Dear Mr McNeil

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

Thanks for your letter of 5th March 2014 and for seeking feedback from NHS Greater Glasgow & Clyde (NHSGGC) on this topic. I welcome the opportunity to clarify the NHSGGC policy position and the rationale for this, in response to recent guidance from the Scottish Government Health Department. You also refer to the concerns which were highlighted by the BOC Consultants to your Committee on 24th February 2014. I will address these issues in particular.

While recognising the need for change to the established IPTR process and while awaiting national guidance to support the PACS process, NHSGGC has devised an interim policy for managing individual treatment requests through consultation with partner Health Boards within the West of Scotland (WoS) Cancer Network (Appendix 1). The goal is a clear, consistent and equitable approach for all medicines which strikes a balance between the extant IPTR guidance and the principles of PACS. In particular the policy embraces ‘flexibility’ and promotes specialist involvement in the decision making process. The SGHD confirmed there were “no objections” to interim guidance proposed by West of Scotland Health Boards on 19th November 2013 (Appendix 2), on which the current NHSGGC Policy Statement is based.

This statement was developed in response to the following guidance:

- SGHD/CMO(2013)20 … Annex 1 to your letter
- CMO / CPO letter, 11th Dec ‘13 … Appendix 3

In particular, the latter guidance stressed that “the transitional period should be about exercising flexibility in relation to the decision making criteria in the extant IPTR best practice guidance”. We reject the concept of exceptionality but we retain the core criteria for IPTR approval, as defined in CMO (2011) 3. I can also reassure you that recent changes in GGC process accommodate additional flexibility and specialist clinical involvement through an expectation that:

- Peer review will be incorporated as part of the evidence base e.g. inclusion of a Multidisciplinary Team Report or the opinion of the Clinical Team Lead.
- Panel membership should include a clinical specialist
- The submitting clinician has an option to contribute directly to the panel discussion
An additional emphasis is placed on "peer approval" where the evidence is equivocal, where there is uncertainty, where the panel opinion is split or where reasonable doubt exists that the IPTR should be rejected.

On appeal, where the decision is in the balance or where further clinical input is considered desirable, deferral to designated clinical specialists from other Health Boards is enabled to achieve a second opinion on specific points.

We believe these measures ensure that patients are not disadvantaged due to the timing of these policy changes and are not adversely affected by the transition from IPTR to PACS. Indeed, the frequency of such requests has increased in 2014 and I am aware of cases where medicines have been approved for use under the new policy, following rejection under the original IPTR arrangements. It is important for the Committee to recognise, however, that GGC panels retain the ability to decline selected individual requests which clearly fail to align with the clinical criteria. This discretion may be unpopular but it's a fundamental principle to retain the integrity of the IPTR / PACS process. It also promotes the allocation of resources to the most effective treatments, not only for requests for medicines indicated for end of life care and rare conditions.

NHS GGC acknowledges the potential for differences in approach across NHS Scotland during the period October 2013 to January 2014 while SGHD guidance on the IPTR to PACS transition was open to interpretation. In response to this, NHSGGC has worked with other West of Scotland Boards to promote wider consensus. Specifically on 29th January 2014, we received confirmation from NHS Lanarkshire, NHS Ayrshire & Arran and NHS Forth Valley that they would align with a West of Scotland process. On 30th January 2014, the Scottish Association of Medical Directors also gave their support to the policy, raising optimism that an NHS Scotland consensus could emerge, to promote consistency of approach and minimise the risk of regional variations in prescribing practice. This is based on the understanding that it’s an interim arrangement which will be displaced when PACS is implemented.

I turn now to the statement from the West of Scotland Cancer Centre consultants of 24th February 2014. I understand the particular pressures which they face and I am anxious to listen to their concerns. Senior NHSGGC colleagues met their committee on 3rd February 2014 and again on 19th March 2014. The first meeting coincided with the introduction of the new NHSGGC IPTR/PACS policy. I understand it was a constructive information exchange and agreement was reached that the policy would be subject to evaluation over a 2 month period, concluding on 31st March 2014.

A particular challenge which the consultants highlighted was regional variability in approach to the management of individual treatment requests. I acknowledge the challenge this raises for prescribers and patients, and the inevitable questions for their elected representatives. As stated above, I believe that the West of Scotland Boards were the first to articulate their policy position, that it aligns with SG guidance, that it has been implemented across NHSGGC and that other NHS Boards recognise the importance of our compromise between IPTR and PACS during this transition period.

