

# Consultation response

## **The King's Fund response to the Department of Health's review of the consequences of additional private drugs for NHS care**

**11 September 2008**

This note responds to the Department of Health's review, led by Professor Mike Richards, into the consequences of additional private drugs for NHS care. The issue is more usually expressed as whether or not patients should be allowed to top up their NHS care by paying for drugs that are not funded by the NHS. Top-up payments are already allowed in some parts of the NHS and these have not proved controversial. The need for a review has arisen because some patients who choose to pay privately for drugs that are not funded on the NHS have been required to pay for the care that they would otherwise have received free on the NHS. In what follows we focus on the issue of top-ups for drugs, although any decision on these has implications for all forms of treatment throughout the NHS.

The King's Fund has also produced a briefing on top-up payments, which includes background information on the processes by which drugs are granted NHS funding; clarifies how top-up payments are distinct from other charges in the NHS; and outlines the relevant existing legislation and guidance in this area. The briefing is available from The King's Fund website at: [www.kingsfund.org.uk/publications/briefings/index.html](http://www.kingsfund.org.uk/publications/briefings/index.html)

### **Introduction**

Public debate has presented the issue of top-ups as a clash between two views of fairness. Those opposing top-ups argue that to allow them runs counter to the principle of fairness underpinning the NHS – equal access for equal need. They argue that allowing top-ups for drugs that have not been approved by the National Institute for Health and Clinical Excellence (NICE) would be inequitable in itself and would create pressure for a two-tier NHS in which those who could afford to do so would be able to buy themselves additional levels of care. Those in favour of top-ups argue that it is not fair to withdraw NHS care, to which people have contributed financially through National Insurance and taxation, simply because someone chooses to make use of their own money to pay for additional treatment. Whereas the costs of opting out of the NHS to pay for the whole episode of care privately are unaffordable to most people, if top-ups were allowed the patient would have to pay only the additional or marginal costs of the non-NHS element. It is likely that this would make the care more affordable to more people. We term these opposing views the solidarity and individualist positions. The individualist position considered here is a moderate one that broadly supports the NHS as it is, but believes that current rules on private spending need revising.

In this response we set out the context in which the debate on top-ups is taking place. We outline the two positions and suggest that whichever course of action the government decides on a number of measures are required to make either option work effectively. We also set out some changes to current arrangements that are desirable regardless of which option is pursued.

## Context

In discussing the issues surrounding the decision on whether to introduce top-ups in the English NHS it is important to be clear about the context in which they would operate. However, there is a lack of evidence available on the numbers of people who could take advantage of any changes in the rules permitting top-ups; the possible costs to the NHS; and the potential opportunity costs of using existing NHS resources. It will be important to gain a better understanding of the scale of the issue and the real impact of different options on NHS budgets now and in the future.

We assume that NICE will continue to determine what drugs or procedures should be available on the NHS. Developments in pharmaceutical, surgical and other treatments and procedures will make new demands on the health care budget. This means that hard decisions will have to be made about what services should be provided, to whom and to what standard. This is no different from the situation in any other health system in the world where there is a third party payer. We expect that these decisions will continue to be made on the basis of cost effectiveness.

We assume that the NHS will continue to enjoy increased levels of public spending. Since 2000 the government has demonstrated that higher levels of spending can be financed through taxation. It is expected these levels of funding will be maintained and increased in future.

We assume that patients will become increasingly well informed through use of the internet. Patients in England can easily find out if drugs or other forms of treatment for their condition are available in other countries. Although these are not necessarily free of charge or funded from the public purse in those countries, the public perception is often that they are.

We also assume that policies such as patient choice and the use of private sector providers to deliver NHS-funded care will continue. This means that rules need to apply to the NHS not only as a provider of care but also as a purchaser of care from the voluntary and independent sectors.

We recognise that there is currently considerable variation in the practices and processes of PCT exception committees, including the numbers of requests for funding they receive, the proportion of requests that are accepted or rejected, whether the committees abide by written protocols and the content of protocols that are in use (Rarer Cancer Forums 2008).

## Actions required to support either position

We consider next what would have to be done if either the solidarity or the individualist position were to be adopted.

### *Solidarity*

If the government decided to opt for the solidarity position – ie, not allowing top-ups for drugs found not to be cost-effective – it would need to provide political and legislative clarity.

- > **Making a positive political statement** – the government would have to make a clear statement justifying the maintenance of a ban set within a broader statement of what 'comprehensiveness' means. This would include why some drugs should not be funded and why it is prepared to deny patients the chance to top up, ie, to ensure that all patients within NHS facilities – or funded by the NHS but in private facilities – are treated equally.
- > **Establishing a clear statutory basis for a ban** – existing practice within the NHS varies, and there are a number of examples where top-ups of NHS provision are allowed. For example, in optical care top-ups are permitted in the case of those eligible for vouchers that can be used to meet the cost of lenses or glasses. Existing

legislation does not provide a secure basis for ruling out top-ups for drugs or other procedures. A legal opinion produced by Nigel Griffin QC concluded that in the case of patients wishing to purchase non-NHS funded drugs and to continue treatment on the NHS, this legislation would only prevent NHS bodies from buying the drugs and charging patients for them. Griffin concluded that it would not prevent a GP writing a private prescription and the patient purchasing the drug directly and having it administered as part of a course of NHS treatment (Griffin 2006).

