



The Scottish Parliament
Pàrlamaid na h-Alba

Health and Sport Committee

T3.60

The Scottish Parliament

Edinburgh

EH99 1SP

Tel: 0131 348 5224

Calls via RNID Typetalk: 18001 0131 348 5224

Email: HealthandSport@scottish.parliament.uk

5 March 2014

Dear

**ACCESS TO MEDICINES FOR END-OF-LIFE AND VERY RARE CONDITIONS:
TRANSITION FROM IPTR TO PACS**

As you will be aware, on 5 November 2013, the Scottish Government Chief Medical Officer and Chief Pharmaceutical Officer wrote to all NHS boards. A copy of the letter is attached at Annexe A. The letter indicates that the Scottish Government does not consider it acceptable for any patient whose clinicians may currently be considering, or in the process of an IPTR, to be disadvantaged because of the timing of events. It goes on to emphasise that the concept of exceptionality should no longer be a factor in any IPTR under consideration but that decisions should be primarily about the individual clinical case. It adds that IPTR panels “should exercise flexibility in their decision making in recognition of the issues highlighted in the Health and Sport Committee Report, and of the fact that we are entering a period of transition to a new clinically led peer review process”. It concludes that patients should not be adversely impacted by this transition.

The Committee agreed to hold a session on 25 February 2014 involving patient organisations, clinicians, the pharmaceutical industry and the SMC, in order to gauge wider reaction to the SMC proposals. A submission was received by the Committee for this session from the Beatson Oncology Centre Consultant Committee. A copy of the submission is attached at Annexe B.

The Committee was concerned at the contents of the submission from the Beatson Consultants, which appeared to suggest that, at least in NHS Greater Glasgow and Clyde, little had changed, despite the CMO’s letter, and patients were effectively still being denied access to certain SMC “not recommended” medicines on the basis of it not being possible to demonstrate exceptionality. The Committee agreed that this required urgent clarification, particularly in the light of the CMO’s letter and the repeated assurances to the Parliament and to the Committee by the Cabinet Secretary that no patient who might not be able to access medicines under the current IPTR system but who would be likely to be able to access them under the proposed new arrangements should be denied access during the interim period.

At its meeting on 4 March 2014, the Committee agreed to write to the four NHS boards whose cancer patients are treated at the West of Scotland Cancer Centre asking them to provide a copy of their current IPTR policy and any associated guidance in respect of this interim period. The Committee also agreed to ask boards to indicate what specific changes had taken place in the light of the CMO letter. The Committee has also written to the Cabinet Secretary about this issue.

I would be grateful if you could reply by Friday 28 March.

Yours sincerely

A handwritten signature in black ink, appearing to read 'D. McNeil'. The signature is written in a cursive, flowing style with a large initial 'D'.

Duncan McNeil MSP
Convener – Health and Sport Committee

Annexe A: Letter from the Scottish Government Chief Medical Officer and Chief Pharmaceutical Officer of 5 November 2013 to NHS boards

ACCESS TO NEW MEDICINES – TRANSITIONAL ARRANGEMENTS FOR PROCESSING INDIVIDUAL PATIENT TREATMENT REQUESTS

You will be aware that the Cabinet Secretary for Health and Wellbeing responded positively to the Health and Sport Committee's Report on Access to New Medicines. A debate held in the Scottish Parliament last month showed a great deal of consensus and support from MSPs across the Chamber to the recommendations from the Committee and the Scottish Government's positive response to them. There is a lot of work that will need to be done in the coming months to put in place these changes and we do not underestimate the impact that this will have on Boards as changes are put in place.

There is one specific aspect of the proposed package of changes that we particularly want to flag up now. The Cabinet Secretary announced that the current IPTR system will be replaced with a new Peer Approved Clinical System (PACS). This will be administered locally (i.e. within NHS territorial Boards) but within a national framework, and will be audited by Healthcare Improvement Scotland. The new system will focus on patient outcomes.