Some of the BOC consultants’ concerns may reflect the relatively short period between GGC policy implementation (3rd February 2014) and their representation to your Committee (24th February 2014). The original NHSGGC process (pre October 2013) was subject to external scrutiny during the Swainson Review and was commended as an example of good practice. The recent changes are a genuine attempt to build on this, with additional emphasis on peer review, clinician involvement and clinical influence on decision making. There is evidence of change both at policy level and at the level of managing the individual requests. No doubt the consultants would like us to move quicker and further on this but I believe this would not be in the long term patient interest and would risk undermining the future PACS arrangements. We have therefore retained the original proforma and the requirement that applications describe the clinical circumstances of the individual patient, in contrast to the characteristics of the trial populations assessed by SMC which informed the ‘not recommended’ advice for prescribing of the medicine in NHS S.
NHSGGC recognises that this process takes up valuable clinical time but presentation of the evidence is necessary for full consideration of the clinical priorities and to ensure equity and fairness of decisions reached. Recent developments, through the use of an electronic submission form, have been generally welcomed to improve the efficiency of the application process. The procedure is available for review by patients, public and professionals on the NHSGGC website. A revised Patient Information Leaflet has been produced which includes reference on sources for patients and the public to receive further information on the IPTR process e.g. from the NHS Board’s helpline or from Citizens Advice Scotland.

The Board’s Medical Director received further guidance from the CMO on 7th March 2014 (Appendix 4) which has been discussed in some detail with the clinical management team in our Regional Services Directorate and with other Boards across the West of Scotland. Of the 3 issues raised by the CMO, “expectations in relation to what flexibility in (IPTR) decision-making would look like in practice”:

- The submitting clinician should have the option to be part of the IPTR panel
  It has been agreed with immediate effect that the clinician should have the option to participate in the panel discussion. This has been incorporated into the NHSGGC policy statement and has been shared with our clinical colleagues
- Where the panel accepts that the submitted evidence shows that the patient’s clinical circumstances mean that they will benefit from the medicine, the IPTR would be approved. We believe this requires further consideration. All medicines considered by IPTR are licensed medicines. To gain a license the manufacturer has to demonstrate that the medicine is more likely than not to be effective. It is not possible to predict if an individual patient will respond. The IPTR process considers whether patients might, because of their individual circumstances, gain additional benefit over and above the patient population which was assessed by SMC when making their recommendation. This is the basis of the clinical peer review decision making process employed within the NHSGGC IPTR policy.
- Where there is a degree of uncertainty and the panel opinion is split about the evidence of benefit, the views of the submitting clinician and Lead Clinician should be influential in the IPTR decision reached.
  This is already built in to the NHSGGC approach

NHSGGC understands the need for compassion and understanding in difficult individual circumstances but also has a duty to ensure fairness in access to medicines for patients with conditions other than cancer who, as a result of their individual clinical circumstances, may be eligible for a medicine not recommended by SMC.

The West of Scotland Boards responded to the CMO on 18th March 2014 outlining their position and including the further revised NHSGGC policy (Appendix 5). Confirmation was received on 19th March 2014 from the Deputy CMO that she and the CMO were content that the revised policy met the requirement for increased flexibility. NHSGGC subsequently wrote to the West of Scotland Boards on 20th March 2014 advising that the revised policy would be implemented as agreed.

I hope this is helpful for your Committee to explain the current NHSGGC policy for access to medicines during the transition from IPTR to PACS, highlighting the changes implemented in light of SG guidance and seeking a balanced position to increase access to medicines ‘not recommended’ by SMC for patients whose individual clinical circumstances indicate additional benefit may be derived while acting in the best interests of all patients in the care of NHSGGC.

Yours sincerely

ROBERT CALDERWOOD
Chief Executive
APPENDIX 1

NHS GGC INTERIM POLICY STATEMENT:
Individual Patient Treatment Requests (IPTRs) and Peer Approved Clinical Systems (PACS)

National context
- SG New Medicines Review: Response to the Health & Sport Committee, October 2013
- “Proposed approach to deal with the transitional period from IPTR to PACS”, CMO / CPO letter, 11 December 2013

Local context
- NHS GGC Medicines Policy 5.2: “Management of Individual Patient Treatment Requests”
- NHS GGC Medicines Policy 5.3: “IPTR Appeal Process”
- “Access to new medicines: Transitional arrangements for processing IPTRs”, Letter to CMO / CPO from the WoS and Lothian NHS Boards’ Medical Directors and Directors of Pharmacy, 19 November ’13

Policy statement

Overall consolidation
- clinicians making a request should have all the relevant information
- patients should be given the GGC IPTR Patient Information Leaflet, including reference to internal and external sources of support and advice
- the process for decision making continues to focus primarily on showing alignment of the case with existing IPTR approval criteria
- these are clinical criteria which are assessed on a case by case basis; current GGC policy makes no reference to ‘exceptionality’
- decisions are not influenced by consideration of cost effectiveness or affordability
- this approach applies to all GGC patients and patients with WoS postcodes who are under the care of a GGC physician
- the option remains for the specialist to appeal against the original directorate IPTR decision; this appeal will be heard by a Board panel, as before.

