring that the NHS provides as many clinically effective drugs as possible on the NHS. I believe that, if implemented, these recommendations will help to maintain the NHS as a system that is free at the point of use, providing care based on need and not on ability to pay.

## **Minimising the number of patients who may want to purchase additional drugs**

It is clear that England is not alone in facing challenges in relation to costly new drugs. Any decision to spend money will have an opportunity cost and consequences in terms of what other services the NHS can deliver. It is therefore right for decisions on drug availability that may have significant cost implications to be subject to rigorous assessment, and NICE has an important role to play in this respect. NICE has deservedly developed an international reputation for its appraisal work and is widely respected. I believe that it is important we respect and retain the independence and integrity for which NICE is renowned.

Most stakeholders expect the NHS to be able to provide a comprehensive service and that this should especially include drugs used to treat patients in the last months of life. International arrangements for the pricing and provision of medicines vary widely, but there is a perception that other countries have managed to develop approaches that enable more patients to access new drugs without having to purchase them privately. The overwhelming priority should therefore be to ensure that patients get access to drugs that could potentially benefit them on the NHS, and I believe there are clear steps that can be taken to achieve this.

Many of the drugs that patients are currently seeking to purchase are scheduled for a NICE technology appraisal, but guidance has yet to be issued. The government and NICE are responding to this challenge by putting measures in place that enable NICE to issue more timely guidance while retaining its quality. Improving the timeliness of NICE decisions will therefore make a significant contribution to minimising the number of patients who are placed in a position where they have to consider purchasing additional drugs. **Recommendation 1: The measures the government is already taking to improve the timeliness of the NICE decision making process are extremely welcome and should be strongly supported. The Department of Health and NICE should publish an update on the timelines for delivering these important commitments.**

However, there will always be a gap between the licensing of a drug and the availability of NICE guidance, and not all drugs will be appraised by NICE. In these circumstances Primary Care Trusts (PCTs) will need to make decisions about funding.

There is a strong case for PCTs to work more collaboratively on making funding decisions, pooling expertise and avoiding unnecessary duplication of effort.

**Recommendation 2: The Department of Health should urgently consider how PCTs can be encouraged to work together to make proactive commissioning decisions. Consideration should be given to whether collaborative**

**processes already developed, such as in the North East for cancer drugs, could be used as a model.**

Greater collaborative working would go some way towards addressing the high levels of concern that exist about the variations that occur in the way PCTs make funding decisions. However, it is important that PCTs should also be able to demonstrate that they are taking decisions in a transparent, rational and consistent manner.

**Recommendation 3: The commitment made in the draft NHS Constitution to ensure transparency in PCT decision making, and the resulting work being undertaken by the Department of Health to support PCTs in delivering this, is extremely welcome. The government should set out as soon as possible more detailed plans for how it will achieve the commitment in the NHS Constitution, including the timescale for this work.**

There are particular challenges for PCTs in making decisions about funding of drugs outside their licensed indication. These requests may occur in very small numbers and there is likely to be little or no published information to inform decisions.

**Recommendation 4: In developing collaborative arrangements for decision making, the government should also consider how PCTs can be better supported to make decisions on funding off-label drugs, whether as a matter of policy or on an exceptions basis.**

Many stakeholders believe that the value society places on supporting people nearing the end of their life is not adequately reflected when the cost-effectiveness of drugs is appraised. With the emergence of even more costly new drugs for relatively small groups of patients whose conditions mean they are in the last months or years of life, such as advanced cancer, this problem could become more acute. To tackle this issue we need greater flexibility from all those involved, including NICE in determining how the benefits that some drugs deliver are valued, and the pharmaceutical industry in adopting new approaches to making their drugs available to the NHS on cost-effective terms. **Recommendation 5: The Department of Health should work:**

- **with NICE to assess urgently what affordable measures could be taken to make available drugs used near the end of life that do not meet the cost-effectiveness criteria currently applied to all drugs; and**
- **with the pharmaceutical industry in the context of the current Pharmaceutical Price Regulation Scheme (PPRS) negotiations to promote more flexible approaches to the pricing and availability of new drugs. This will require partnership working with the pharmaceutical industry and greater flexibility in approach from all parties.**

There is a perception that usage of new drugs is low in England, especially for new anti-cancer drugs, but further work is required to fully understand the extent, reasons for and implications of any international variations. **Recommendation 6: The Department of Health should urgently undertake further work to investigate the extent and causes of international variations in drug usage.**

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## Establishing clear guidance on additional drugs

If accepted, the recommendations I have made above, together with collaborative working from the Department of Health and industry to enable a more flexible approach to the pricing of new drugs, will help to keep the numbers of patients who may wish to purchase additional drugs to a minimum, and I believe that this should be the main focus of government action. I am also clear that clinicians should satisfy themselves that all reasonable avenues for securing NHS funding have been exhausted before a patient has to consider whether to purchase additional private drugs. However, there may still be some situations where a patient wishes to pursue this course of action. It is important not only that these patients are not penalised for this choice but also that their action does not disadvantage other NHS users.

I found that current guidance on the issue, which was not developed to deal with the complexities of modern drug treatment, is unclear. It is being interpreted in many different ways, resulting in differing approaches for patients with the same condition who require the same drug. **Recommendation 7: The Department of Health should clarify the policy on how the NHS should handle situations where a patient wishes to purchase additional treatment. The objective should be to ensure consistency in practice across the NHS.**

During the course of the Review it also became apparent to me that a wide variety of different terms have been used to describe issues relating to the mixing of NHS and private treatment. These terms have often been used interchangeably and are defined in different ways by different stakeholders. I have therefore used a common framework to consider the issue. The options considered broadly range along a spectrum from ensuring the complete separation of NHS care and treatment purchased privately to encouraging complete integration.

The clearest way to ensure separation between NHS and private care is to force patients to make a choice from the outset whether they wish to be a private patient or an NHS patient for the duration of their treatment for that condition. I share the view of the large majority of stakeholders that this option is unfair, as it would deny patients NHS care they would have otherwise received. **Recommendation 8: The Department of Health should make clear that no patient should lose their entitlement to NHS care they would have otherwise received, simply because they opt to purchase additional treatment for their condition.**

It is important to stress that every possible approach to implementing this recommendation has practical difficulties and I have tried to balance these considerations in recommending a way forward.

The most integrated solution would be to introduce a system of NHS top-ups whereby patients would pay a user charge to receive additional drugs. However, I believe that this approach presents significant practical challenges and is inequitable for those NHS patients who could not afford to top up. It would also place the NHS in the perverse position of charging for treatments that have not been deemed as

cost-effective. For these reasons I believe that the option of NHS top-ups should be rejected.

My preferred option for ensuring that patients do not lose their entitlement to NHS care because they purchase additional drugs is for the government to clarify that individuals may pay for these drugs while continuing to be treated as an NHS patient for other elements of care as long as the two elements of care are provided separately. This ensures that there is a separation between NHS and private care, in line with strongly held views on the desirability of maintaining equality on NHS wards and day clinics. **Recommendation 9: The government should make clear that:**

- **clinicians should exhaust all reasonable avenues for securing NHS funding before a patient considers whether to purchase additional drugs;**
- **patients should be able to receive additional private drugs as long as these are delivered separately from the NHS elements of their care; and**
- **providers should establish clear clinical governance arrangements to ensure that patients who do elect to purchase additional private treatment receive good continuity of care.**

Not all NHS hospitals have private facilities or a private hospital nearby. In these circumstances there may be practical difficulties in implementing the parallel arrangements. However, with goodwill, I believe these can be overcome.

**Recommendation 10: Strategic Health Authorities, working where appropriate through cancer networks, should ensure that local policies are developed to ensure that any revised guidance issued by the government is implemented properly. This might include using a designated hospital with private facilities for all patients wishing to purchase additional drugs, making use of homecare provision or designating an area of an NHS hospital for the delivery of privately funded treatments.**

During the course of the Review it became apparent that there is little reliable data on the true extent of the demand for currently unfunded drugs, or the clinical benefit that patients gain from such drugs in practice. Gaining a better understanding of this demand will be important in informing future policy decisions about the availability of drugs. **Recommendation 11: The Department of Health should take a lead on commissioning a national audit of demand for unfunded drugs and on the outcome of treatments, working closely with professional organisations and NHS managers.**

Discussions between patients and clinicians about treatments given towards the end of life which have uncertain benefits and toxicities for individual patients can be extremely difficult. These difficulties can be compounded if the conversations also need to cover funding of drugs. I strongly believe that we need to do more to assist clinicians who have to undertake these difficult discussions.



## Recommendation 12:


- **Doctors who are likely to have conversations with patients about treatments that are not routinely funded on the NHS should ensure that they have the necessary knowledge and skills to communicate complex information effectively and in a balanced way. This will help patients to make informed assessments about the balance of risk, cost and benefit involved in any potential treatment.**
- **The Department of Health should commission a training programme for clinicians to enhance the quality of discussion about these difficult issues.**
- **Relevant Royal Colleges should consider how assessment of communication skills could best be incorporated into recertification processes.**

Good face-to-face communication should be supplemented by high quality written information. **Recommendation 13: The Department of Health should consider how patients could best be given access to balanced written information on the benefits, toxicities and, where appropriate, costs of novel treatments, especially those given to patients near the end of life.**

Finally, stakeholders have also drawn my attention to issues relating to devices and procedures that do not involve drugs and suggested that national guidance should also apply to non-drug interventions. These issues are beyond the scope of the Review and so have not been considered in detail, but it is evident that clarity on the issue is desirable. **Recommendation 14: In responding to this Review, the government should confirm how situations where patients wish to purchase additional non-drug interventions should be handled.**

In conducting my Review I have been guided by the need to promote high quality healthcare for all NHS patients and be true to the founding principles of the NHS. I believe that my recommendations offer a consistent, fair and affordable way forward. I set out in an annex to this letter the benefits I believe they will bring to patients, and I hope that the government will feel able to accept them.

Yours sincerely



Professor Mike Richards CBE MD FRCP  
National Cancer Director

## Benefits to patients

If my recommendations are accepted, I believe they will bring the following benefits for patients:

### **The number of patients needing to purchase additional drugs will be minimised**

- There will be quicker availability of NICE guidance, ensuring a national approach to new drugs where possible.
- More drugs that are used in the last months or years of life will be available on the NHS.
- PCTs will work together to pool expertise when making decisions on funding of new drugs, including those that clinicians wish to use “off label”.
- PCTs will make decisions in a transparent and timely manner.

### **There will be a consistent approach for those few patients who may still wish to purchase additional drugs**

- By opting to purchase additional private drugs, no patient will lose their entitlement to NHS care they would have otherwise received.
- Clear national guidance will mean there is a consistent interpretation across the NHS.
- NHS top-ups will not be introduced. The few patients who may want to purchase additional drugs will be able to receive them separately from their NHS care, in a separate setting.
- Clear arrangements for delivering separate care will be put in place in every geographical area.

### **Patients will be better informed about the implications of purchasing additional drugs**

- Doctors will be given additional training on how to approach conversations with patients about treatments that are not routinely funded on the NHS, and high quality written information will be developed. This will enable patients to make informed choices about the benefits, costs and risk of additional drugs.

## **Improved information on additional drugs will be collected and used to inform patient choices and future policy decisions**

- A national audit of unfunded drugs will be commissioned, giving a better picture of demand for additional drugs and the outcomes from additional treatment. This will be used to help other patients make an informed choice and to enable decisions to be made about the future availability of unfunded drugs.

## Acknowledgements

Many individuals and organisations have assisted me in undertaking this Review. I am deeply grateful to the following organisations which kindly arranged seminars, workshops, citizens' juries and/or focus groups involving members of the public, patients, carers, health professionals, NHS managers, academics, experts from other countries and representatives of the pharmaceutical and insurance industries:

- Beating Bowel Cancer
- Breakthrough Breast Cancer
- Breast Cancer Care
- European Health Policy Group
- Guy's and St. Thomas' NHS Foundation Trust
- King's Fund
- KPMG
- Long Term Conditions Alliance
- Macmillan Cancer Support
- National Voices
- NHS Confederation
- Nuffield Trust
- Research Works Limited
- Roy Castle Lung Cancer Foundation
- The Royal Marsden NHS Foundation Trust

Representatives of several organisations generously supplied me with information, often before it was available in the public domain. These include:

- The Christie NHS Foundation Trust
- Leeds Teaching Hospitals NHS Trust
- The Royal Marsden NHS Foundation Trust
- Joint Collegiate Council for Oncology
- Rarer Cancers Forum
- University Hospital Birmingham NHS Foundation Trust
- London School of Hygiene and Tropical Medicine
- National Institute for Health and Clinical Excellence

I am very grateful to Professor Lesley Fallowfield for the work she undertook for the Review related to the difficulties that clinicians have in communicating about treatments for patients near the end of life, particularly when they are unfunded. I am also grateful to many others who have contributed to my thinking through one-to-one discussions.

Most of all, I am deeply indebted to the team who have supported me in conducting the Review and preparing the report: Kristen McLeod, Sarah Fisher-Mackey, Mike Birtwistle, Jo Aracena, Robert Parsons, Robert Brown and Samuel Littlejohns.