We are very mindful that as these changes are put in place (and the Cabinet Secretary has asked that they are implemented urgently) there are patients across Scotland whose clinicians may currently be considering, or in the process of, an IPTR. The Scottish Government does not think that it is acceptable for these patients to be disadvantaged because of the timing of events. We are therefore writing to you to ask you to consider 2 things.

Firstly, the Cabinet Secretary has asked us to re-emphasise that the concept of exceptionality should not be a factor in any IPTR under consideration in your Board but should be primarily about the individual clinical case. In addition, IPTR panels should exercise flexibility in their decision making in recognition of the issues highlighted in the Health and Sport Committee Report, and of the fact that we are entering a period of transition to a new clinically led peer review process. Patients should not be adversely impacted by this transition.

Secondly, we will be seeking input from you and others in putting in place the PACS. To help implement this new system, and to be able to assess the impact and effect of the changes made, we will need information on the types of applications you are currently dealing with. Therefore we are asking that you take the steps necessary within your Board to be able to share information on IPTR applications made in this transitional phase with the Scottish Government.

We will keep in contact with you as the process develops.

Annexe B: Letter from the Beatson West of Scotland Cancer Centre Consultant Committee to the Scottish Parliament Health and Sport Committee

We are writing regarding the forthcoming Health & Sport Committee meeting at which access to newly licensed medicines will be discussed again. We would appreciate the opportunity to comment on current aspects of access to medicines in our Cancer Centre, the largest in Scotland, serving more than 50% of the Scottish population.

As Glasgow-based cancer clinicians trying to provide the most effective and most appropriate treatments for our patients, the issue of access to drugs through the IPTR process remains highly problematic. We continue to experience repeated rejection of well-articulated IPTR applications. Following the Chief Medical Officer's letter of November 2013, we had hoped that there would be a noticeable change in the application process as well as a significant improvement in access to these important medicines.

Unfortunately, this has not been evident. Despite the wording of the CMO letter, which emphasised that "the concept of exceptionality should not be a factor in any IPTR under consideration" and the recommendation that decisions "should be primarily about the individual clinical case", our applications are still being repeatedly rejected.

The following rejection letter is not atypical: *"The panel agreed that this application could not be accepted as one or more of the access criteria were not met i.e. there was no evidence presented that this patient would have a significantly different response to 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"*

We find it difficult to see how this statement suggests any change from the previous requirement that we demonstrate that (a) patients are in some way different to those in the medical literature reviewed by SMC or NICE and (b) that this difference means they are more likely to derive benefit from the treatment. These responses to our applications seem simply to be evidence of a continuing requirement to demonstrate exceptionality. Indeed, our Clinical Director stated in a Consultants' meeting of 2nd December 2013 that, as far as he could tell, the CMO letter would have no bearing on the implementation of the IPTR process and that it was "business as usual".

We have since had more detailed electronic correspondence from our Director and Head of pharmacy outlining what they suggest are changes to the approach in line with the CMO letter. However, these changes appear to suggest little difference other than the presence of superficial statements suggesting a more flexible intent in the review of applications. The document states "core IPTR policies remain intact" and "the process for decision making remains unchanged; the onus remains on the specialist to demonstrate alignment of the case with existing IPTR approval criteria". Although the document outlines mechanisms by which 'flexibility' in the process will be enhanced, many of these recommendations should already be in place locally, albeit a part of the process that has largely not been followed.

We have seen no evidence of any difference in approach to date. Importantly, the documentation we complete remains unchanged and continues to require us to

provide supportive evidence of specific differences between the patient for whom we are making the application and those in the literature appraised by SMC / NICE.

None of us is aware of patients who have had these medicines approved for use in circumstances where they would previously have been rejected. Our greater concern, however, is that colleagues in Oncology departments elsewhere in Scotland report that their access to these medicines has improved since November 2013. The existence of postcode prescribing within Scotland adds to the injustice experienced by our patients.