Access to newly licensed medicines

Bristol-Myers Squibb

Bristol-Myers Squibb (BMS) is a global biopharma company committed to discovering, developing and delivering innovative medicines that help patients prevail over serious diseases.

Introduction

BMS would like to thank the Health and Sport Committee for holding an investigation on this important issue and we welcome the opportunity to submit our views on how access to medicines policy in Scotland can be improved. BMS is concerned that current access arrangements may prevent patients from receiving treatments that could benefit them.

Whilst BMS believes that the Cancer Drugs Fund (CDF) has proved effective in improving patient access to cancer treatments in England, we do not see this submission as an opportunity to call for a CDF in Scotland. Nevertheless, BMS does believe that the Scottish Government needs to address the problems, particularly with the SMC and IPTR system, that a wide range of stakeholders, including Parliamentarians, clinicians, industry representatives, and, most importantly, patients, have identified.

In recent years, BMS has met with many MSPs, patients and stakeholder groups to discuss the broad issue of access to medicines in Scotland, and - more recently - specific problems associated with the IPTR system. This response has been formed both on the basis of these discussions and our own experience of the uptake of our medicines by the NHS in Scotland. We are keen to work closely with both the Health and Sport Committee and the Scottish Government on this issue and are happy to provide further details if required. We would also welcome the opportunity to appear before the Committee at its session on 18 September or subsequently to highlight our experiences in this area.

Our submission covers the following points:

The Scottish Medicines Consortium
i. The current relationship between NICE and SMC guidance
ii. Funding of End of Life Treatments in Scotland and England
iii. Transparency within the Quality-Adjusted Life Year Multipliers

The Individual Patient Treatment Request System
i. The application of exceptionality criteria
ii. Geographical variations in patient access
iii. Treatments not yet appraised by the SMC
Executive Summary

BMS believes that there are a number of steps that can be taken in order to improve access to medicines in Scotland. In particular we feel that the application of exceptionality criteria through the IPTR system makes it difficult for a request to be successful. The difficulty in obtaining treatment through the IPTR system is restricting patient access to medicines and as a result clinicians are being discouraged from submitting IPTR applications. BMS believes that NHS Boards should be directed to remove such criteria from their IPTR systems. Instead, NHS Boards should be provided with a clear, clinically-led process that allows clinicians to access medicines for their patients based on whether other treatments have proved ineffective and they believe that the patient is likely to benefit from the treatment requested.

BMS is also concerned that the IPTR system does not provide geographically equitable access to treatments as some NHS Boards have higher approval rates than others. To ensure that patients have equal access to medicines across Scotland, the Government should set mandatory guidance which Boards would have to follow, replacing the current guidance framework. We also feel that the IPTR system would benefit from further clarity surrounding the arrangements for treatments that have not yet been appraised by the SMC. We believe that in order to encourage consistent decision making, these principles should be the same as those set out for medicines that have been appraised by the SMC.

In order to improve access to medicines in Scotland it is also important that the role of the SMC is examined. BMS is concerned that Scottish patients do not have the same access to medicines as they do in England. This is certainly true for patients approaching the end of their life as evidence suggests that the SMC is operating a cost per QALY threshold of £42,000 compared to a threshold of £50,000 per QALY used by NICE for England and Wales.

Despite the fact that the SMC does not follow NICE guidance on Single Technology Appraisals (STAs), it is required to do so when NICE has issued Multiple Technology Appraisal (MTA) guidance. This means that, as in the case of Dasatinib (Sprycel) BMS’s drug for the treatment of Chronic Myeloid Leukaemia (CML), positive SMC guidance can be overruled by negative NICE MTA in England. BMS is concerned that this again leads to patients missing out on clinically effective treatments from which they could benefit.

Access to medicines policy in Scotland is a crucial issue and BMS remains committed to ensuring that patients have access to the medicines that they need. Should the Committee require it, we would be happy to provide further details on any of these points or give evidence directly to the committee itself. We look forward to hearing the committee’s discussions on 18th September and to the details of the conclusions of this investigation in due course.
The Scottish Medicines Consortium (SMC)

i. NICE and SMC guidance

When a new licensed treatment is appraised by the SMC in Scotland or NICE in England it is conducted either by a Single Technology Appraisal (STA) or Multiple Technology Appraisal (MTA). An STA is an appraisal in which one treatment is appraised individually, whereas an MTA compares a treatment alongside or against several similar other treatments. Under current arrangements, if NICE assesses a drug through an MTA, the resulting guidance supersedes that of the SMC and is applied in Scotland.