# Part 1: Background

## Chapter 1 – Introduction

### Background

- 1.1 Access to medicines attracts a great deal of interest from patients, clinicians and the public. Over recent years there have been significant developments in drug treatments for different medical conditions and these look set to continue. Many of these new drugs offer exciting opportunities to improve the treatment options available to patients, extending and adding to the quality of their lives. However, some new drugs also present challenges to the NHS. They are often expensive, and may only give modest clinical benefits. Funding them can divert resources away from other NHS services, meaning that difficult decisions have to be made about whether these drugs offer enough benefit to patients to justify their cost.
- 1.2 In 1999, the government established the National Institute for Health and Clinical Excellence (NICE), in part to help promote a uniform approach to high cost medicines, ensuring that access is based on cost-effectiveness. NICE has created greater transparency over which treatments the NHS should be funding and has also successfully reduced variations in access to new drugs across England. NICE is acknowledged as a world leader in its field, and a number of other countries have sought to emulate its health technology assessment approach. Even when stakeholders express reservations about specific NICE recommendations, they usually acknowledge that NICE has a difficult but necessary job to do and that it is right for such decisions to be made independently on the basis of an assessment of the evidence.
- 1.3 However, there are some situations where a clinician wishes to prescribe a drug for a patient but a Primary Care Trust (PCT) declines to fund it. In this situation a patient may wish to purchase the treatment themselves. In recent months, how NHS organisations handle this issue has been called into question.

### Purpose of the Review

- 1.4 This Review was established to:
  - examine current policy relating to patients who choose to pay privately for drugs that are not funded on the NHS and who, as a result, are required to pay for the care that they would otherwise have received free on the NHS; and
  - make recommendations on whether and how policy or guidance could be clarified or improved.

- 1.5 The issues that the Review has considered are of great interest to patients, clinicians and the public, as well as to a wide variety of other stakeholders such as charities, pharmaceutical companies and insurers. The task of the Review would have been considerably more difficult had it not been for the thousands of people and organisations who have contributed ideas, opinions and evidence.
- 1.6 Many people have emphasised that any decisions the government may make on this issue could have far reaching consequences for the future of the NHS. The issue generates heartfelt, but polarised, views, with two ethical principles potentially coming into conflict: equity and personal autonomy.
- 1.7 Since the NHS was founded 60 years ago, there has been a tension between the principles of equity – that every person should have access to health services based on their need and not on their ability to pay – and personal autonomy – that people should be free to spend their money as they choose. Current controversies about when and how a person may purchase additional drugs alongside their NHS care are the latest iteration of this historic tension.

***“The national minimum... means that no one is to fall below a certain standard. It leaves everyone free to spend his income above that standard as he will. It preserves the maximum of individual freedom and responsibility that is consistent with the abolition of human want.”***

*William Beveridge*, explaining the recommendations contained in his report, 1942

***“The first evil that we must deal with is that... a person ought to be able to receive medical and hospital help without being involved in financial anxiety.”***

*Aneurin Bevan*, speaking during the second reading debate of the NHS Bill, April 1946

### Principles underpinning the Review

- 1.8 The Review has been guided by the principle that recommendations should:
  - be consistent with the founding principles of the NHS: universality, comprehensiveness, equity, free at the point of need and removing people’s financial worries;
  - reaffirm the values set out in the draft NHS Constitution;

- help deliver the vision of a patient-centred, clinician-led NHS, as set out in the NHS Next Stage Review;
- promote high quality and safe care;
- encourage informed patient choice and personal autonomy, including protecting a person's right to try to extend their life through whatever means necessary;
- ensure that one person's choice does not disadvantage other NHS patients;
- support the role of NICE in promoting and spreading clinical excellence;
- bolster public, patient and clinician confidence in the NHS and its ability to deliver world class health services;
- be clear and enforceable; and
- be affordable to the NHS and to individual patients.

## Review approach

1.9 The timescale for the Review has been deliberately challenging in order that current problems which are causing concern and distress to patients and their families could be resolved as soon as possible.

1.10 Given the complexity of the issues involved and the strong feelings they elicit, it has been a priority to gather as much evidence as possible. Since the Review was established in June 2008, a number of actions have been undertaken:

- establishing a baseline – understanding the current position as set out in law and guidance, developing a picture of current NHS practice and investigating the situation in other countries;
- seeking views – speaking to a wide variety of stakeholders, including patients, the public, clinicians, NHS managers, the pharmaceutical industry and others, to gain a better understanding of their views on the current situation and the most appropriate way forward;
- developing and evaluating possible solutions – in relation to both when and how patients should be allowed to purchase additional treatment and how the number of patients needing to do so could be minimised; and
- making recommendations on how the government should proceed.

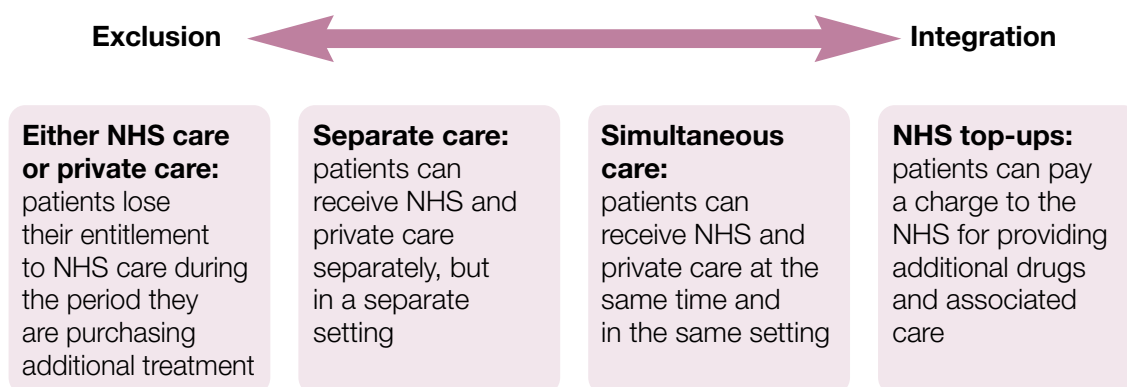
## Definitions

1.11 During the course of the Review it has become apparent that a number of different terms are being used to describe issues relating to the mixing of NHS and private treatment, including:

- top-ups;
- co-payments;
- user charges; and
- patient contributions.

1.12 These terms have often been used interchangeably and are defined in different ways by different stakeholders. It is clear that discussion has been hampered by this confusion.

1.13 Whatever terminology is used, it is important that there is clarity about what the range of options considered during the Review mean in practice. The Review has therefore used a common framework into which the varying views received can fit. The options considered broadly range along a spectrum from excluding from the NHS patients who opt to purchase additional drugs to full integration. These options are explored in more detail in Chapters 4 and 6.





# Part 2: Findings

## Chapter 2 – Nature and magnitude of the situation

2.1 Although there have been a number of reports in the media, particularly relating to cancer and wet age-related macular degeneration, very little information exists about demand for unfunded drugs. A key task for the Review was therefore to gain a better understanding of the nature and magnitude of the situation.

2.2 This chapter:

- estimates the overall demand for unfunded drugs;
- examines when and why demand for unfunded drugs occurs;
- assesses regional variations in demand and processes for determining funding;
- scopes future trends in drug availability;
- looks at the willingness of patients to purchase additional drugs; and
- compares the situation in England with that in other countries.

### Overall demand for unfunded drugs

2.3 Most drugs are available on the NHS to all patients whose clinician thinks they could benefit. However, there are some circumstances in which NHS funding for drugs may not be available. It is difficult to assess the overall extent of demand for unfunded drugs. When a drug is not normally funded by the NHS, a clinician may apply to a PCT for funding for individual cases. This process is often referred to as an “exceptional funding” request. Examining requests made by clinicians to PCTs for exceptional funding gives a minimum figure for current demand. In other cases, a clinician may believe that a drug should be offered to a patient, but may not make a request for funding (e.g. because of previous experience of applications being rejected).

2.4 A survey conducted by the Department of Health as part of the Review found that around 15,000 requests for exceptional case funding are currently being made to PCTs in England per annum (Appendix 1). An average PCT will therefore receive around 100 applications each year. Around one-quarter of these requests relate to cancer and three-quarters to other conditions.

- 2.5 Applications for exceptional funding relate to around 50 different drugs. An audit conducted by the Rarer Cancers Forum identified over 30 different cancer drugs for which applications had been made over a 20 month period. Data provided by Leeds Teaching Hospitals NHS Trust shows that applications were made for 46 different drugs (27 for cancer, 19 for other conditions) over a similar period.
- 2.6 Applications for drugs on which NICE has yet to issue final guidance appear to be by far the largest category of requests. Applications for off-label use are largely related to non-cancerous conditions and are numerous. True “exceptional case” requests for drugs that have been declined by NICE appear to be uncommon. It is uncertain whether this reflects demand or previous experience by clinicians or provider Trusts of rejections of such applications.

### Applications for exceptional funding made by Leeds Teaching Hospitals NHS Trust

- Over a 19 month period (December 2006–June 2008), a total of 831 requests for exceptional case funding were made to PCTs.
- 5 non-cancer drugs accounted for 75% of non-cancer requests. Ranibizumab for wet age-related macular degeneration was the most commonly applied for drug, with monoclonal antibodies for inflammatory conditions related to rheumatoid arthritis or Crohn’s disease also being frequently applied for.
- 5 drugs accounted for over 70% of cancer requests made by the Trust. These included drugs for lung cancer, myeloma, renal cancer and chronic myeloid leukaemia.
- For many of the other drugs, individual PCTs were typically receiving 0, 1 or 2 applications in the course of a year.
- If and when NICE approves a particular drug, the number of applications falls abruptly.

### Applications for exceptional funding made by The Christie NHS Foundation Trust

- Over a 22 month period (July 2006–May 2008), 102 requests were made for exceptional funding.
- These requests related to 7 cancer drugs: bevacizumab, cetuximab, irinotecan, lenalidomide, rituximab, sorafenib and sunitinib.
- The requests were made to 27 different PCTs. 11 PCTs received 1 application only, and a further 9 PCTs received 2–5 applications. 1 PCT received 17 applications.
- The proportion of applications that were approved varied substantially between PCTs. 1 PCT approved 15 of 17 (88%), while another approved only 1 of 8 (12.5%).
- The mean time to approval was 37 days (with a range of 0–231 days).
- Drug costs were assessed for 50 patients who received treatment as “exceptional cases”. The total cost was around £400,000, indicating an average of £8,000 per patient (exclusive of on-costs).

### Applications for exceptional funding made by The Royal Marsden NHS Foundation Trust

- 1,113 applications were made between April 2005 and August 2008, i.e. around 325 per annum.
- Applications were made to 90 different PCTs.
- 3 PCTs received over 100 applications each, but 25 PCTs received only a single application.
- 42 different anti-cancer drugs were involved over this period, with 10 drugs accounting for 67% of all applications.
- On first application 60% of cases were approved, 36% declined and 4% cancelled.
- Approximately one-quarter of those initially declined were appealed, with 52% of appeals succeeding.
- Overall, 65% of cases were approved, 30% declined and 4% cancelled.

## Reasons for demand for unfunded drugs

- 2.7 Evidence collected by the Review indicates that drugs for which funding is requested from PCTs can be classified in three separate categories:
- drugs on which NICE has yet to issue final guidance;
  - drugs that NICE will not appraise or that a clinician wishes to use “off label”; and
  - drugs that NICE has declined to recommend for use in the NHS.
- 2.8 If a PCT declines to fund a drug but a clinician believes that it would be clinically beneficial, then a patient may decide to fund the treatment themselves.
- 2.9 Demand for unfunded drugs may arise when a patient hears about a particular treatment (e.g. through word of mouth or via the internet) or when a clinician recommends it. Guidance issued by the General Medical Council is clear that doctors should inform patients of all appropriate treatment options to meet their clinical needs. However, an online study conducted by the Joint Collegiate Council for Oncology (JCCO) suggests that this is not always the case.

### Joint Collegiate Council for Oncology survey

In an online study conducted by the JCCO, to which 289 oncologists responded, 63% of respondents said they discussed unfunded drugs, 30% said they did not and 7% said the situation did not arise for them.

## Regional variations in applications and approval rates

- 2.10 The Department of Health’s survey found that 13% of responding PCTs reported that they have funded some drugs rejected by NICE and 43% reported that they have funded some drugs not yet appraised by NICE.
- 2.11 There appear to be significant variations between PCTs, both in the number of applications made for exceptional funding and whether the application was approved or rejected.
- 2.12 Overall, the level of approvals differs somewhat between data sources:
- The Department of Health survey found that around two-thirds (64%) of cancer drug requests and approximately three-quarters (74%) of applications for non-cancer drugs were approved.
  - The Rarer Cancers Forum audit found that 74% of requests for cancer drugs were approved.

