Access to newly licensed medicines

Cancer Research UK

Key points

- Patients should get equal access to drugs that are proven to be effective, regardless of where they live.
- Cancer Research UK believes greater transparency is needed to ensure there is confidence in the process for introducing new drugs. This is important so patients understand how funding decisions will be made.
- We welcome a system of reimbursement that rewards innovation and makes more cancer treatments available to patients in the UK.
- It is important to achieve a workable solution in negotiations over Value Based Pricing, the proposed replacement for the current Pharmaceutical Price Regulation Scheme.
- We understand that this is a complex issue. We believe that it may be useful to convene discussion sessions between SMC and the wider clinical community to explore possible solutions and to look at the wider issue of access to new medicines in Scotland.

About us
Cancer Research UK is the world’s leading charity dedicated to beating cancer through research. We have contributed to most of the world’s top cancer drugs, including tamoxifen, herceptin and temozolomide. We pioneered the use of radiotherapy treatments, with shorter treatment schedules and fewer side effects. Cancer Research UK spends around £31 million a year in Scotland on some of the UK’s leading scientific and clinical research.

Our aim is to save lives from cancer. We do this through funding world-class research, providing information for patients, health professionals and the public, and influencing public policy to keep cancer at the top of the health agenda.

Background
Cancer drugs, including chemotherapy, hormone therapy and biological therapies, are an important part of cancer treatment. However, we also believe that it’s vitally important that patients also have access to other effective forms of treatment, such as surgery and radiotherapy, and that there is government support for cancer prevention and early diagnosis of cancer in order to reduce cancer incidence and improve outcomes for all cancer patients.

Introduction of new drugs
We know that the UK is often slower than other comparable countries to introduce new technologies to the NHS. There are several reasons for this. The current process of approval, through the Scottish Medicines Consortium (and NICE elsewhere in the UK) is one part of this. Doctors in the UK are also considered to be more conservative in their prescribing habits than their colleagues overseas. Usage of cancer drugs is approximately 60% of the
European average, whereas equivalent usage for cardiovascular drugs is approximately 90% and mental health drugs 100%. Cancer Research UK wants government to ensure that the process by which drugs are priced and approved for use encourages the introduction of new, effective, cancer treatments into the NHS. All patients, regardless of where they live, should have access to all treatments which their clinician thinks will benefit them.

The cost of cancer drugs
According to the ABPI, it takes an average of 12 years and over £500 million investment to bring one new drug to patients. Companies also generally price cancer drugs at higher levels than those in other therapeutic areas, where more competition exists. The strain on the NHS budget from new cancer drugs is likely to increase as future best practice focuses on using combinations of newer, more expensive treatments. Due to improvements in research, treatments are becoming much more targeted and tailored to individual cancers. Treating only those patients who might benefit, and reducing unnecessary side effects, could mean greater value for money the NHS.

Value Based Pricing
The current UK-wide Pharmaceutical Price Regulation Scheme (PPRS) is to be replaced by Value Based Pricing (VBP) in 2014 (medicines pricing is reserved). VBP allows the price of drugs to be based on a range of factors which assess value. Cancer Research UK welcomes these proposals.

It will be important that this new scheme is designed to reward companies for their investment in innovative new treatments, and is easy for the NHS to use. We also need to ensure that the process by which ‘value’ is considered takes into account the specific needs of cancer patients. The nature of progress in developing new cancer treatments means that incremental improvements are more likely to occur than large steps forward in innovation. Attempts to reward innovation under VBP must still recognise the value of small steps that make a significant difference to the lives of cancer patients.