Under existing arrangements this is only applicable to MTAs, however if NICE endorses a drug through an STA that has not been approved by the SMC, then under current SMC processes the manufacturer has an opportunity to resubmit the dossier with or without a patient access scheme (PAS).

BMS is concerned that this arrangement is restricting patient access to drugs that were available on the NHS in Scotland. This is certainly true in BMS’s experience, as Dasatinib (Sprycel) our drug for the treatment of Chronic Myeloid Leukaemia, was in January 2012 issued negative guidance by NICE via a Multiple Technology Appraisal. Despite the fact that the SMC had previously approved Dasatinib for use in the treatment of patients in the chronic phase of Myeloid Leukaemia in April 2007, Healthcare Improvement Scotland ruled that the NICE recommendations were “as valid for Scotland as England and Wales”. As a result of this decision, Dasatinib is no longer available in Scotland on the NHS.

BMS is concerned that there is insufficient rationale for superseding and overturning an SMC decision when a NICE MTA contradicts it. SMC decisions are considered to be thorough and robust. Given this, BMS would question the rationale for a NICE MTA superseding an SMC decision, particularly given that this process has led to SMC approved treatments like Dasatinib being made unavailable.

ii. End of Life Thresholds

BMS is concerned that Scottish patients approaching the end of their life (normally with less than 24 months to live) have worse access to treatments than they would if they lived in England. This is because the SMC sets its End of Life (EOL) threshold at £42,000 per Quality-Adjusted Life Year (QALY) whereas NICE has a higher threshold at £50,000 per QALY.

This creates a system of inequitable access as patients in England are able to access more expensive treatments than they would in Scotland. BMS believes that the SMC EOL threshold should operate at the same level applied by NICE, ensuring that patients are able to receive the same treatments in Scotland as they would in England.
iii. Quality-Adjusted Life Year Multipliers

BMS is also concerned that the Quality-Adjusted Life Year (QALY) multipliers are currently not transparent, making the decision-making process less predictable. The QALY measure is the value of health outcomes and is used to appraise the effectiveness of a treatment in extending length and quality of life. QALYs are calculated by multiplying the utility value (quality of life) by the year of life (how long life is extended) and then calculating the QALY score assigned to a treatment. However BMS is concerned that since the SMC is not transparent in how it calculates its QALY, it is difficult to understand how a decision will be made. We therefore support moves to provide more information on how the QALY multipliers can be calculated, making the system more transparent.

The Individual Patient Treatment Request System

The Individual Patient Treatment Request (IPTR) system was introduced by the Scottish Government to allow patients, on an individual or ‘case by case’ basis to access medicines not recommended by either the SMC or NHS Quality Improvement Scotland.

Whilst BMS supports the aims of the IPTR system, we are concerned about how it is operating in practice. The current system has been widely criticised for a number of reasons. Research carried out by the Rarer Cancers Foundation in 2011 suggested that there were at least 23 cancer treatments not routinely available in Scotland which may be available in England through the Cancer Drugs Fund\(^{vii}\).

This is due to the application of restrictive exceptionality criteria which often prevents patients from accessing the treatments they require. This has certainly been BMS’s experience with our melanoma drug Ipilimumab. Since it was licensed in August 2011, of the 11 applications made via the IPTR system, all 11 have been rejected\(^{vi}\).

i. Exceptionality criteria

BMS is concerned that clinicians are not making requests through the IPTR system because they believe that their application will prove unsuccessful. This is due to the national guidance set out in SGHD/CMO(2011)\(^{vii}\) which applies exceptionality criteria limiting the circumstances under which a patient can access treatment via the IPTR system.