Changes at Directorate level (IPTRs)
- the Directorate panels will exercise ‘flexibility’ via
  o the expectation that peer review will be incorporated as part of the evidence base e.g. an MDT report or the opinion of the Clinical Team Lead
  o the expectation that panel membership should include a clinical specialist
  o the option for the IPTR / PACS applicant to contribute directly to the panel discussion
  o the additional emphasis on ‘peer approval’ where the evidence is equivocal, where the panel opinion is split or where reasonable doubt exists for rejection of the IPTR criteria

Changes at Board level (IPTR appeals)
- the appeal panel will exercise additional ‘flexibility’ in cases where the decision is in the balance or where further clinical opinion is considered desirable, by deferring to designated clinical specialists from other boards for a second opinion on specific questions. This will be influential in the final outcome.

Rationale
- The aim is that patients should be positively supported and should not be adversely affected during the transition from IPTR to PACS, with patients / specialists and IPTR panel members kept fully informed
- NHS GGC policy statement now supports a balance of existing and new arrangements for all individual requests for licensed medicines in their licensed indications which are not recommended by SMC
- The CMO / CPO letters refer to “the decision making criteria in the extant best practice guidance” and IPTR panels should exercise “flexibility in their decision making”
- NHS GGC acknowledges the principles of PACS are to increase patient access to new medicines, by promoting greater clinical involvement in decision making about individual cases.
- NHS GGC will therefore introduce policy variations, as above, in the spirit of the New Medicines Review and subsequent CMO / CPO correspondence (national context above)
- This policy is a form of ‘peer approved clinical system’ with retention of the existing basis for decision making until an acceptable alternative is agreed which is consistent and equitable, locally and nationally
- It will be subject to review on 30th April 2014, or earlier in response to further guidance from SGHD.
Dear Harry and Bill

Access to New Medicines: Transitional Arrangements for Processing Individual Patient Treatment Requests (IPTRs)

We refer to the SG announcement of 8 October that the IPTR process will be replaced with a Peer Approved Clinical System (PACS). In particular, we are writing to seek clarity on your letter of 5 November ‘13 to NHS Boards which has its focus on transitional arrangements for processing individual patient treatment requests.

We acknowledge the principles of PACS are to increase patient access to new medicines, by promoting greater clinical involvement in decision making about individual cases and increased consideration of patient outcomes. Statements by the Cabinet Secretary in Scottish Parliament indicated his determination for minimal delay in moving from one process to another. This perception is shared by some specialist prescribers, patients and their elected representatives. While we recognise that work is in progress to guide implementation, we believe the scale of change is substantial and we understand there is therefore no fixed timescale for the transition.

The components of PACS which have been announced include:

- A single national system which will be applied locally;
- A clinically led, peer review approach;
- A standard application form for NHS Scotland;
- A centralised patient support team established by SG;
• Development of training materials for NHS clinicians;
• Development of improved information for patients, families and their carers;
• A register of clinical specialists to assist NHS Boards with the provision of specialist clinical advice
• Strict auditing arrangements to minimise variation in decision making

None of the above is in place at this time.

Your letter of 5 November introduces another challenge to the management of individual requests for access to medicines which are not recommended by SMC. The letter emphasises that Scottish Government does not wish patients to be disadvantaged during the transition from IPTR to PACS and states that NHS Boards should now have processes in place such that:

• The concept of exceptionality should not be a factor in any IPTR under consideration;
• The focus should be on individual clinical cases;
• IPTR panels should exercise flexibility in their decision making, in recognition of points highlighted in the Health and Sport Committee Report;
• Patients should not be adversely affected by the transition to PACS;
• Information on IPTR applications made in this transition phase should be shared with the SG.

NHS Boards will support development of the Scottish Government implementation plan for PACS. We understand this was initiated through engagement with representatives of the regional cancer networks on 13 November. Feedback indicates that the meeting was a useful starting point for PACS implementation but it highlighted some of the challenges which lie ahead, both in the transition phase and in the longer term.