- In the JCCO survey, oncologists reported that 52% of requests were approved.
- Data from Leeds Teaching Hospitals NHS Trust found that 88% of cancer requests and 91% of non-cancer requests had been approved.
- The Christie NHS Foundation Trust reported that around three-quarters of applications for cancer drugs were approved.

2.13 There is, however, evidence of significant geographical variation in the outcomes of requests. The Rarer Cancers Forum found that PCT approval rates vary from 0% to 100%.

2.14 These differences may reflect both local priority setting processes and individual clinicians' determination to seek funding. Low numbers of applications in the North East of England (observed in the JCCO survey) may, for example, reflect well-developed approaches to priority setting across a cancer network or Strategic Health Authority (SHA). In such circumstances any requests are made on the grounds of exceptionality, rather than simply because a decision on routine use has not been made. This will impact on the proportion of requests that will be approved or rejected.

2.15 These variations in outcome appear to be matched by differences in the processes used by PCTs to determine exceptional funding applications.

### Variations in processes used by PCTs to assess exceptional funding requests

An audit by the Rarer Cancers Forum found significant variation in the processes used by PCTs to assess exceptional funding applications:

- 15% of responding PCTs had no written protocols for processing exceptional cases.
- 6% of PCTs reported that they did not have a panel for considering exceptional cases.
- 18% of PCTs with a panel did not provide details of membership.
- For those reporting panel membership, involvement of clinicians is variable.
- PCTs vary in their approach to the consideration of social circumstances in relation to exceptional case funding: 38% do; 62% do not.
- The timescales in which PCTs reach decisions also vary significantly.

### Future trends in drugs

- 2.16 Drug treatments have developed substantially over the past 20 years and are set to develop still further. This is particularly the case for conditions that have traditionally been seen as very difficult to treat, including cancer, severe rheumatoid arthritis and wet age-related macular degeneration. To date, NICE has either fully or partly recommended the vast majority of drugs it has appraised for use in the NHS.
- 2.17 In recent months there have been a few drugs that have not been recommended on the grounds of cost-effectiveness. Evidence suggests that, in the future, in certain circumstances it may become more challenging to demonstrate cost-effectiveness according to the criteria currently used. It is likely that there will be particular challenges for drugs used near the end of life. Evidence is now emerging from NICE appraisals that cancer drugs tend to be more cost effective when used in earlier stage disease than they are at the end of life, where they are first licensed.
- 2.18 Treatments are already beginning to make greater use of advances in genetic profiling to target drugs at specific gene products. The potential benefits to patients of these developments are significant, but the groups of patients to whom each drug will apply are relatively small.
- 2.19 The pharmaceutical industry currently has a large number of drugs in development. The expectation is that a significant proportion of these will prove to be clinically effective but, without partnership working between government and industry, some will fail the cost-effectiveness tests that are currently used. The result may well be that higher numbers of patients will be placed in a position where their clinician feels that they could benefit from a drug that will not be funded by the NHS. The NHS and the pharmaceutical industry need to accept shared responsibility for this challenge, with the latter accepting that there will be situations in which they need to exercise greater flexibility in their commercial approach to enable uptake of their products by the NHS.

### Pharmacogenetics

Advances in knowledge of genetics and biochemical pathways are now being translated into new targeted drugs. This means that it will be possible to target drugs at smaller groups of patients with a particular genetic characteristic, enabling improved efficacy, more accurate dosing and reduced side effects. Suitable patients are identified through a variety of tests. Examples include the HER2 test, which predicts whether a breast cancer patient will respond to trastuzumab or lapatinib. Similarly, the K-RAS test can help predict how well a bowel cancer patient will respond to cetuximab.

This could potentially improve the cost-effectiveness of some new drugs and reduce the overall costs to the NHS, by ensuring that they are given to the patients on whom they will have most effect. However, the costs of identifying targeted therapies are high, and the groups of patients to whom they are given are smaller than for untargeted therapies, so potentially reducing the volume of sales that could be expected for a particular drug.

## The willingness of patients to purchase additional drugs

- 2.20 There is evidence to suggest that, overall, patients are willing to undergo further treatment for relatively small gains in survival. A study of attitudes to chemotherapy was published by Slevin et al. in the *British Medical Journal (BMJ)* in 1990. In the study, cancer patients, age-matched (healthy) controls, GPs, cancer nurses and cancer doctors were all asked about the degree of benefit from cancer chemotherapy that would make treatment worthwhile, given two hypothetical treatments of differing toxicity. In general, the cancer patients were most likely, and the controls were least likely, to say that they would accept treatment for a potentially small benefit. Health professionals gave intermediate responses. For example 42% of cancer patients said that they would accept an intensive treatment even if it only prolonged their life by three months, while only 10% of controls said that they would do so.
- 2.21 However, patients' willingness to accept chemotherapy for the treatment of advanced cancer varies widely. In a study from the USA, patients who had already received cisplatin-based (i.e. intensive) chemotherapy for advanced lung cancer were asked to indicate the minimum survival benefit for them to accept further treatment under two scenarios (mild and severe toxicity). Many would not choose chemotherapy for a survival benefit of three months, but would if it improved quality of life. The median survival threshold for accepting chemotherapy was 4.5 months for mild toxicity and 9 months for severe toxicity (Silvestri et al., *BMJ*, 1998).
- 2.22 Overall, these studies do suggest that the benefit derived from additional treatment would only have to be relatively small for some patients to consider it worthwhile. Evidence on the willingness of patients to pay for unfunded drugs is extremely limited. However, the JCCO survey indicated that over half (252/482) of the patients for whom PCT funding had been denied had chosen to pay for the treatment themselves. It is uncertain how many of these patients will have made out-of-pocket payments and how many will have been covered by insurance.

## Comparisons with other countries

- 2.23 Chapter 4 sets out in some detail the views of stakeholders which were collected as part of the Review. There is a perception that England is a low user of new medicines in comparison with other countries.

- 2.24 Stakeholder perceptions support the findings reported in the Department of Health's *Cancer Reform Strategy*, published in 2007, that usage of new anti-cancer drugs is estimated to be considerably lower in England, with usage at approximately 60% of that in other major European countries. This is despite the positive role that NICE guidance has played in increasing access to medicines and reducing variations in usage.
- 2.25 There may be a variety of explanations for these differences, including greater conservatism on the part of English clinicians, disparities in health service funding, capacity problems, delays in the delivery of definitive NICE guidance to the NHS, and the fact that NICE has declined to recommend some drugs for use in the NHS which are available elsewhere.
- 2.26 It is important to note that there are technical difficulties in comparing international levels of drug usage, and these require further investigation. There is also little consensus about the most appropriate level of drug usage. Many experts believe that levels of drug usage in some other countries are inappropriately high, and this will have an impact on international comparisons.
- 2.27 However, work undertaken by the London School of Hygiene and Tropical Medicine for the Review shows that different countries use different systems for assessing cost-effectiveness and determining drug availability.



## **Chapter 3 – Current legislation, guidance and practice**

- 3.1 The Review was necessary because it had become evident that there was confusion about the guidance on when and how people could purchase additional drugs, and what impact this had on their entitlement to NHS care. In addition, stakeholders have said that they are unclear about how guidance relating to purchasing additional drugs links to the other forms of NHS charging for additional services which already exist.
- 3.2 An early task for the Review was therefore to clarify the current legal position and assess whether the existing guidance provides a useful basis for assisting the NHS in making complex decisions about the provision of care at a local level.
- 3.3 This chapter:
- reviews the legislation relating to charging in the NHS;
  - examines the guidance relevant to discussions about purchasing additional treatment;
  - assesses current NHS practice; and
  - summarises other forms of charges that exist in the NHS.

### **Primary legislation**

- 3.4 One of the principles at the heart of the NHS is that care should be provided to all on the basis of need and not according to ability to pay. This is reflected in the primary legislation restricting the charging of patients for NHS services.
- 3.5 Section 1(1) and (2) of the National Health Service Act 2006 (“the Act”) require the Secretary of State to continue the promotion of a comprehensive health service and secure the provision of services for that purpose. Section 1(3) of the Act states that these services “must be provided free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment, whenever passed”. In practice, the Act means that the NHS may not charge for any NHS service unless the Act is amended or any other legislation has been passed allowing it to do so. In this way, legislation extending powers to charge are subject to the approval or scrutiny of Parliament, thereby retaining democratic accountability in relation to new charging proposals.
- 3.6 This principle was most recently restated in the draft NHS Constitution, which states “You have the right to receive NHS services free of charge, apart from certain limited exceptions sanctioned by Parliament.”
-

- 3.7 In primary care, Schedules 1 and 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 enable patients to be charged for certain drugs (those on the “black” and “grey” lists respectively). No legislation has been passed to allow the NHS to charge patients for the provision, as an NHS service, of additional drugs in secondary care.
- 3.8 Legislation does, however, allow NHS bodies, including NHS Trusts and Foundation Trusts, to provide private services to patients, subject to certain conditions (section 44 of the Act in relation to Foundation Trusts, and paragraphs 19 and 20 of Schedule 4 in relation to NHS Trusts). NHS clinicians are also able to use NHS facilities for the purpose of providing services to private patients, subject to agreement and reimbursement of the relevant NHS body, and relevant policy guidance (see the following section). The legislation requires a clear distinction between NHS and private provision within hospitals.

### Policy guidance

- 3.9 In addition to the statutory restrictions, there are two key pieces of guidance that set out the parameters within which NHS bodies or NHS clinicians may provide private services.
- 3.10 *Management of private practice in health service hospitals in England and Wales*, published in 1986, sets out how NHS patients should never be disadvantaged by the decision of an NHS provider also to offer private services. This consideration is relevant to determining how and when patients should be allowed to purchase additional treatment.
- 3.11 The guidance states that:
- the provision of accommodation and services for private patients should not significantly prejudice non-paying patients;
  - an outpatient cannot be both a private and an NHS patient for the treatment of one condition during a single visit to a health service hospital;
  - a private outpatient at an NHS hospital is nonetheless legally entitled to change their status at a subsequent visit and seek treatment under the NHS, subject to the terms of any undertaking they have made to pay charges; and
  - an inpatient has a similar legal entitlement to change their status during the course of their stay in hospital.

3.12 The *Code of conduct for private practice*, published in 2004, restates these principles. Specifically, it states that:

- the provision of services for private patients should not prejudice the interests of NHS patients or disrupt NHS services;
- in the course of their NHS duties and responsibilities, consultants should not initiate discussions about providing private services for NHS patients, nor should they ask other NHS staff to initiate such discussions on their behalf;
- a patient cannot be both a private and an NHS patient for the treatment of one condition during a single visit to an NHS organisation;
- a patient seen privately is entitled to subsequently change their status and seek treatment as an NHS patient;
- private patients should normally be seen separately from scheduled NHS patients; and
- NHS consultants may not use NHS staff for the provision of private services without the agreement of their NHS employer.

3.13 In determining how and when patients can mix private and public care for all forms of treatment, the most important of these principles for NHS organisations has been the one stating that patients cannot be a private patient and an NHS patient for the treatment of one condition during a single visit to a health service hospital. How this guidance is put into practice at a local level has been for NHS organisations to interpret.

## Interpretation

3.14 The Review has found that widely differing interpretations of the guidance are being applied across England. Many stakeholders, including NHS organisations, feel that this disparity has undermined patient confidence in the NHS.

3.15 The Review has not assessed whether the existing guidance has been applied appropriately, but has instead sought to develop a view on whether it is sufficiently comprehensive or clear to provide a useful resource to the NHS in the future.

3.16 The term “episode of care” has been used as a mechanism for separating NHS and private treatment and applying the “single visit” principle. It is important to note that the guidance was developed at a time when the primary area of concern about the mixing of NHS and private treatment was the area of elective surgery. Waiting times were long and there was legitimate concern that NHS patients should not be disadvantaged by others seeking to expedite their wait by purchasing additional care, for example scans.

- 3.17 Although the “episode of care” distinction may have been an appropriate way of ensuring separation in the past, it has become apparent during the course of this Review that it is not easily applicable to modern drug treatments, which often take place over a prolonged period of time and are used in combination with other interventions. Given this evolution in modern medicine, it is clear that “episode of care” is no longer an appropriate definition for issues related to the purchasing of additional treatments.
- 3.18 In practice, some Trusts allow patients to buy additional private drugs while continuing their NHS care for the same condition as long as the patient is able to receive the private drug, as a private patient, in a private setting. However, another common interpretation has been that any mixing of NHS and private care for the same condition is not allowed. Some Trusts have maintained that if a patient wishes to purchase an additional private drug, they must then have the whole course of treatment for that condition as a private patient, including that treatment which the patient would usually have received free of charge on the NHS. Such patients therefore lost their entitlement to NHS care.
- 3.19 This lack of clarity has had significant consequences. In addition to coming to terms with the fact that their condition is likely to carry a poor prognosis, patients and their families are also having to negotiate complex and confusing arrangements, different for almost every NHS organisation, which govern how and when they can supplement their NHS care with additional private drugs.