As a result of this guidance health boards are applying restrictive exceptionality criteria which requires clinicians to demonstrate that the patient’s clinical circumstances (condition and characteristics) are significantly different from either: the general population of patients covered by the medicine’s licence; or the population of patients included in the clinical trials for the medicine’s licensed indication as appraised\(^{vii}\).
The restrictive nature of this criteria means that many applications are rejected and are then often not submitted due to the small likelihood of success and the heavy administrative burden involved.

To rectify this, BMS believes that the Scottish Government should replace the IPTR ‘referral criteria’ that it set out in its SGHD/CMO(2011)vii guidance of March 2011. They should also:

- Direct Local NHS Boards to remove these criteria from their own policies;
- The Scottish Government needs to take further steps to ensure that clinicians have confidence in the operation of the IPTR system so that they are not unnecessarily deterred from making appropriate applications on behalf of their patients;
- Ensure that in both national and local guidance, the criteria should be replaced by a clear, clinically-led process that allows clinicians to access medicines for their patients based on an assessment of whether:
  - Other treatments recommended in national guidance for the patient’s condition at their current stage in the pathway have proved, or are likely to prove, ineffective and;
  - They believe that their patient is likely to benefit from the treatment requested.

ii. Geographical variations in patient access

Despite these problems, it is not the case that all patients are being denied access to medicines that might benefit them. The Government has recently cited figures that state that of the 126 applications made via the IPTR system, 87 have been approved and 39 rejectedviii. This is a figure supported by Freedom of Information requests carried out independently by BMS in conjunction with the office of Richard Simpson MSP. However, BMS’s research showed significant variation in the approval rates of different NHS Boards with patients in one area denied treatments that have been made available in other parts of Scotland.

In addition, concerns have been expressed over whether there is currently appropriate clinical expertise and representation on individual Boards’ IPTR panels. BMS believes that it is crucial that there is a clinician with expertise in the relevant condition who is able to support the IPTR Board in reaching its decision based on the evidence supplied by the patient’s clinician.

In order to improve this system, BMS believes that a system that encourages more consistent decision-making should be developed. To achieve this, BMS recommends:
Patients should have geographically equitable access to treatments through the IPTR system. In order to achieve this the Government should set mandatory guidance to be followed by all Health Boards rather than simply outlining a guidance ‘framework’ for Boards to follow.

The Government should consider whether, in the case of cancer, the IPTR system could be administered more effectively and consistently by the three cancer networks, rather than individually by the 14 Health Boards. This may be more likely to ensure that an appropriate clinician with knowledge and expertise of the condition under discussion is present on the IPTR Board to consider an individual’s request.

iii. Treatments not yet appraised by the SMC

Through the IPTR system, most individual Boards state very clearly that the purpose of their IPTR policies is not to encourage or support applications made for treatments that have not yet been appraised by the SMC, or for which the appraisal has not yet been completed.

BMS recognises that this is the right principle to ensure that the established access to medicines system in Scotland is not subverted. However, as the Boards themselves all acknowledge, there may be individual circumstances which necessitate or justify pre-SMC access through the IPTR system. BMS believes that it is important to recognise that pre-SMC access for patients via IPTRs may be necessary – in some circumstances – especially if there is further evidence in the future to suggest that the SMC, due to an ever increasing workload, is struggling to complete its assessments as swiftly as has been the case in the past.

We propose that in order to amend this:

- The Scottish Government should provide further clarity on the arrangements for patients to access treatments through the IPTR system in some cases where the SMC has not yet completed its assessment.

- Arrangements for access to drugs not yet appraised by the SMC should follow the same principles as those set out above for medicines that have been appraised by the SMC.

References:

1 Scottish Executive: Health Department, Directorate of Healthcare Policy and Strategy (2007): Scottish Medicines Consortium Advice and single technology appraisals (STAs) from the National Institute for Health and Clinical Excellence (NICE) http://www.scottishmedicines.org.uk/General/FAQs#4

2 Dasatinib, high dose imatinib and nilotinib for the treatment of imatinib resistant chronic myeloid leukaemia (CML) (part review of NICE technology appraisal guidance 70), and dasatinib and nilotinib for people with CML for whom treatment with Imatinib has failed because of intolerance. http://www.nice.org.uk/guidance/TA241


Figures based on evidence from the BMS field team


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10 September 2012