- > **Establishing clear guidance for practice** – the current ban on top-ups ‘within the same episode’ or ‘visit to a hospital’ derives from guidelines designed to regulate the boundary for hospital consultants between NHS and private practice. In addition, these terms are not sufficiently precise to prevent some trusts circumventing them. Very clear guidelines and definitions are needed for day-to-day application at local level to reduce the extent to which people in different areas are given different treatments.

Even if the government is able to give both political and legal clarity to uphold the solidarity position it is likely to face continued pressure from the media and patient groups focused on individual patients who have been denied care. The existing high level of public support for the NHS may be undermined if it does not appear to be offering services people feel ought to be available because of their potential benefits or because they feel that through taxes and national insurance they have already paid for them. A number of policy measures that might reduce such pressure are outlined in the final section.

#### *Individualist*

If the government took the individualist position and decided to allow patients to pay out of their own pockets for some element of their care a number of issues would need to be addressed.

- > **Calculating the costs of the additional care** – while the costs of an individual drug or device might be fairly straightforward to calculate, the additional costs required for the administration of the privately funded drug, or for fitting the device, might be more difficult to calculate (eg, more intensive nursing care, or a longer stay in hospital). If all these costs were not calculated and charged to the individual then there would be a cost to the NHS with other patients losing out.
- > **Defining in what circumstances top-ups apply** – although the current review focuses on drugs, other procedures and therapies present similar issues. For example, should patients be able to pay for more expensive prostheses for hip replacements or variable focus lenses for cataracts? It would be extremely difficult to limit the decision on top-ups to life-extending drugs only. For one thing, it would be difficult to agree criteria for what constituted life-threatening situations. Furthermore, account would have to be taken of those cases where top-ups are already available.
- > **Defining the level of the top-up** – should individuals pay the full cost of the drug that is not NHS funded or should they pay only the excess cost - ie, the difference between the price of the requested drug and an existing drug with similar therapeutic properties? In the case of unique drugs the top-up might be defined as the difference between the price actually charged by the drug company and the price that, if charged, would make the cost of the drug to the NHS cost-effective according to NICE. This would mean that the part of the cost funded by the NHS would satisfy NICE's cost-effectiveness criterion.
- > **Ensuring that individuals understand the financial liabilities they may face if they top-up their care** – individuals with a terminal illness may feel they want to risk their resources on an expensive drug with relatively low efficacy, but if the

drug proves to extend their life they may find themselves unable to finance payments in the medium or long term. One way in which costs to the individual could be capped and cost effectiveness to the NHS assured would be to introduce a time limit for each drug after which the NHS would pay if sufficient levels of efficacy had been demonstrated for that individual. Further work is needed to establish how such decisions could be made in practice.

The main problem with the individualist position as defined here is the obvious inequity between those who can afford top-ups and those who cannot. If nothing is done to reduce these apparent inequities, it is likely the pressure to make cost-ineffective drugs available would increase, particularly for life-threatening conditions. This would tend to undermine the existing role of NICE and make it harder to ensure that NHS resources as a whole are effectively used.

So can a way be found of allowing top-ups but maintaining access for those who cannot pay? Two possible options might be:

- > to set charges on a scale related to ability to pay so that everyone pays something. Charges might be levied in the manner of social care – ie, on people's assets including their estates. The weakness of this approach is that public money would be used to subsidise access to cost-ineffective treatments for those unable to pay anything.
- > to create 'hardship' funds supported from charitable and other donations - effectively the basis on which much palliative care has been provided in the past to be used for those with very few resources. Such an approach would be unreliable and in effect discretionary, with some patients still likely to find themselves without support.

### **Wider system improvements**

The experiences of patients and clinicians are that the way in which new drugs come into use is unsatisfactory. Whatever the decision on top-up payments, a number of wider improvements are needed in this system.

#### *NICE decision-making process*

A number of changes could be made to the system of assessing the cost effectiveness of drugs and procedures by NICE.

- > Extend NICE's remit to cover all new drugs - thus there would be fewer drugs for which decisions on funding were made by PCTs.
- > Speed up the NICE decision-making process so that decisions on funding are made as soon after licensing as possible. This proposal, made in the final report of Lord Darzi's NHS Next Stage Review, should reduce the period during which it is uncertain whether a drug will or will not be judged to be cost-effective. However, this would mean that drugs were brought into use without a thorough economic evaluation; NICE approval takes time precisely because the evidence base in relation to cost-effectiveness is usually weak when a drug is licensed.
- > To overcome this, put in place transitional arrangements for funding with a requirement that use is monitored and cost-effectiveness data collected. Drugs could be given a 'transitional' status allowing them to be used within the NHS while their cost-effectiveness is assessed, but only for a limited period. A continuing appraisal regime should be put in place for any such drug, checking whether the trial data holds good in clinical practice and/or whether there are patient subgroups that are likely/unlikely to benefit. However, this would still mean that in some circumstances drugs that had been temporarily available to patients would be withdrawn.
- > Introduce risk-sharing schemes with the pharmaceutical industry to reduce the cost to the NHS. There are already precedents for this with beta interferon (Department of Health 2002) – though exactly how this scheme has worked has never been