However, there are still significant unanswered questions about the way in which this process will work. There is currently no clear guidance about how the new scheme will interact with existing arrangements (for example the work of the SMC) in Scotland. We therefore urge the Scottish Government to work with colleagues in the UK Government to ensure that the new scheme meets the needs of patients in Scotland. For example, consideration will need to be given to which body/ bodies should carry out assessments of cost effectiveness as part of the proposed value-based pricing process, and how, if at all, this might interact with any further post-pricing assessments or recommendations that the Scottish Government might wish to implement. It is

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1 Department of Health 2010 Extent and causes of international variations in drug usage: a report for the Secretary of State for Health by Professor Sir Mike Richards CBE
vitally important that we consider the implications of VBP for the availability of medicines for patients in Scotland.

Scottish Medicines Consortium
Cancer Research UK recognises the important, and often difficult, job that SMC does in making decisions about value for money on behalf of the NHS. SMC’s methodology has developed over its lifetime to be responsive to the needs of society, for example, through its use of modifiers. However, we believe that a complex disease such as cancer still challenges this methodology. A more flexible approach is needed to support innovation and give patients in Scotland access to those treatments which we already see benefiting patients elsewhere in the world.

The SMC works to a very specific process of appraisal, which is appropriate for conditions and treatments for which good clinical evidence is available. However, in certain conditions, including many cancers, randomised clinical trial data are often impossible to attain due to small populations of patients or the lack of suitable alternative treatments. In these cases, SMC needs more flexibility within its appraisal system. Cancer Research UK would welcome acknowledgement of this need and a more intelligent approach to decision making, informed at all times by the best clinical expertise.

We also believe that further consideration should be given to how to deal with treatments delivered at the end of patients’ lives which can give extra weeks or months of life which might otherwise have been denied. This is especially important where cancer is only detected at a late stage, when life expectancy can be very short. While the SMC has introduced ‘modifiers’ where they may exercise greater flexibility in decision making, to allow consideration of additional factors, including treatments for patients at the end of life, these may prove insufficient to allow effective treatments to be approved. NICE has also introduced end of life criteria, and these offer far greater flexibility than those currently used by SMC. We think SMC should reconsider its approach to these treatments. There is also a need for further debate about what the public particularly value (for example, treatments for patients at the end of their lives) and how those priorities can be reflected in the appraisal process.

While SMC has proved to be swift in appraising new treatments, there have been cases where treatments are resubmitted following a rejection, and it has taken a significant additional period of time for a reappraisal to take place. An example of this is the recent case of Abiraterone, where the treatment was rejected at first appraisal, then resubmitted with a new patient access scheme. This delay can be very distressing for patients who might benefit from the treatment, and we therefore urge both the SMC and pharmaceutical companies to find a way to expedite this process.

It would also help if SMC could be clearer in communicating the rationale for decisions, so patients fully understand why certain drugs are not approved for use on the NHS in Scotland. While this communication has improved, we believe further advances could be made. Where SMC feels unable to
recommend a treatment which may benefit patients due to poor data or unrealistic pricing, it should be able to say so.

Implementation and local decision making
Greater transparency is needed in the local implementation of SMC guidance. Health Board Area Drugs and Therapeutics Committee (ADTC) decision-making is often not transparent and it is difficult to know why certain decisions have been reached at a local level. Where a Board decides not to make treatments available which have been approved by SMC, the reasons behind this decision should be made explicit.

Individual Patient Treatment Requests (IPTR)
Where SMC has made the decision that a certain drug is not sufficiently cost-effective to recommend its use, clinicians may consider applying to local IPTR committees. As we understand it, the IPTR process is designed for patients to access treatments on an individual basis, where they are likely to gain additional benefit from the treatment compared to the general patient population. They are therefore not a comprehensive response to the issue of population access to treatment. While some patients may be able to access treatments rejected by the SMC through this route, this will not be the case for the vast majority of patients.