### Other forms of voluntary payments and NHS charging

- 3.20 During the Review many stakeholders have drawn attention to the extent of current out-of-pocket payment for healthcare alongside NHS-funded care. Many patients choose to purchase private services such as scans, physiotherapy and psychological therapies in addition to the NHS care they are receiving for that condition. It is also common for patients to purchase private fertility treatment and then have all their obstetric care in the NHS.
- 3.21 Different forms of NHS charging include those where:
- flat-rate charges are levied, for example for NHS prescriptions, NHS dentistry or NHS wigs (unless an exemption applies);
  - vouchers are issued to NHS patients, enabling them to contribute to the cost of a medical device beyond that which is provided as standard, for example for wheelchairs and optical appliances in secondary care;
  - an NHS patient can opt to pay privately for the provision of some medical services, for example on being issued a private prescription for a “greylisted” drug as part of an NHS primary care consultation; and

- an NHS patient can pay an ancillary charge for accessing services that are nothing to do with their clinical need, for example hospital amenity beds.

3.22 However, patient charges for NHS services (mainly for dental services and prescription services) currently only comprise 1.3% of total NHS spending in the United Kingdom – the lowest proportion since charges were introduced (Tony Delamothe, *BMJ*, 21 June 2008).

3.23 It is important to note that the different forms of charging currently in place in the NHS are of a different order of magnitude to the situation that occurs when a patient is considering whether to purchase additional drug treatment, such as for cancer. A prescription charge costs £7.10 per item, while opting to purchase additional drugs for conditions such as cancer can result in costs running into tens of thousands of pounds for an individual patient. The Rarer Cancers Forum has estimated that the average cost of an unfunded cancer treatment is £20,821.

## Chapter 4 – Stakeholder opinions

- 4.1 Eliciting views from as wide a range of stakeholders as possible has been a key priority during this Review. As the NHS belongs to everyone in this country, it is not surprising that people from all walks of life have strong opinions on what the NHS should pay for and how privately funded and NHS funded care should or should not be mixed.
- 4.2 This chapter summarises the feedback received during the Review and sets out the key areas of concern that have been voiced, including views on:
- the desirability of the NHS offering a “comprehensive” service;
  - the desirability of allowing geographical variations in approach;
  - the acceptability of requiring patients to choose whether to receive all their treatment in the NHS or the private sector;
  - mechanisms for enabling patients to purchase drugs unavailable on the NHS; and
  - the practical implications of any solution.

### Seeking views

- 4.3 The Review has sought the views of a wide variety of stakeholders, including patients, the public, healthcare professionals, NHS managers and representatives from the pharmaceutical and insurance industries:
- Over 400 organisations and individuals have submitted their thoughts to the Review mailbox (see Appendix 2 for more details).
  - Workshops have been held in collaboration with different charities to enable groups of patients, carers and their representatives to consider the issues in detail.
  - Discussion groups have been held with members of the public, patients, carers and healthcare professionals. The groups encompassed people from different geographical locations, social classes and age groups.
  - Meetings with groups of cancer clinicians and non-cancer clinicians were held.
  - The views of NHS managers were canvassed through meetings organised by the NHS Confederation, the Foundation Trust Network and the PCT Network.
  - A cross-party Parliamentary discussion event was organised.
-

- Members of the Review team attended meetings with a wide variety of stakeholders.
- Private discussion meetings were held with small groups of experts in conjunction with the King's Fund and the Nuffield Trust.

4.4 The views expressed have been crucial to enabling this Review to appraise potential options and make subsequent recommendations.

## **A “comprehensive” NHS?**

4.5 Most, but not all, stakeholders believe that the NHS should remain a comprehensive service, wherever possible offering the most effective treatments to patients. However, there is a general recognition that there is a limit to the level of services that the NHS can deliver and that this will inevitably lead to difficult decisions having to be made about the availability of treatments.

4.6 There is also a strong feeling that the NHS should be able to offer at least a comparable level of treatment to that available in other countries. Many stakeholders have the perception that, currently, some of the drugs that people have to purchase privately in England are available within the health services of some comparable countries. While there may be a variety of reasons for this, and international comparisons are not without difficulties, patients, the public and clinicians find this situation hard to understand.

***“It is difficult to accept that people in other countries with my condition can get these drugs.”***

*Lung cancer patient*

***“I find it very frustrating that I cannot offer my NHS patients the same treatments my European colleagues can.”***

*Oncologist*

4.7 There is broad support for the concept of NICE, and an acknowledgement that it performs a difficult but essential role in addressing a set of issues around value and trade-offs that are common to all health systems. However, many stakeholders expressed concern that:

- NICE technology appraisals are published too long after a new drug becomes available, resulting in variations in access to drugs in the period between licensing and publication of guidance; and
- current processes for determining whether drugs should be recommended for use in the NHS may not fully reflect the complexities of all medical conditions. In particular, challenges were identified with the appraisal of

treatments for rarer conditions and treatments for conditions where the patient had a very poor prognosis and might realistically be expected to be in the final months or years of life.

- 4.8 Concern was also expressed about the price of new drugs and it was felt that action to address this, including greater flexibility from the pharmaceutical industry, had an important role to play in improving access to medicines. In this context the decision to renegotiate the Pharmaceutical Price Regulation Scheme (PPRS) to better reflect the value that drugs deliver to patients was welcomed. Stakeholders were also encouraged by some of the recent arrangements to make drugs more cost-effective which have been agreed between the Department of Health and industry and appraised by NICE.

### National or local?

- 4.9 Many stakeholders support the principle that many decisions are best made by local NHS organisations which are in a position to understand the needs of their local population. However, there is strong concern that variations in practice in relation to the availability of drugs are undermining confidence in the NHS. In particular, stakeholders feel that:

- the variations in the processes used by PCTs to determine applications for exceptional funding for drugs are unacceptable; and
- the variations in the arrangements in place for when a patient wishes to purchase additional private treatment are unacceptable.

- 4.10 As set out in Chapter 2, there are substantial variations in the processes used by PCTs to determine whether to allow funding for treatment on an “exceptional” basis. Most stakeholders accept that there will be occasions when PCTs do refuse exceptional funding applications. However, concerns with exceptional funding processes have led many stakeholders to call for clear national guidance to be issued on how PCTs should conduct these processes. In particular, there is a desire for a clearer, more timely process, better quality decision making and better explanations of any decisions, preferably in writing. Overall, there is a strongly held view that the current variations mean that not every patient is afforded a “fair hearing”.

- 4.11 Chapter 3 set out how the current legislation and guidance on when and how patients can purchase additional treatment are being interpreted in varying ways. Patients reported that this variation was having a significant effect on their experience of care:

- Not all patients were told about drugs that were not available on the NHS but which might benefit them nonetheless.

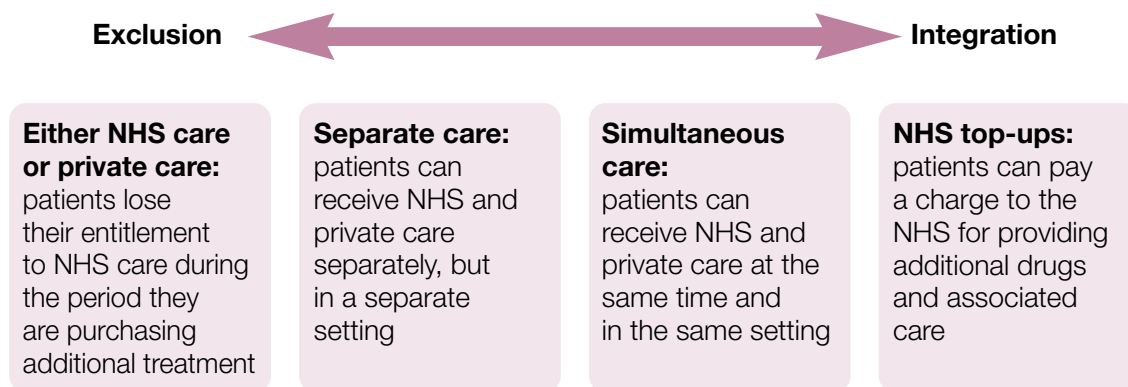


- Some patients were told that all existing NHS care would be withdrawn if they opted to purchase additional private treatment, but some patients were allowed to continue receiving care on the NHS.
- Patients who did opt to purchase additional private treatment were charged different amounts for the same drug.

4.12 There was near unanimous support from stakeholders for the government making clear what the policy is at a national level, so that there is a consistent approach across the country.

## Opinions on mixing NHS and private treatment

4.13 As described in Chapter 1, the Review has used a common framework in which to fit the views received. The options considered broadly range along a spectrum from excluding from the NHS patients who opt to purchase additional drugs to encouraging complete integration:



## Should NHS and private treatment be kept entirely separate?

4.14 The solution that ensures greatest separation between NHS and private care would entail patients losing their entitlement to NHS care if they choose to pay for additional private treatment for the same condition. Patients would therefore choose from the outset whether they wish to be a private patient or an NHS patient for the duration of their treatment for that condition. Stakeholders who advocate this approach argue that it ensures equity within the NHS system.

4.15 It is clear that some patients are being told that if they elect to purchase additional treatment then they will lose their entitlement to the NHS care that they would have otherwise received. However, other patients have been allowed to continue receiving NHS care so long as the additional treatment they have purchased is delivered in a private setting.

4.16 There was a strong consensus from stakeholders that withdrawing NHS care was wrong. Words used by patients and the public to describe this approach include “despicable”, “appalling”, “uncivilised”, “spiteful”, “cruel”, “abhorrent”, “perverse”, “inhuman” and “unjust”.

***“It’s unethical to deny patients basic care whichever way you look at it.”***

*Member of the public*

***“I understand that patients may have to fund their own medicine but withdrawing services is simply unacceptable.”***

*Patient*

***“Denying patients NHS care is scandalous, horrific and wrong.”***

*Nurse*

***“You can’t refuse to treat a patient who is paying for a drug that we can’t afford to give them.”***

*Hospital doctor*

4.17 Many NHS staff shared the feeling that this approach was unfair, even if there was an acceptance that this interpretation had been applied for the sound reasons of attempting to keep NHS and private treatment separate.

4.18 However, it is important to note that a small but significant minority felt that if a patient wishes to pay for a drug while other NHS patients may not be able to do so, the only way to protect equity is for that patient to renounce their entitlement to the collective care the NHS provides, and become a private patient for the entirety of the package of care.

**Most respondents to the Review felt that patients should not lose their entitlement to NHS care if they opt to purchase additional treatment**

Around three-quarters of respondents were in favour of allowing patients to purchase additional private treatment without losing their entitlement to NHS care. Roughly one in six believed that patients should have to choose between being an NHS patient and receiving all their treatment privately, and a small minority did not come to a definitive conclusion.

### **In what circumstances should patients be able to purchase additional drugs?**

4.19 Although there is a general view that patients should not lose their entitlement to NHS care, views on how and in what setting patients should be allowed to purchase additional drugs are much more polarised. A range of options could be envisaged which would enable patients to purchase

additional treatment without losing their entitlement to NHS care, including:

- separate care: patients can receive NHS and private care alongside each other, but in a separate setting;
- simultaneous care: patients can receive NHS and private care at the same time and in the same setting; and
- NHS top-ups: patients can pay a charge to the NHS for providing additional drugs and associated care.

4.20 There is no consensus about which of these is the optimum approach. Many people feel passionately that to allow either simultaneous care or NHS top-ups would breach the principle that treatment should be available free at the point of delivery, based on clinical need not ability to pay. These stakeholders argue that simultaneous care or NHS top-ups should not be allowed, because either system would mean two NHS patients on the same ward or day care unit receiving different treatment on the basis of their ability to pay. This feeling is strongest among NHS staff.

4.21 A further concern expressed during the Review is that if simultaneous treatment or NHS top-ups were allowed, it might be the “thin end of the wedge”, eventually leading to NHS care becoming a basic package which then has to be supplemented with private health insurance. Stakeholders who believe this argue that any move away from a genuinely comprehensive NHS would have significant equity implications, arguing that wealthier groups in society would then opt out of the NHS, so widening health inequalities.

***“What concerns me is that this is the beginning of a creeping development of the NHS cutting back from all sorts of things.”***

*Member of the public*

4.22 Set against this, many others felt that the separate care option establishes an artificial distinction that is unhelpful. NHS staff also expressed concern regarding quality and safety. The importance of patient convenience and continuity of care were also highlighted as an argument to support a more closely integrated approach. This feeling was strongest among patients and the public.

4.23 Some stakeholders also expressed a concern that the separate care option would, in reality, deny some patients the opportunity to purchase additional treatment, for example if a patient were too ill to move between NHS and private settings.

4.24 A small minority favoured introducing NHS top-ups in the belief that a fully tax-funded health service is unsustainable. They pointed to the fact that patients routinely supplement the state-based provision with copayments across Europe.

### Extracts from a letter sent to the Review

“Dear Prof Richards,

I am an advanced cancer patient and I recently filled in a questionnaire about top-up payments. I have little money but ticked the box allowing top-ups because how could I possibly deny this to a fellow patient. I sent off the form (and felt good).

Then I thought about it more deeply – the implications. Very wealthy people go private – no change there.