We are particularly concerned about the impact on patients in the transition phase whose requests are in progress, who are currently receiving medicines via co-payment arrangements or who have recently been denied access on the basis of their own IPTR or clinical precedent. Expectations have been raised for these patients and their specialist consultants, but NHS Boards currently have no basis to introduce change which is consistent and equitable on a national scale. This has created uncertainty and distress for the individuals affected.
We understand that the deputy CMO reassured our colleagues at the meeting of 13th November that the existing guidance remains extant. Therefore, until we have the PACS process agreed, the current basis for decision making on individual cases must be maintained (as defined in CMO (2011)3 – Implementing CEL 17 (2010): Introduction and availability of newly licensed medicines in the NHS in Scotland – Good practice guidance for NHS board management of individual patient treatment requests (IPTRs) - paragraphs 11 and 12). This makes no reference to exceptionality, cost effectiveness or affordability.

However, we can immediately reflect the CMO/CPO letter of 5th November to moderate our approach and introduce some flexibility to ensure that:

- clinicians making the request have all the relevant information;
- patients are given the Patient Information Leaflet and reference to internal and external sources of support and advice;
- panels invite clinical input as a standard contribution to the review of evidence, either via MDTs, other peer groups or individual specialists with a particular interest;
- each panel membership includes a clinical specialist, wherever possible;
- where the evidence is equivocal, where there is any doubt that the SMC advice applies to the individual patient or where the panel opinion is split, it would seem appropriate to put additional emphasis on ‘peer approval’
- all IPTR activity continues to be monitored through agreed NHS Board reporting arrangements to SG.

The goal is a clear, consistent and equitable process. We will endeavour to introduce change as above. We believe this aligns with the spirit of your letter of 5 November and supports patients affected by the transition, while not undermining recent IPTR decisions or future PACS requests. We caution against any further ‘flexibility’ which would undermine current policy, remove the objective basis for decision making, disadvantage patients and create new risks for Boards and for NHS Scotland. Our focus is clinical risk, on the understanding that affordability repercussions will be considered through other mechanisms.

Some Boards face current challenges from the management of difficult copayment cases and appeals. We are aware of specific ongoing requests for oncology medicines but there are wide ranging repercussions across the full range of medicines that are not recommended by SMC. We therefore seek your assurance that SG will support this balance of existing and new arrangements with all individual requests for medicines in the transition from IPTR to PACS. What we are proposing is essentially a ‘Peer Approved Clinical System’ but with retention of the existing basis for decision making until an acceptable alternative is agreed.
We seek your immediate decision on this in light of the urgency of specific individual cases under consideration. Representatives of our groups would of course be willing to meet you and provide ongoing support / advice to develop PACS and manage the unique challenges of the transition from IPTR.

Thank you.

Yours sincerely

Dr Jennifer L Armstrong

Dr Alison Graham

Dr Iain Wallace

Dr Peter Murdoch

Dr David Farquharson
Professor Catherine E McKean
Head of PPSU

Professor Norman Lannigan
Acting Head of PPSU

Michele Caldwell

Gail Caldwell

Christine Gilmour

Angela Timoney

Medical Directors and Directors of Pharmacy
NHS Greater Glasgow & Clyde, Lanarkshire, Ayrshire & Arran, Forth Valley & Lothian

cc: Chief Executives
    Directors of Finance
    Clinical Lead for the Regional Cancer Networks
    Clinical Director, Beatson
Thank you for your letter of 19 November seeking the Scottish Government’s support to your proposed approach to deal with the transitional period from IPTR to PACS. The letter of 5 November reinforced the message given by the Cabinet Secretary in the Parliamentary debate on this subject in October.

We do not have any objection to the steps you have set out however would suggest that if the approach is to attempt to replicate what a peer based system should do then a clinical specialist must be included in the panel. We should also make clear that the request for flexibility extends to decision making. PACS will operate on a different basis and in a different context from IPTR. We anticipate that when PACS is rolled out it will be in the context of the change of approach of Scottish Medicines Consortium that the Cabinet Secretary has directed. In PACS we want to see an end to the current system which has occasionally meant that patients who are in a position to receive private treatment are at times able to use this to get a subsequent positive IPTR decision but those patients who are not able to fund private treatment do not have the same option. Ministers do not envisage that the PACS will operate on the basis of policy criteria in the same way that the IPTR has done. Ministers want a new system where the treating clinician is at the heart of the decision making process and for decisions to be able to be taken for individual patients that operates on the basis of the outcome that the treating clinician wants to achieve. Therefore flexibility in the transitional period should be about exercising flexibility in relation to the decision making criteria in the extant IPTR best practice guidance and in cognisance of the work ongoing at SMC to look at changing decision making parameters for medicines for ‘end of life’ and very rare conditions.