We are concerned that some of the rhetoric around IPTRs has raised false expectations for patients; encourages MSPs to suggest this route for their constituents where it might not be appropriate; puts pressure on clinicians to explain to patients why this is not the case; and deflects the debate from the real issue - treatments being turned down by the SMC which are deemed to be clinically effective but not cost-effective, and the need to find a workable solution to improving access for all those who might benefit from a treatment. We also know from our clinicians that proving a patient’s exceptionality is extremely difficult to do. Similarly, while the good practice guidance issued by the Chief Medical Officer in March 2011 outlined a “framework to support local decision-making on IPTRs through a consistent approach”\(^3\), it is still not clear how, if at all, boards are making these decisions, and concerns remain that different boards may take different approaches. Clinicians often encounter patients who may benefit from a treatment, but for whom they do not submit an IPTR as they are unable to prove exceptionality, or know that the request will be turned down. Cancer Research UK believes that patients should be able to expect a standardised approach to be adopted by IPTR panels across the country. We have anecdotal evidence that the IPTR process has been improved by mandating who should be on the panel, as this should help to standardise the decision-making processes. Having the correct level of expertise involved on IPTR decision-making panels is crucially important. However, this may have an impact on the timeliness of decisions and should be monitored.

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IPTR committees must be as transparent and iterative as possible, with a focus on good communication with both the patient and their clinician. Better information on the decisions reached by these committees and how they are being made will help ensure fairer access for patients. We note that the Chief Medical Officer’s (CMO) letter required boards to have “robust systems in place to collate core data in relation to IPTRs, including the need to be able to produce summary management in confidence information to the Scottish Government on request” and that the guidance is intended to be reviewed by the end of 2013, or earlier if required. We believe that this is necessary in order to monitor use of IPTRs and compliance with the guidance, and to highlight any issues. This should include discussions with clinicians to analyse not only those IPTRs they lodge, but also those they decided not to lodge, in order to capture a true picture of the implementation of this policy. We would also like the Scottish Government to consider whether IPTRs would be better handled at national level in order to avoid the current variation in application, and to better support the inclusion of appropriate experts.

Early Access
The MHRA is currently consulting on an ‘early access scheme’ for England to allow promising new drugs to get to patients more quickly – before they have a licence. There are also discussions at the EU level about how an ‘adaptive licensing’ scheme could work. Adaptive licensing refers to a more flexible approach to drug licensing whereby a conditional licence is granted at an earlier stage of development based on less information than would currently be required, and adapted as and when more information becomes available. This would also allow patients to access promising new treatments more quickly. We believe that the Scottish Government should consider whether Scotland should establish similar schemes (or take part in those already proposed) in order to allow access to promising new treatments more quickly.

Patient access schemes
The pharmaceutical industry has a part to play in solving the problems of poor access to the latest treatments in the UK. It should work with government to develop pricing arrangements which enable access to innovative drugs. We believe that patient access schemes should be encouraged. These schemes have the potential to make treatments available to patients which would otherwise be turned down by SMC.

Cancer Drugs Fund
The Cancer Drugs Fund (CDF) for England was announced before the 2010 general election to deal with perceived inequalities in access to cancer drugs either through rejection at the Health Technology Assessment stage or through lack of funding at a local level. This Fund is regionally distributed through expert groups. Thanks to the existence of the CDF, patients in England are getting access to cancer drugs they might otherwise not have been able to. Cancer Research UK has welcomed this additional access, but we believe that the much bigger prize, with longer term implications, is in ensuring that a new and sustainable system of Value Based Pricing works for

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4 ibid.
cancer patients across the UK. As mentioned above, the importance of other treatments (such as surgery and radiotherapy) should not be overlooked in the context of a Cancer Drugs Fund.

Impact on cancer research
The UK’s lower rate of uptake for new cancer drugs may be damaging to our ability to design and run internationally competitive studies. If very few patients can get licensed drugs that are the standard of care outside the UK, this could lead to fewer industry-supported trials being conducted in the UK since the questions we can answer will not be relevant to the rest of the world.

Possible solutions
We understand that this is a complex issue. We believe that it may be useful to convene discussion sessions between SMC and the wider clinical community to explore possible solutions and to look at the wider issue of access to new medicines in Scotland.

Cancer Research UK
05 September 2012