Moderately well-off NHS families will be put under enormous pressure at the worst possible time when they are coping with the imminent loss of a family member, and that family member with the loss of them and their life. This now strikes me as cruel.

The families who find the money may find themselves under considerable financial stress in the future. The families who do not may be left with a burden of guilt. What an inheritance.

This does not directly affect me as I have little money and therefore no choice. And yet it does affect me. Throughout my treatment... I have been cared for. Care implies much more than treatment. How would I feel when I approach my final days knowing that I am being let go because of cost while others in the same hospital are being held on to? How would my relatives feel? How would the doctors and nurses feel?

Comparisons have been made with state education and private tuition, but this is not a life or death issue, nor generally is dentistry... if the better off (who tend to be better educated and informed) are allowed to pay for top-ups they will not be motivated to argue for important treatments in the NHS as a whole.

I am not speaking from a position of moral superiority – if I had the money I would buy the best possible treatment, including top-ups, if allowed – but that is not the point. The principles of the NHS are important to all of us as a caring society both now and in the future.

Even in writing this I feel guilty that I might prevent a fellow patient from extending their life. I know this is not an easy decision and I wish you well with it.”

## Practical implications

4.25 A key principle for the Review is that any solution must be clear and enforceable. A number of stakeholders very helpfully highlighted practical considerations that any new approach must address. In particular, the NHS Confederation undertook extensive work with its members to identify issues that might affect implementation.

4.26 Practical questions identified by stakeholders include:

- What should be included in the pricing of the additional drugs?
- Should pricing be set nationally or locally?
- How should billing be arranged?
- How would debts to the NHS be recovered? Should patients be asked for upfront payments? Could costs be charged to a patient's estate after their death?
- Should the NHS pick up the costs of treatment for patients who are responding to treatment and may therefore argue that the treatment is effective in their individual case?
- How broadly or narrowly should the list of treatments for which patients can make additional payments be defined?
- If a narrow set of criteria (e.g. declined by NICE) were set, would this be the thin end of a wedge?
- Would private payment for additional drugs breach the cap on private income set for Foundation Trusts?
- Should patients be entitled to a second opinion regarding the benefits/harms of treatments for which they would have to pay? If so, who would pay for the consultation?
- Should clinicians who object to patients purchasing additional private drugs be allowed to opt out of prescribing in these circumstances?
- How would medico-legal responsibility be handled between an NHS provider and a private provider?
- How can the delivery of balanced information to patients best be ensured?

### Financial implications

- 4.27 There was a general view that NHS organisations and clinicians should neither benefit nor suffer financially from a patient's decision to purchase additional treatment.
- 4.28 Stakeholders felt that NHS organisations should not financially suffer from any decision by a patient to purchase additional treatment. This was seen as important, as it would ensure that NHS resources are not diverted away from treating other patients requiring NHS treatment. In practice this means that patients purchasing additional drugs should pay the full commercial cost of the drug, as well as any predictable additional costs such as those relating to the administration of treatment.
- 4.29 Modern drug treatment, particularly for life-threatening conditions, is not without its risks. There was little consensus about whether patients who purchase additional private treatment should be required to pay for the management of complications from that treatment. Some stakeholders pointed out that, unless these costs were recovered, other NHS patients would effectively be disadvantaged as resources would have to be diverted away from other services to pay for the management of complications. However, others argued that the NHS currently treats other patients who have suffered complications as a result of private sector treatment and this should be seen as no different.
- 4.30 Although there was support for the principle that NHS organisations should not financially suffer from a patient's decision to purchase additional treatment, it was also felt that clinicians or hospitals should not financially benefit from the situation. Otherwise a "perverse incentive" could be put in place whereby there might be a perception that patients would be encouraged to purchase additional drugs which might not benefit them.

### Communications issues

- 4.31 Many stakeholders raised the potential impact that discussions about unfunded drugs could have on the relationship between patients and clinicians.
- 4.32 A large majority of stakeholders felt that doctors should discuss all treatment options that they feel could have clinical benefit with their patients, whether or not the treatment is available on the NHS. This is in line with the *Cancer Reform Strategy* and guidance issued to doctors from the General Medical Council.
- 4.33 However, as outlined in Chapter 2, evidence suggests that some doctors are not informing patients of all treatment options, irrespective of whether they will be funded by the NHS. In addition, a recent study from South West England indicated that many cancer patients were not being given

clear information about the survival gains to be expected with palliative chemotherapy (Audrey et al., *BMJ*, 2008).

- 4.34 Both patients and clinicians felt strongly that balanced information about the costs and benefits of different treatment approaches will be vital to enable patients to make an informed choice about whether to proceed with an additional drug treatment. It was felt that doctors may need additional training to help them communicate with patients effectively during these difficult conversations.

## Part 3: Recommendations

### Chapter 5 – Minimising the need for patients to purchase additional private drugs

- 5.1 As set out in Chapter 2, the drugs that patients are seeking to gain access to fall into three main categories:
- drugs on which NICE has yet to issue final guidance;
  - drugs that NICE will not appraise or that a clinician wishes to use “off label”; and
  - drugs that NICE has declined to recommend for use in the NHS.
- 5.2 During this Review stakeholders have expressed a strong desire for the NHS to continue to provide a comprehensive service and a belief that, for it to do so, it should be providing a similar range of treatments to those available in other countries.
- 5.3 As identified in Chapter 2, there are a variety of explanations for international differences in the usage of medicines, including funding, capacity, clinical attitudes and health technology assessment processes.
- 5.4 The Review has identified a series of actions that could be taken to minimise the number of patients who wish to fund additional private treatment in each of the three categories set out above, and to improve the way in which the local NHS makes decisions on funding treatment.

#### Improving the timeliness of the NICE technology appraisal process

- 5.5 A number of steps have already been taken to improve the timeliness of NICE guidance, including the introduction of the Single Technology Appraisal process which has been used successfully for drugs such as trastuzumab. However, there has been an inevitable time lag in its application as the default process for the appraisal of new drugs and its benefits has not yet been fully realised. The commitment in *High Quality Care For All* to continue to speed up the NICE decisions is therefore extremely welcome.
- 5.6 **Recommendation 1: The measures the government is already taking to improve the timeliness of the NICE decision making process are extremely welcome and should be strongly supported. The Department of Health and NICE should publish an update on the timelines for delivering these important commitments.**



## Improving PCT decision making

- 5.7 However, there will always be occasions when NICE guidance is not available, because a drug has only just been licensed, it is licensed for a rare condition that NICE will not assess, or a clinician wishes to use it outside its licensed indication.
- 5.8 In these circumstances PCTs, as the bodies with the legal responsibility for commissioning, will have to make often very difficult decisions about whether to provide funding for a drug.
- 5.9 Where NICE has made a decision not to recommend the routine use of a drug in the NHS or where no NICE guidance is available and a PCT has established a clear and rational policy that a drug will not normally be funded, PCTs, as the statutory decision maker, have a legal obligation to make case-by-case decisions on exceptional funding requests, taking into account the circumstances of each individual.
- 5.10 However, it is apparent that some PCTs are using exceptions processes inappropriately, as a substitute for making a proper commissioning decision on a drug. Exceptional funding committees should be there to consider, in light of the facts of an individual case, whether an exception to the general funding policy should be made, and not to define the general funding policy of the PCT.
- 5.11 PCTs therefore need to work proactively to ensure that proper funding policies are in place, rather than relying on ad hoc policies being developed through exceptional funding committees. There is a strong case for PCTs to work more collaboratively on making funding decisions, pooling expertise and avoiding unnecessary duplication of effort. SHAs will have an important role to play in encouraging this collaborative working. It is important to be clear, however, that local collaborations between PCTs on decision making will not result in completely uniform decisions across the NHS, because there are often genuinely difficult issues to weigh up and local priorities and resources may differ.
- 5.12 **Recommendation 2: The Department of Health should urgently consider how PCTs can be encouraged to work together to make proactive commissioning decisions. Consideration should be given to whether collaborative processes already developed, such as in the North East for cancer drugs, could be used as a model.**

### **North of England Cancer Drug Approval Group (NECDAG)**

The North of England Cancer Drug Approval Group (NECDAG) was established in May 2006 with the mission of ensuring that all patients with cancer in the North East receive equitable access to a clinically defined appropriate range of cancer medicines.

The NECDAG serves all of the North of England Cancer Network organisations, encompassing nine Acute Trusts, five Primary Care Organisations and several Hospices/Specialist Palliative Care services, and spans two SHA areas. North Yorkshire and York PCT representatives also attend these meetings as observers. The NECDAG considers applications for drugs that are not in the NICE system or are more than six months away from being considered by NICE.

Those involved in the NECDAG have identified the following elements as central to its success:

- the backing and support of the SHAs in the North East and in Cumbria;
- close integration with the North of England Cancer Network and with the SHA;
- clinical involvement from oncologists, both in supporting applications and as members of the committee;
- commitment from PCTs to collective decision making to ensure equity for patients; and
- strong leadership and close links with NHS senior management.

### **Determining exceptional cases**

5.13 There will of course be occasions when decisions should be made on an exceptional case basis. These might include when NICE has declined to recommend a drug for use in the NHS, often on the grounds of cost-effectiveness, but a clinician believes there is a compelling case why a patient should be treated as an exception.

5.14 The exceptional funding committees of each PCT should continue to consider individual requests for any exceptions to be made to general funding policies, although they could draw on collaborative expertise to support that process. It is well worth noting that better initial commissioning decisions have been shown to result in significantly fewer exceptional funding applications.

- 5.15 Many stakeholders have expressed strong concern about the current variability in the processes used by PCTs to determine exceptional cases. Patients have expressed concern that the process is often unclear and lengthy with decisions not being fully explained. There is a strong case for PCTs reassessing their policies to ensure a clearer, more timely process, better quality decision making and better explanations of decisions, preferably in writing.
- 5.16 **Recommendation 3: The commitment made in the draft NHS Constitution to ensure transparency in PCT decision making, and the resulting work being undertaken by the Department of Health to support PCTs in delivering this, is extremely welcome. The government should set out as soon as possible more detailed plans for how it will achieve the commitment in the NHS Constitution, including the timescale for this work.**

***“You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.”***

*Draft NHS Constitution*

## **Handling off-label usage**

- 5.17 The licensing process for new drugs is a very important part of protecting patients and ensuring that the drugs that they take for their condition are safe. Clinicians do have the flexibility to prescribe drugs outside of their licensed indication where there is a reasonable prospect that the drug will lead to clinical benefit, but they must be clear about their responsibilities in doing so, and must make sure that the patient is aware of the possible risks and benefits. This is known as off-label usage of a drug and usually arises when the underlying disease process is similar to that for which the drug does have a licence.
- 5.18 The individual illnesses where this occurs are relatively uncommon, though collectively the demand for such treatments is significant. Manufacturers are unlikely to undertake all the research needed to file for additional licences for these conditions and NICE only appraises drugs within their licensed indications.
- 5.19 There are particular challenges for PCTs in making decisions about funding of drugs outside their licensed indication. For example, these requests may occur in very small numbers and there is likely to be little or no published information to inform decisions. This is another area where better collaborative use of expertise can support PCTs in making better quality

decisions on such applications. An individual clinician needs to retain clear responsibility for the decision to prescribe an off-label drug to an individual patient, and to make sure that the patient understands any potential risk.

- 5.20 **Recommendation 4: In developing collaborative arrangements for decision making, the government should also consider how PCTs can be better supported to make decisions on funding off-label drugs, whether as a matter of policy or on an exceptions basis.**

### Reassessing the availability of drugs

- 5.21 As set out in Chapter 4, there is a common perception that the value that society places on supporting patients nearing the end of their life is not sufficiently reflected in assessing the cost-effectiveness of new drugs. There is a general view among stakeholders that drugs to treat patients in the last months or years of life should be regarded as having a very high priority. Unless a new approach is found, significant numbers of NHS patients will be placed in the position where they have to consider purchasing additional drugs.
- 5.22 In the past, NICE has been able to recommend to the NHS the use of many drugs used to treat patients in the last months or years of their life within the boundaries of its existing approach to interpreting cost-effectiveness. However, the emergence of increasing numbers of drugs that are targeted to treat often relatively small groups of patients for a short period of time near the end of their life will challenge existing processes. There is a strong case both for introducing new arrangements for assessing these drugs on behalf of the NHS, and for complementary efforts on the part of the pharmaceutical industry to be more flexible in their approaches.
- 5.23 There are measures that the Department of Health, NICE and the pharmaceutical industry could take to increase the availability of drugs to NHS patients. These might include introducing greater flexibility into cost-effectiveness thresholds to reflect the challenges inherent in drugs used near the end of a patient's life for less common and rare conditions, as well as variable pricing and a greater emphasis on improving affordability of and access to new drugs. These might also build on the use of new pricing models such as the bortezomib and ranibizumab schemes. These schemes have allowed pharmaceutical companies to make their drugs more affordable, and NICE to approve them as cost effective and ensure patients have access to drugs that would not otherwise have been available to them through the NHS. While application of these schemes is limited by the administrative burden on the NHS, the industry and government might build on this experience of a flexible approach to develop further ways in which the availability of drugs to patients could be improved.