made clear – and the industry itself has expressed interest in deals of this kind. Most recently GSK, in relation to the cancer drug Tyverb, has put forward what it terms a price/volume proposal, which is designed to make the drug more accessible to NHS patients (Jack 2008). Roche proposed a similar scheme to reduce the cost of the renal cancer drug Avastin, though without success (Timmins 2008). Novartis has come to an agreement designed to make its macular deterioration drug Lucentis available to NHS patients (The Pharmaceutical Journal 2008).

- > Review the valuation applied to extra years of life in terminal cases. Recent Department of Health documents including the Cancer Reform Strategy have used criteria based on the value attached to reducing the risk of death (Department of Health 2007). This yields higher values than those implied in NICE decisions. NICE has recently indicated its intention to reconsider its current criteria by commissioning research to assess whether its current threshold is reasonable. However, any such re-assessment should extend to the impact assessments carried out by the Department of Health. In addition, any decision to implement revised values should only be taken in the light of an assessment of the opportunity costs – ie, what other care could be provided by use of the resources. Recent work by the University of York suggest that some new drugs gaining NICE approval are less cost-effective than other forms of expenditure on cancer and other conditions (Martin *et al* 2007).

#### *PCT decision-making process*

Changes could be made to the process for deciding on funding decisions by PCTs. The process for gaining access to drugs that are not yet approved by NICE is lengthy and unpredictable and not based on a clear set of principles or guidelines (Rarer Cancers Forum 2008). This means there is a real risk to the reputation of the NHS as a fair organisation that is responsive to its patients. The NHS Constitution Handbook proposes that guidance should be issued in this area but it does not go far enough in specifying the content of the guidance and the timeframe of the process.

#### *Patient information and consent*

Patients should be offered information about the costs and benefits of all licensed drugs in order to be able to make an informed choice. There must be an agreed procedure for setting out the realistic possibilities of people benefiting from taking drugs that have been judged not to be cost-effective and where the chances of substantial benefit are limited. At the moment, practice in some areas seems to fall short in relation to informed consent (Audrey *et al* 2008). Such a procedure and the information provided must be, and must be seen to be, objective and impartial. Although any such procedure would have to be implemented locally it would be desirable that its information content was standardised as far as possible. There are indications that NICE has recognised this problem and is preparing to issue information to help patients make decisions on drugs which NICE does not approve (Winnett *et al* 2008).

### **Conclusion**

The King's Fund believes the current policy and practice on top-ups is untenable.

The existing legislation and guidance is unclear and practice is inconsistent. There are areas of the NHS, such as optical care and dental care, in which top-ups exist, and current legislation does not provide clear direction to patients or the NHS about why these top-ups are allowed but others – for example, the use of non-NICE approved drugs – are not.

In addition, the basis on which decisions are made locally as to whether drugs are available before they have received NICE approval or the basis on which appeals can be made if NICE has rejected them is not clear. The rules that do exist are not applied consistently and result in significant variations between primary care trusts (PCTs) in the decisions reached – precisely the situation that NICE was established to avoid.

Furthermore, the current situation in which highly vulnerable patients may be forced to abandon their NHS treatment because they wish to pay for a drug themselves is unfair and risks damaging the reputation of the NHS as a caring and compassionate service. For this reason, on balance, The King's Fund believes that NHS treatment should not be withdrawn from patients who choose to purchase drugs privately.

The King's Fund recognises, however, there are significant implications of such a decision not least concerns about equity as there will inevitably be some patients who cannot afford top-ups. This is one of the costs associated with this option. There is also a risk that the current media attention on the plight of those denied NHS-funded care who choose to purchase non-NICE approved drugs privately will shift to those who have been denied these drugs because they can't afford them, thus increasing pressure on the NHS to fund cost-ineffective care. However, we believe there are some measures that the government should adopt to limit the risks of unfairness:

- > identify and specify the circumstances in which top-ups are allowed – the review is focusing on drugs only but there are other procedures and therapies that NICE has assessed and recommended should not be funded by the NHS
- > calculate the associated costs, such as the costs of administering a drug and ensure that these are paid by the patient
- > ensure that individuals understand the financial liabilities they may face if they top up their care.

Finally, the government can use the opportunity created by the top-up debate to improve the way that new medicines – and by extension other forms of treatment – come into use. The present system is overly dependent on trial data supplied by the pharmaceutical companies that do not necessarily reflect the realities of clinical practice. We need a more systematic and ongoing appraisal of new drugs in both clinical and economic terms. The pharmaceutical industry has itself recognised that the introduction of new and expensive drugs must be handled in innovative ways. These measures might reduce the number of drugs that are excluded from NHS funding and would reduce the level of variation in the availability of non-NICE appraised drugs and treatments and reduce uncertainty for patients and the public.

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