Access to newly licensed medicines

On behalf of Oncologists specialising in the treatment of colorectal cancer within Scotland

We should like to make, on behalf of Oncologists specialising in the treatment of colorectal cancer within Scotland, a written submission to the above committee. This is with particular regard to the Individual Patient Treatment Request (IPTR) system and our concerns over this process. We feel the current system has inherent deficiencies and would like to suggest consideration is given to its urgent review.

We acknowledge the need for guidance from bodies such as the Scottish Medicines Consortium (SMC) and the National Institute of Health & Clinical Excellence (NICE) and for many years have worked within the framework of their recommendations. This has become increasingly difficult since the advent of the Cancer Drugs Fund (CDF).

The CDF allows cancer patients to access many new cancer medicines that lack NICE approval on cost / clinical effectiveness grounds and which are thus unavailable to Scottish patients with colorectal and a range of other cancers. Whilst the medicines in question have proven clinical efficacy they have been deemed not cost-effective by the Health Technology Appraisal bodies. Our lack of a funding stream, such as the CDF, means that for the vast majority of Scottish NHS patients, access to such treatments is precluded. This is a source of great concern and anguish for our patients, their families as well as ourselves as their treating clinicians.

In recently published documentation the Scottish Government state “The IPTR process is not about showing exceptionality but is designed to provide an opportunity for clinicians to pursue, on a case by case basis for individual patients, treatment with a medicine that has not been accepted by the Scottish Medicines Consortium (SMC) or Healthcare Improvement Scotland”. (http://www.scottish.parliament.uk/S4_HealthandSportCommittee/Meeting%20Papers/HS_Committee_papers_12_June_2012_public.pdf).

The criteria required to be met to permit the use of these non-approved treatments via IPTR are defined in CMO (2011)3 as:

a) 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

AND

b) That these circumstances imply that the patient is likely to gain significantly more benefit from the medicine than would normally be expected.
Adherence to the defined IPTR criteria has had several consequences including -

(i) To prove an individual patient fulfils these specific criteria requires us to confirm that the patient is both similar to patients within published series describing the treatment in question (providing the rationale for wanting to use the treatment in the first place) and at the same time, dissimilar to patients within these publications (providing the rationale that they may gain more from the treatment than patients within these trials). These two positions are frequently mutually exclusive.

(ii) Fulfilment of the IPTR medical criteria is such a rarity, and adherence to IPTR documentation states approval will not be granted on any other grounds, IPTR requests are usually only submitted for those rare cases that are likely to be successful. IPTR requests are thus not submitted for the majority of patients who we feel might benefit from ‘non-recommended’ drugs, for whom we know there will be a negative outcome and no sensible option of appeal. This reluctance to submit IPTRs with low chance of success results in a positive bias for IPTR approval ratios, falsely reassuring the Scottish Government that unfunded drugs are frequently approved via the IPTR system. This ratio is further clouded by the inclusion of applications for the use of drugs “off-label” within the IPTR process and the continued requirement to submit IPTR documentation, sometimes for several months, after SMC approval of a specific treatment, pending inclusion on hospital formulary.

When providing recommendations the SMC states “This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgment in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer”. (www.scottishmedicines.org.uk/files/cetuximab_Erbitux_RESUBMISSION_FINAL_January_2010_for_website.pdf).

This statement suggests that, as clinicians, we have an obligation to do what we feel is best for patients, independent of SMC advice whilst in reality a process by which we can prescribe these drugs in the NHS does not exist. We believe the statement in the NHS Scotland patient information sheet ‘New medicines in Scotland – who decides what the NHS can provide?’ (http://www.scotland.gov.uk/Resource/Doc/924/0098594.pdf) is similarly misleading, giving the impression that if the treating clinician thinks a specific drug will provide benefit, it can potentially be accessed – we do not feel this is true in the vast majority of patients.

The perception that the IPTR process represents a mechanism whereby Scottish doctors can access treatments which they feel they may benefit patients is disingenuous and does not reflect the reality of current practice. Our experience suggests the restrictions imposed by the IPTR process mean
those patients who we, with multidisciplinary peer support, consider would benefit from the use of these drugs are in effect ineligible for treatment.

Finally we also feel it should be recognised the lack of access to and experience with these types of drugs, internationally considered to be standards of care, may have longer term implications for the Scottish cancer community. We have reason to pride ourselves on the standard of cancer medicine training in this country, which has produced many of the UK’s most prominent cancer clinicians and has engendered a culture of cancer research excellence. Our ability to participate within clinical trials, a measure of our credibility within the research community, is already limited for studies of agents in early development for colorectal cancer and is potentially under threat for subsequent larger scale studies. This is in part because we are unable to access many agents viewed as standard therapies elsewhere in the UK and around the world. These difficulties may ultimately result in an efflux of talented physicians from Scotland and reluctance on the part of trainees to seek experience in Scotland.

We hope that the information provided in this letter is taken as constructive and informative for the committee panel. If further information would be helpful then representatives from our group would be happy to provide this.

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12 September 2012