5.24 **Recommendation 5: The Department of Health should work:**

- **with NICE to assess urgently what affordable measures could be taken to make available drugs used near the end of life that do not meet the cost-effectiveness criteria currently applied to all drugs; and**
- **with the pharmaceutical industry in the context of the current Pharmaceutical Price Regulation Scheme (PPRS) negotiations to promote more flexible approaches to the pricing and availability of new drugs. This will require partnership working with the pharmaceutical industry and greater flexibility in approach from all parties.**

### **Understanding international variations in drug usage**

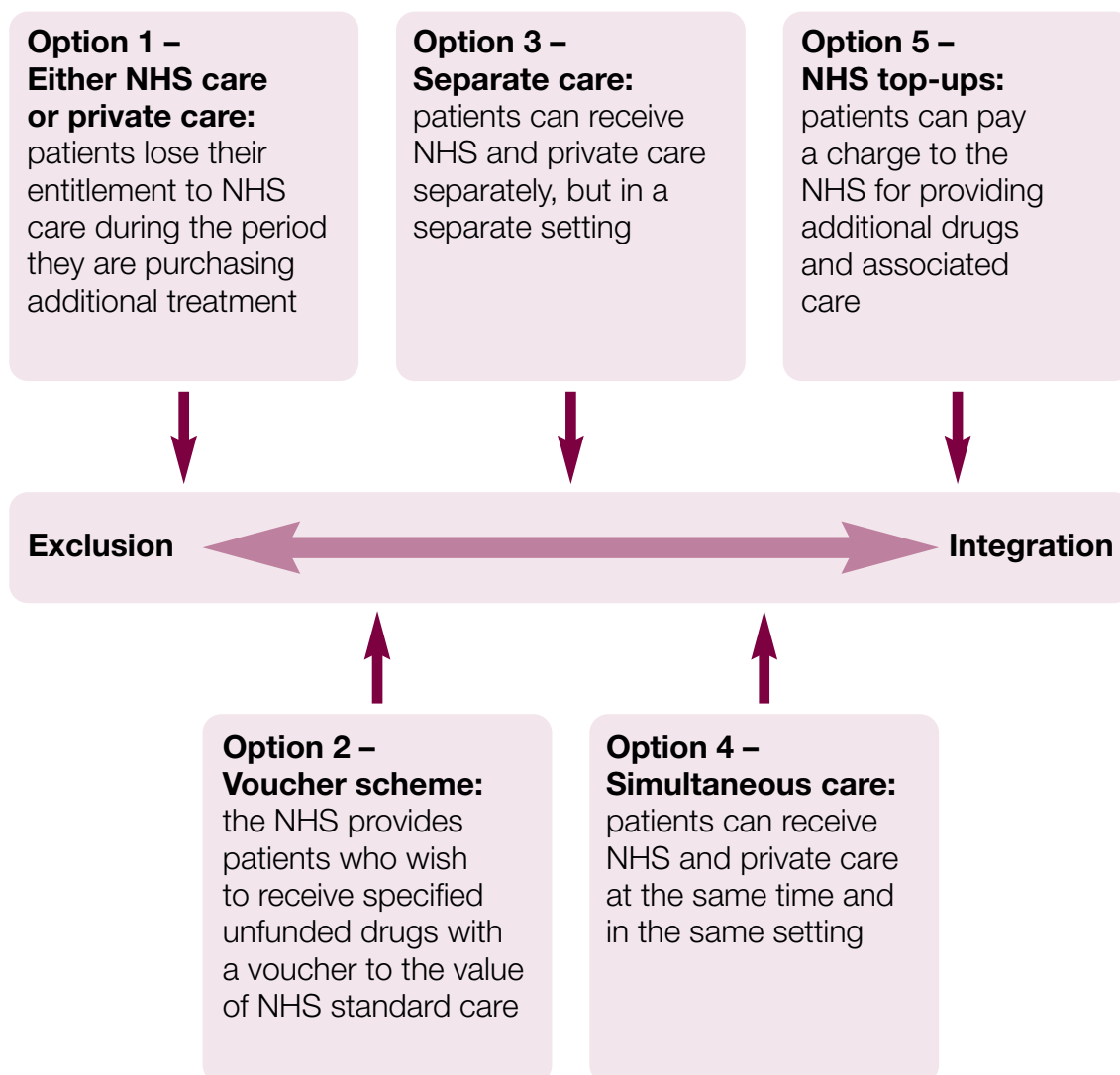
5.25 As set out in Chapter 4, there is a perception among stakeholders that usage of new drugs for some conditions is low in England when compared with other countries. This supports evidence that already exists for cancer medicines. However, there are technical challenges in comparing international drug usage and the extent, reasons for and implications of any international variations are not fully understood. Developing a more comprehensive picture of international drug usage will be important in informing future policy decisions on funding for drugs.

5.26 **Recommendation 6: The Department of Health should urgently undertake further work to investigate the extent and causes of international variations in drug usage.**

## Chapter 6 – Clarifying national guidance on additional drugs

- 6.1 There is a strong belief that the number of patients who are placed in a position where they have to purchase additional treatment should be kept to a minimum and the recommendations set out in Chapter 5 provide a framework for achieving this objective. However, it is inevitable that some patients will always wish to purchase treatment that is not available on the NHS.
- 6.2 Stakeholders are clear that they wish to see a national approach to the challenging issue of when and how patients should be able to purchase additional treatment and the findings of this Review support this view.  
**Recommendation 7: The Department of Health should clarify the policy on how the NHS should handle situations where a patient wishes to purchase additional treatment. The objective should be to ensure consistency in practice across the NHS.**
- 6.3 This chapter:
- sets out in more detail the potential options that exist on the spectrum from ensuring complete separation between NHS and private care to encouraging full integration;
  - evaluates five potential options that have been identified across this spectrum; and
  - makes recommendations about the approach that should be adopted in national guidance.

## Potential options



### Option 1: Either NHS care or private care

6.4 The solution that ensures greatest separation between NHS and private care would entail patients losing their entitlement to NHS care if they choose to pay for additional private treatment for the same condition. Patients must therefore choose from the outset whether they wish to be a private patient or an NHS patient for the duration of their treatment for that condition. Stakeholders who advocate this approach argue that it ensures equity within the NHS system.

### Option 2: Voucher scheme

6.5 This would mean that patients who choose to pay for additional private drugs would be issued with a voucher to the value of the care they would have received on the NHS, which could be used to buy care either from an

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independent sector provider or the NHS acting as a private provider. Once in the private setting for the entirety of their NHS care, they could then choose to pay for additional services such as drugs. Stakeholders who advocate this approach argue that it promotes patient choice while maintaining the separation between NHS and private care.

### Option 3: Separate care

- 6.6 This approach ensures that patients are able to purchase private care, in the private sector, while they continue to receive NHS care for the same condition. The private provider could be an independent sector organisation or a private facility within an NHS organisation. The private provider would charge the cost of the drug itself, plus any costs associated with its delivery. This would mean that patients are not penalised for choosing to enter into arrangements with private providers to provide additional services, but they must receive this additional care in parallel to their NHS care. Stakeholders who support this approach argue that it does not result in patients losing access to NHS care they would have otherwise received, while also ensuring that patients within the NHS are not treated differently.

### Option 4: Simultaneous care

- 6.7 This approach enables greater integration, with patients being able to receive NHS and private care at the same time, in the same setting, alongside other patients who would not be paying for additional treatment. The NHS, acting as a private provider in this instance, would charge the cost of the drug itself, in addition to any costs associated with its delivery. Stakeholders who advocate this approach argue that it encourages good clinical governance and is more convenient for patients.

### Option 5: NHS top-ups

- 6.8 The most integrated solution is to introduce a system of NHS top-ups whereby patients pay a charge to the NHS to receive drugs that are not available to all NHS patients free of charge. This would mean that the NHS is given a new power to charge for drugs that are not funded on the NHS. The patient would remain an NHS patient throughout and would receive this additional service alongside patients who could not afford the NHS charge. In order not to divert funds away from other NHS patients, the NHS charge would include the cost of the drug in addition to any costs associated with its delivery. Stakeholders who advocate this approach argue that it enables patients to stay within the NHS system and so enables the NHS to exercise greater control over the charges that may be applied to patients.

### Criteria for options appraisal

- 6.9 These options have been evaluated against a range of criteria, which reflect the principles set out in Chapter 1 of this report. The feedback received
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from stakeholders during the Review has been invaluable in evaluating these options and developing recommendations. Any chosen option will also have to comply with equality and competition legislation.

- The need to protect the founding principles of the NHS: universality, comprehensiveness, equity, free at the point of need and removing people’s financial worries.
- The need to protect a patient’s right to seek to extend his or her life through whatever means necessary.
- The potential impact on public and patient confidence in the NHS.
- The need to ensure that NHS patients are not disadvantaged by another patient’s choice to buy additional private drugs.
- The potential impact on quality and safety of care for the individual patient.
- The ease of implementation and enforceability for the NHS.
- The potential cost to the NHS and to individuals.

## Options appraisal

### Option 1: Either NHS care or private care

Criteria	For	Against
Protect founding principles of NHS	Patients on NHS wards will receive care based on their clinical need not ability to pay.	
Protect patient’s right to try to extend life		Patients who want to pay for drugs not provided in the NHS will have to find the money to pay for the entirety of their care. This will be prohibitively expensive for many patients.

## Improving access to medicines for NHS patients

Impact on confidence in the NHS	Some NHS staff feel that relaxing this rule would lead to a two-tier service which would ultimately lead to a lack of confidence in the NHS.	Stakeholders are broadly opposed. They feel it is unfair to deny NHS care that would have otherwise been given.
Ensure other NHS patients are not disadvantaged	All patients will receive the same care within the NHS.	Those patients who want to pay will be prevented from doing so.
Potential impact on quality and safety of care		Patients who are desperate to prolong their lives might access private drugs without telling their NHS clinician so as not to lose their entitlement to NHS care. This could have serious safety implications.
Ease of implementation and enforceability	Many Trusts are already maintaining this policy.	It would be very difficult for Trusts to know if patients decide to break the rules. Many Trusts and individual clinicians will look for ways round the rules as they feel the policy is unfair to patients.
Potential cost to NHS and individuals	There will be no additional costs to the NHS. The NHS will save money as a result of some patients transferring entirely to the private sector.	Many patients will simply be unable to afford the cost of paying for their whole treatment as this may run into several thousands of pounds.

## Option 2: Voucher scheme

<b>Criteria</b>	<b>For</b>	<b>Against</b>
Protect founding principles of NHS	Patients on NHS wards will always receive care based on their clinical need not ability to pay.	Patients who can afford to pay will be subsidised to “opt out” of the NHS.
Protect patient’s right to try to extend life	All patients will have the choice to buy additional private drugs from the private sector.	Many patients will be unable to afford additional private treatment. As the value of the NHS voucher is likely to be less than is needed to pay for equivalent care in the private sector, patients would have to supplement the voucher with their own money in addition to paying for the additional drug and any costs associated with its delivery.
Impact on confidence in the NHS		Many patients will be very unhappy about having to leave the NHS for all their care. They may feel they are being “abandoned” by their local NHS hospital, especially if there is no private hospital nearby.
Ensure other NHS patients are not disadvantaged	As the private sector organisation will charge the full commercial cost of providing the additional private drug, the NHS will not be subsidising those patients who choose to pay for additional drugs privately.	There may be some costs associated with complications that arise as a result of the private drug which the NHS ends up picking up. A voucher scheme would also divert resources away from NHS organisations.

Potential impact on quality and safety of care	Patients will not need to take risks by taking private drugs without telling their NHS doctor. Having all treatment under the supervision of one doctor will be better for continuity of care.	
Ease of implementation and enforceability		Such a scheme would be complicated and difficult to administer. It would be difficult for the NHS to estimate the value of the voucher.
Potential cost to NHS and individuals		The NHS may have to pick up the cost of complications as a result of private drugs and increased administrative costs. Patients will have to pay more under this option than under options 3, 4 and 5.

### Option 3: Separate care

<b>Criteria</b>	<b>For</b>	<b>Against</b>
Protect founding principles of NHS	Patients on NHS wards will receive care based on their clinical need not ability to pay.	
Protect patient's right to try to extend life	Patients will have the choice to buy additional private drugs from the private sector.	Many patients will be unable to afford additional private treatment.
Impact on confidence in the NHS	Patients, the public and NHS staff are likely to feel that this is a fair policy for patients.	
Ensure other NHS patients are not disadvantaged	As the private sector will charge the full commercial cost of delivering the NHS care, the NHS will not be subsidising patients who pay privately at the expense of NHS patients.	There may be some costs associated with complications that arise as a result of the private drug which the NHS ends up picking up.
Potential impact on quality and safety of care	Patients will not need to take risks by taking private drugs without telling their NHS doctor.	Steps will have to be taken to ensure continuity of care as patients will be receiving different care from the NHS and the private provider (although this will often be the NHS).
Ease of implementation and enforceability	Some Trusts are already maintaining this policy. Those NHS Trusts already providing private services will already have the necessary framework for charging patients.	If the numbers seeking to purchase additional private treatment are high, this could cause difficulties for Foundation Trusts because of the cap on private income.

<p>Potential cost to NHS and individuals</p>	<p>Patients will pay significantly less for the cost of the drug and its delivery than the cost of the whole of their treatment for that condition. As the NHS can choose whether to provide the drug as a private service, and can charge a fee that covers all its costs, there should be very little additional cost to the NHS.</p>	<p>The NHS may have to pick up some of the costs of complications as a result of private drugs.</p>
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## Option 4: Simultaneous care

Criteria	For	Against
Protect founding principles of NHS		Patients on NHS wards will regularly receive different care based on their ability to pay. This has substantial implications for equity in the NHS.
Protect patient's right to try to extend life	Patients will have the choice to buy additional private drugs from the private sector.	Many patients will be unable to afford additional private treatment.
Impact on confidence in the NHS		Patients who cannot afford to pay for additional private drugs while the NHS provides them privately to other patients in the same ward are likely to feel that the NHS has let them down.
Ensure other NHS patients are not disadvantaged	As the NHS acting as a private provider will charge the full commercial cost of delivering the additional drug, the NHS will not be subsidising patients who pay privately at the expense of NHS patients.	There may be some costs associated with complications that arise as a result of the additional drug which the NHS ends up picking up.
Potential impact on quality and safety of care	Patients will not need to take risks by taking private drugs without telling their NHS doctor. Receiving the private drug alongside NHS care will be better for continuity of care.	

Ease of implementation and enforceability	Those NHS Trusts already providing private services will already have the necessary framework for charging patients.	A significant number of Trusts do not provide private services and would therefore need to develop this capacity.
Potential cost to NHS and individuals	Patients will pay significantly less for the cost of the drug and its delivery than the cost of the whole of their treatment for that condition.	There may be some costs associated with complications that arise as a result of the additional drug which the NHS ends up picking up.



## Option 5: NHS top-ups

Criteria	For	Against
Protect founding principles of NHS		NHS patients will routinely receive different care according to their ability to pay. As it will be the NHS offering the additional service as an “add on” to what the NHS usually provides, the equity implications are significant. This would be a two-tier service within the NHS – with extra services only available to those who pay. This would breach the core principles of the NHS.
Protect patient’s right to try to extend life	All patients will have the choice of paying to access additional drugs not usually funded by the NHS.	Many patients will be unable to afford the NHS top-up.
Impact on confidence in the NHS	Some patients will feel more confident in the NHS as they will know the NHS can provide every treatment option available, although some options would carry a charge.	The NHS will be in the perverse position of charging for treatments that have not been deemed as cost effective. Some patients will feel badly let down by the NHS as it will be selling services to those who can afford them. Even though many of these drugs have marginal clinical benefit over existing treatments, patients who cannot afford them may feel very strongly that they are being denied access to a potentially life-saving treatment.

Ensure other NHS patients are not disadvantaged	As the NHS charge will encompass the full cost of delivering the additional drug, the NHS will not be subsidising those patients who choose to pay for additional drugs privately.	There may be some costs associated with complications that arise as a result of the additional drug which the NHS ends up picking up.
Potential impact on quality and safety of care	Patients will not need to take risks by taking private drugs without telling their NHS doctor. Having all treatment under the supervision of one doctor will be better for continuity of care.	
Ease of implementation and enforceability		A new system of NHS charging would have to be introduced, requiring legislation. This would involve identifying a list of all treatments for which patients should be charged and defining appropriate prices.
Potential cost to NHS and individuals		The NHS may have to pick up the cost of complications as a result of private drugs and increased administrative costs.

6.10 The potential impact on equality of each of these options has been considered in detail, and there is no evidence to suggest that there are any potential inequalities on the basis of race, gender, disability, age or sexual orientation. All of these options do present affordability issues for patients and that is why the recommendations in Chapter 5 aim to ensure that as few people as possible seek to purchase additional private drugs. The overriding aim of the Review has been to promote equality of access for all patients.

## Recommendations for making the policy clear

- 6.11 The issue of patients seeking to purchase additional treatment is complex and emotive and there is no consensus on the most appropriate way forward. However, it is clear that stakeholders expect the government to take a lead on this issue by making clear the policy, so enabling a more uniform approach to be adopted across the NHS in England.
- 6.12 Forcing patients to choose between either NHS care or private care (Option 1) is untenable given the strength of stakeholder feeling on the issue. There is a significant concern that patients put in this position may purchase private care, including drugs from the internet, without informing their NHS care provider. This would have significant safety issues. **Recommendation 8: The Department of Health should make clear that no patient should lose their entitlement to NHS care they would have otherwise received, simply because they opt to purchase additional treatment for their condition.**
- 6.13 The question then becomes one about how the NHS should handle the situation where a patient wishes to purchase additional treatment. As set out above, there are several ways in which this could be achieved and the benefits and drawbacks of the different options are finely balanced.
- 6.14 Options 2 (voucher scheme) and 3 (separate care) both preserve a high degree of separation between NHS care and private care. Options 4 (simultaneous care) and 5 (NHS top-ups) provide varying degrees of integration, with Option 5 offering a fully integrated system. None of these options is without practical difficulties.
- 6.15 Option 2 (voucher scheme) means that all patients would have the option to have additional private drugs. A patient's entire care would take place in the private sector separate from NHS patients on NHS wards. However, it is by far the most expensive way for patients to access private drugs as patients will have to pay to supplement their NHS voucher to secure the same level of care in the private sector before they even pay for additional treatment. For patients, it is therefore the most inequitable way of delivering a system in which patients are able to buy additional private drugs because it will significantly reduce the number of people who will be able to afford them.
- 6.16 The most affordable and convenient option for the patients who do want to buy private drugs is Option 5 (NHS top-ups) as the NHS would deliver the private drugs at cost price on an NHS ward. This option could therefore ensure consistency in how much patients would be charged for additional drugs. However, for every other NHS patient, this is by far the most overtly inequitable option, as the NHS will routinely provide treatment, on NHS wards, according to ability to pay. Patients who cannot afford to pay will feel let down by the NHS. The NHS would also be in the perverse position of charging for treatments that have not been deemed as cost effective. There are also significant practical difficulties associated with accurately costing additional drug treatments and forecasting implications for NHS capacity.

- 6.17 Option 3 (separate care) would allow patients to buy additional private drugs from the private sector and for these to be delivered in a setting separate from routine NHS care. This ensures that there is a separation between NHS and private care, with all NHS patients receiving the same level of care on NHS wards irrespective of their ability to pay. Not all NHS hospitals will have private facilities or a private hospital nearby. In these circumstances there may be practical difficulties in implementing the parallel arrangements which would have to be addressed (see box on page 59).
- 6.18 Option 4 (simultaneous care) would remove some of these problems by allowing patients the right to have additional private drugs, as a private service, at the same time as their NHS care, on an NHS ward. Although this would give all patients the same opportunity and remove the challenges created by the lack of private facilities in some areas, the implications for other NHS patients would be significant, resulting in patients on the same ward routinely receiving different treatment according to their ability to pay, and not their clinical need. It could also result in different patients being charged different amounts due to variations in clinician practice. This may have a significant impact on public confidence in the NHS. It would also pose practical difficulties in terms of accurate costing and planning appropriate capacity.
- 6.19 The choice between options 3, 4 and 5 is finely balanced. Taking all these considerations together, and as long as overall access to new medicines is improved in line with earlier recommendations, the separate care option has the fewest downsides. However, before clinicians discuss the potential to pursue separate care with individual patients, they should satisfy themselves that all reasonable avenues for securing NHS funding have been exhausted.

### Proposed options for funding drugs

- If a drug has positive NICE technology appraisal guidance for the relevant indication then it must be made available on the NHS.
- If not, a PCT may have a local policy to fund the treatment, perhaps based on collaboration with other PCTs or, in the case of cancer drugs, advice from a cancer network. In this case it should be made available on the NHS.
- If not, a clinician can apply to a PCT for exceptional funding. If this is successful, treatment should be funded on the NHS.

Only once these options have been exhausted should a patient have to consider whether he or she wishes to purchase the additional treatment privately.

6.20 **Recommendation 9: The government should make clear that:**

- **clinicians should exhaust all reasonable avenues for securing NHS funding before a patient considers whether to purchase additional drugs;**
- **patients should be able to receive additional private drugs as long as these are delivered separately from the NHS elements of their care; and**
- **providers should establish clear clinical governance arrangements to ensure that patients who do elect to purchase additional private treatment receive good continuity of care.**

6.21 If the recommendations made in Chapter 5 are implemented, the number of patients who may wish to purchase additional drugs will be kept to a minimum. Nonetheless, circumstances may still arise where a patient wishes to receive an additional drug privately. Arrangements for providing separate care will differ between localities depending on the availability of facilities. However, it would be good practice for each health economy to have in place arrangements that enable patients to receive separate care. This might include using existing private facilities within the NHS, a specially designated area within an NHS Trust, a private hospital, or making use of homecare provision. **Recommendation 10: Strategic Health Authorities, working where appropriate through cancer networks, should ensure that local policies are developed to ensure that any revised guidance issued by the government is implemented properly. This might include using a designated hospital with private facilities for all patients wishing to purchase additional drugs, making use of homecare provision or designating an area of an NHS hospital for the delivery of privately funded treatments.**

### Separate care in practice – cancer as a worked example

Implementation of separate care would need to take account of the availability of local services, but should maintain the key principles of not disadvantaging other NHS patients and keeping private and NHS care separate.

- Local protocols should take account of access to NHS private facilities, independent sector private facilities and home healthcare facilities. It would seem sensible to take a cancer network-wide approach to implementation.

- Each step of the chemotherapy care pathway would need to be considered in local protocol development, i.e. patient assessment and decision making, prescribing, dispensing, delivery, post-treatment monitoring and management of complications. Billing issues will also need to be considered if the private element of care is delivered in an NHS facility.
- Patient assessment and decision making regarding unfunded drugs should always be undertaken by a consultant in partnership with the patient. A strong case can be made on safety grounds for a single consultant to be in charge of both the NHS and private aspects of a patient's care. Safeguards would, however, be needed to ensure that personal financial interest does not influence consultants' recommendations.
- Dispensing of privately funded NHS drugs might be undertaken by an NHS pharmacy (if the treatment is to be delivered on NHS premises) or by a private provider.
- Delivery of the privately funded drugs could be undertaken in a variety of settings, e.g:
  - A dedicated private facility within an NHS Trust
  - A specially designated area for those Trusts without private facilities
  - A private hospital
  - At home by a private healthcare provider
- Monitoring would normally be undertaken within the NHS as patients will in any case need to be followed up for their cancer and for the NHS-funded aspects of treatment. Any additional tests related specifically to a privately funded drug will need to be charged for.

### Monitoring and audit

6.22 It has become clear during the Review that there is little accurate information on the actual level of demand for unfunded drugs. Such information will be important in monitoring the implementation of the new guidance, assessing variations in clinical practice and ensuring that the principles outlined in Chapter 1 of this Review are safeguarded. Data on the instances in which

clinicians discuss unfunded drugs with patients, the uptake of these drugs and the outcome of such treatments would provide valuable information on demand and on cost-effectiveness.

- 6.23 **Recommendation 11: The Department of Health should take a lead on commissioning a national audit of demand for unfunded drugs and on the outcome of treatments, working closely with professional organisations and NHS managers.**

## **Information and communication between doctors and patients**

6.24 Work commissioned as part of the Review demonstrates the very difficult nature of the discussions that take place between doctors and patients about new drugs that are not routinely available on the NHS. Patients have reported that how such information is communicated can be vital to enabling a patient to make an informed choice. Poor communication skills can damage the relationship between clinicians and patients. Conversely, good communication can improve levels of trust.

- 6.25 **Recommendation 12:**

- **Doctors who are likely to have conversations with patients about treatments that are not routinely funded on the NHS should ensure that they have the necessary knowledge and skills to communicate complex information effectively and in a balanced way. This will help patients to make informed assessments about the balance of risk, cost and benefit involved in any potential treatment.**
- **The Department of Health should commission a training programme for clinicians to enhance the quality of discussion about these difficult issues.**
- **Relevant Royal Colleges should consider how assessment of communication skills could best be incorporated into recertification processes.**

6.26 Throughout the Review the need for high quality written information to supplement face-to-face communication was emphasised. Written information, giving a balanced view of the benefits, toxicities and, where appropriate, costs of treatments should be widely available. This could potentially be developed by NICE, working in partnership with professional and patient groups. For cancer drugs, this should be linked with the existing patient information pathway initiative.

- 6.27 **Recommendation 13: The Department of Health should consider how patients could best be given access to balanced written information on the benefits, toxicities and, where appropriate, costs of novel treatments, especially those given to patients near the end of life.**

### Non-drug treatments

- 6.28 The terms of reference for the Review relate specifically to the purchase of additional drugs. However, stakeholders have also drawn attention to issues relating to devices and procedures that do not involve drugs and suggested that national guidance should also apply to non-drug interventions. It appears that, in many instances, separate care as advocated in this Report for drug treatments is already well established for devices.
- 6.29 Detailed consideration of these issues is beyond the scope of the Review and so has not been undertaken. However, requests for clarity on these issues have been heard during the course of this Review. **Recommendation 14: In responding to this Review, the government should confirm how situations where patients wish to purchase additional non-drug interventions should be handled.**



## Appendix 1: Department of Health survey of PCTs

PCTs in England were asked to respond to a survey intended to gain an understanding of how exceptional funding procedures are currently being used and to give an indication of the demand for drugs not routinely funded on the NHS.

Overall, the results showed great variation in relation to drug approval practices and exceptional circumstances procedures. The findings of this survey are strongly supported by those of a similar piece of work commissioned by the Rarer Cancers Forum (which was, however, limited to assessment of cancer drugs).

### Response rate

- Overall, 80 PCTs responded in full to the questionnaire, with a further 6 providing partial responses.

### Applications

- A total of 14,133 exceptional circumstances requests were made in the last year to the 80 PCTs that responded in full (equivalent to around 26,000 applications for England as a whole).
- Individual PCTs received total applications ranging from one to 1,017, with a mean of 177 per PCT.
- Around 8,000 of the applications related to drug treatments (equivalent to around 15,000 drug applications for England as a whole). Of these 26% were for cancer and 74% for non-cancer conditions.
- 13% of PCTs surveyed had funded drugs rejected by NICE, and 43% had funded drugs that NICE had not yet appraised. This gives some indication of where demand for unfunded drugs is coming from, and where it is met.

### Approval rates

- 64% of all cancer requests were approved, and 74% of all non-cancer requests. This implies that demand for additional private drugs may be lower than originally expected, given that many of those people seeking drugs that are not regularly funded by the NHS can still receive them through their PCT.
- On an individual PCT level though, overall approval ratings from exceptional circumstances spanned the full range from 0% (one Trust) to 100% (six Trusts). This demonstrates the variation in application of current policies.

## **Geographical variation**

- The three areas (as defined by SHA) with the highest exceptional funding application levels were Yorkshire and the Humber (2,705), London (1,306) and the South West (1,264).
- Applications were lowest in the North East (62), South Central (188) and South East Coast (239) areas.
- Across the country, there was little variation from the mean approval rate of exceptional funding applications by region.
- It should be noted that the populations served by individual SHAs vary.

## **Appendix 2: Summary of engagement strategy**

A major information gathering and opinion seeking exercise was undertaken to underpin this review. This was not a formal consultation, as the primary aim was to seek views without a presumption of the issues people might want to raise. As options for moving forward developed over the course of the review these were tested informally through a range of seminars and workshops.

The key components of the engagement exercise were as follows:

- An online and postal mailbox: All interested parties were encouraged to submit their views. Over 400 responses were received.
- Focus groups: Focus groups conducted by Research Works Limited were held with representative samples from the “well public” (based on age, gender, socioeconomic group and geographical location) and with patients and carers.
- Workshops: Several major charities held workshops which were professionally facilitated and which focused on discussion of case studies.
- A survey of nearly 300 clinical and medical oncologists was undertaken by the Joint Collegiate Council for Oncology.
- Cambridge University Hospitals NHS Foundation Trust undertook two surveys. One involved over 50 clinicians, the other over 800 patients.

### **Mailbox**

A total of 414 responses were received. These included:

- 138 (33%) patients/individuals
- 43 (10%) patient groups or charities
- 74 (18%) doctors
- 41 (10%) Royal Colleges or professional groups
- 78 (19%) NHS organisations
- 10 (2%) pharmaceutical organisations
- 2 (<1%) insurance organisations.

Overall just over three-quarters were in favour of allowing the purchase of additional private drugs alongside receiving NHS care. Around one in five respondents were against and one in ten came to no clear conclusion. Of those who were in favour, a small but notable minority stated that they thought this should only be allowed as a last resort, should the NHS not find any other way of providing certain drugs.

Major themes from the mailbox responses were as follows:

- “Reform of NICE processes”: This was the most frequently mentioned theme, featuring in nearly half of submissions. There was a strong consensus that changes to the processes used by NICE were required in order to give patients access to a wider range of drugs and for decisions to be made sooner after licensing.
- “Reform of PCT exceptional circumstances processes”: A significant number of respondents mentioned the need to change the processes used by PCTs to assess whether patients should have drugs funded by the NHS. Three-quarters of respondents who mentioned PCT processes were strongly in favour of change, with the other quarter indicating some desire for change. Increased collaboration between PCTs was frequently proposed on the grounds that this would improve efficiency and quality of decision making especially for drugs that are not being considered by NICE or are awaiting a NICE appraisal.
- “Rationing is inevitable in the NHS”: This was referred to in around one-third of submissions.
- “Associated costs of administering additional drugs”: Over half of all respondents felt that patients should pay the full cost associated with additional drugs. They were concerned that care given to other NHS patients might otherwise be prejudiced. However, just under one-third were against patients having to pay the full costs.
- “Receiving additional private drugs in the same location as NHS care”: Over half of respondents mentioning this issue were strongly against allowing patients to receive additional private drugs in the same location as NHS patients. They believed that this would be a manifest inequality, which would make those who could not pay feel disempowered. Only a tiny minority of respondents who addressed this issue were strongly in favour of co-locating NHS and private care.
- “Provision of information to patients”: Over two-thirds of respondents who addressed this issue were in favour of doctors having to outline all possible drug therapies, whether or not these were available on the NHS. In contrast, some felt that to provide this information could cause unnecessary distress to patients who could not afford to purchase the treatment. However, it was also noted that clinicians could not possibly assess the financial situations of individual patients accurately.
- “Clarification and definition of the issues”: A small number of respondents commented that greater clarification and definition of the issues related to

additional private drugs was needed and that detailed proposals should be published for comment.

- “Non-drug treatments”: Although the terms of reference for the review relate specifically to drug treatments, a considerable number of respondents mentioned non-drug treatments. Of these, two-thirds argued that policy should cover non-drug treatments as well as drug treatments, while a quarter felt strongly that the policy should be restricted to drug treatments.

### Mailbox analysis by respondent group

- Some differences in responses were observed between different groups of respondents. Individual patients or members of the public and patient groups strongly supported the idea that patients should be able to purchase additional drugs without losing their entitlement to NHS care. Over 90% of these respondents either supported this unambiguously or supported it as a “last resort” if NHS funding is not available.
- Individual doctors and professional organisations were also overwhelmingly in favour of this, as were respondents from the pharmaceutical and insurance industries.
- Individual NHS managers and NHS organisations and charities were, however, more wary of allowing private payments for drugs, with a substantial minority of these respondents being opposed (NHS around 32%; charities around 40%). Charities were generally opposed on the grounds that NHS provision should be improved so that all patients could have access to these drugs. NHS respondents were generally opposed on the grounds that private payments would undermine the founding principle of the NHS that access to care should be based on need, not on ability to pay. NHS respondents also frequently drew attention to the practical difficulties associated with any system of payment.

### Focus groups

Research Works Limited was commissioned by the Department of Health to run focus groups on the issue of payment for additional drugs as part of the review. These groups involved the “well public” (from different geographical locations and involving different age and socioeconomic groups), patients and their carers and NHS employees (including junior hospital doctors). Probing questions and hypothetical case studies were used to examine participants’ responses.

**Overall comment:** The responses from the different groups showed a large degree of consensus on the key themes examined.

**Rationing:** There was agreement across all groups that it was impossible to expect that all drugs could be funded entirely by the NHS, and that therefore rationing was inevitable in the NHS. The “well public” did express a view that,

given the inevitable budgetary restraints that create this position, spending on health tourists and over-the-counter drugs could be reduced in order to better prioritise resources. An overemphasis on the provision of “standard” and over-the-counter drugs such as paracetamol was also raised as a problem by NHS managers. Hospital doctors expressed concern that there was not the resource to fund all effective treatments – they had a great desire to prescribe everything they felt could improve the health of their patients.

**Two-tier system:** Overall, there was a strong consensus that, while differing levels of healthcare were undesirable, this presented a much lesser problem than denying NHS care to certain groups. It was accepted that the private sector already allowed those with the ability to pay to access different healthcare. NHS managers voiced concerns that a system of additional drugs payments could attract NHS staff to potentially more lucrative private jobs.

**Patient choice:** There was a strong, shared view that patient choice should be a core priority, and that any steps to restrict patient choice would be highly detrimental to patients and the NHS. Many used this argument to justify allowing the purchasing of additional private drugs. Those involved felt patients should be able to access a range of treatments, and if such treatments are not available on the NHS, patients should be able to access them privately without losing their NHS entitlement.

**Withdrawal of care:** All participants agreed that NHS care should not be withdrawn from patients if they choose to buy drugs privately. One member of the “well public” summarised the feeling that constant NHS care is “appreciated but expected”.

**Private involvement in NHS care:** Views were generally negative towards an increase in private sector involvement in the delivery of NHS/public healthcare, although often for different reasons. The “well public” felt that the full effects of increased private provision were not possible for them to predict, although they expressed concerns that patients were extremely vulnerable and therefore at risk if exposed directly to large-scale private involvement. They stated that the profit orientation of these organisations meant that they could not work effectively within the NHS.

**NICE:** All of the groups still recognised the importance of rationing and prioritisation as principles. However, all groups also shared a sense that NICE was too slow in processing its appraisals, and therefore restricted access to key, effective treatments. There were calls from patients and carers for a new system to be developed to allow all effective treatments to be accessed in some form. Several groups independently suggested that, were a system of additional drug payments to be allowed, a pool of private patients would be created who could provide NICE with evidence on new drugs. However, while patients and the public were fairly keen on this idea, NHS employees believed that the timescales involved meant that this suggestion was impractical.

**Will NHS care be degraded?** Patients and their carers could see no reason for the standard of NHS care being degraded if a system of additional private drug payments was allowed on the basis that staff would want to give the best care possible regardless. GPs also felt that there would be no decline in the NHS “standard package”, arguing that the number of cases under any potential system would be too small to have an effect on the mainstream NHS.

## Charity workshops

A number of leading UK charities held workshops with representatives who were likely to be affected by policy on the purchase of additional private drugs. Hypothetical situations were presented for discussion. The situations involved patients who might want to purchase additional private drugs for their conditions and detailed their situation, asking how the representatives would like such cases dealt with. A number of areas of consensus emerged across all the workshops. The charities involved were:

- Beating Bowel Cancer;
- Breakthrough Breast Cancer;
- The Long Term Conditions Alliance;
- Macmillan Cancer Support; and
- The Roy Castle Lung Cancer Foundation.

**Rationing:** Some form of limiting of new treatments on the NHS is thought to be a “harsh and unavoidable reality”.

**NICE processes:** Many of the current challenges exist because of delays in the NICE processes and speeding these up should be a priority.

**Decision making:** There needs to be either a national process for making decisions on funding or better quality decision making by PCTs based on national guidelines. The consistency, transparency and timeliness of processes need to be improved.

**Status quo:** The current system needs clarifying and national guidance is required on what is and is not allowed.

**Entitlement to NHS care:** Patients should never lose their entitlement to NHS care where they choose to purchase additional private drugs for the same condition.

**Setting:** The importance of continuity of care and doing what is clinically best for the patient should take precedence over the need to administer the private drug in a different private setting or at a different time.

**Payment:** Different groups had different opinions regarding how much of their care they should pay for: some argued that they should only have to pay for the additional cost of the actual drug; some argued that the patient should have to pay for all costs associated (e.g. tests) with the administration of the additional treatment.

**Clinical approval:** Patients should only be able to supplement their NHS care with additional private care where a clinician agrees that this is clinically appropriate.

**Patient choice:** Clinicians should always inform all patients of all appropriate treatment options, irrespective of whether they are available on the NHS.

**Information:** Balanced information about the costs and benefits of different treatment approaches will be vital to enable patients to make an informed choice about whether to proceed with an additional drug treatment. It need not necessarily be just doctors who are the source of such information, but they should be able to provide it.

**Communications:** Doctors should have training on how to communicate with patients about these difficult issues.

### Surveys conducted by Cambridge University Hospitals NHS Foundation Trust

Cambridge University Hospitals NHS Foundation Trust undertook two surveys related to additional private drugs. The first involved over 800 patients, the second over 50 clinicians.

#### Patient survey

- Over 80% of respondents were in favour of the principle that people should be allowed to supplement their NHS care by paying for additional drugs not funded by the NHS.
- Just over a quarter of respondents answered a question about whether they, as individuals, would pay for additional private drug treatments if this was possible. Just over half of these said that they would.
- 121 patients responded to a question about how much they would be willing to pay. 55% said that they would pay up to £10,000 while 30% were willing to pay over £30,000.

#### Clinician survey

- The vast majority of clinicians surveyed were strongly in favour of allowing additional drugs to be purchased privately. There was also strong support for additional drugs being delivered in an NHS setting.



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