We would like to reassure you that we do not think that a change in approach in either the interim or under the new system will result in undermining previous decisions. Ministers and the Parliament are seeking a different approach – we are moving in to different territory.
We should also be clear that Ministers are aware of the risks of the new approaches however the Scottish Government and the Scottish Parliament are strongly of the view that change is required.

Yours sincerely

Harry Burns                   Bill Scott

HARRY BURNS                   PROFESSOR BILL SCOTT
7 March 2014

Dear Jennifer

I refer to the joint CMO/CPO letters issued dated 5 November 2013 sent under cover of SGHD/CMO(2013)20 and 11 December 2013 in which it was requested that, in light of the fact that the Scottish Government does not think that it is acceptable for patients currently going through the IPTR process to be disadvantaged during the transition from IPTR to PACS, NHS Boards should exercise flexibility in their IPTR decision-making.

I have immediate concern around the restrictive interpretation of interim guidance and the representation made to the Health and Sport Committee from the Beatson Consultants Committee.

I understand that NHS Greater Glasgow & Clyde are engaging with the Beatson Consultants Committee about the transitional arrangements for IPTRs. To assist with this, and to provide further advice of what the Government expects (and also to reflect the Health & Sport Committee’s expectation of IPTR handling during the transition), I thought it would be helpful if I set out what our expectation is in relation to what flexibility in decision-making would look like in practice:

- The submitting clinician should have the option to be part of the IPTR panel;
- Where the panel accepts that the submitted evidence shows that the patient’s clinical circumstances mean that they will benefit from the medicine, the IPTR would be approved.
Where there is a degree of uncertainty and the panel opinion is split about the evidence of benefit, the views of the submitting clinician and Lead Clinician should be influential in the IPTR decision reached.

I am happy to discuss this with you.

Yours sincerely

Harry Burns

HARRY BURNS
Dear Harry

Re: NHS GGC Interim Policy Statement: IPTR to PACS transition

Thanks for your letter of 7th March ‘14. As you know, the interim policy was developed across the West of Scotland as this process is run by GGC with the consent of the WoS boards for all patients in the region whose clinical care is led by a GGC clinician. We have therefore shared your letter with these boards and respond on their behalf as well as GGC.

We acknowledge the recent concerns expressed by the BOC Consultants’ Committee. At a recent meeting, the agreement with the BOC clinicians is that we would review this policy on the 31st of March. With leadership from the Regional Services Directorate, my senior colleagues have agreed to meet representatives of the BOC Consultants on 19th March. We therefore welcome further clarification of what ‘flexibility’ in decision making’ would look like in practice. More importantly, there are 15 patient requests currently awaiting review by the BOC IPTR/PACS panel from all boards across the west of Scotland.

The focus is on individual requests for access to medicines not recommended by SMC, in the interim between IPTR and PACS processes. As you know, NHS GGC has developed an interim policy (attached), in response to your letters of 5th November and 11th December 2013. This was implemented on 3rd February 2014 with the full support of the Boards which constitute the West of Scotland Cancer network. We all believe that the criteria set out in your letter would result in all requests being accepted and therefore would query whether the whole process would become obsolete. This would incur high opportunity costs for boards and ultimately compromise other patients.
We are open to further adaptation of the NHS GGC Interim Policy. I hope it’s helpful to address each of your bullet points in turn:

- **The submitting clinician should have the option to be part of the IPTR panel**
  
  We recognise the potential benefit of direct participation by the submitting clinician. This is the format we adopt when conducting an IPTR Appeal Panel at Board level. This is manageable at appeal where activity is low. We question the feasibility of the clinician routinely participating in the directorate IPTR/PACS panels, both in practical and in governance terms. This means that clinicians at the BOC would have less time to see patients and spend more time on panels. We do not believe this is good for patients.
  
  Proposal:
  
  We support the option of more active contribution by the applicant, particularly to clarify any uncertainties and provide additional clinical detail, but without full voting membership. Given the frequency of this activity in NHS GGC, this input will be received in various formats, prompting full discussion of all the issues by all the existing panel members, including the Clinical Team Lead, and allowing the decision to be reached dispassionately without conflict of interest.

- **Where the panel accepts that the submitted evidence shows that the patient’s clinical circumstances mean that they will benefit from the medicine, the IPTR would be approved.**

  You are aware that IPTR eligibility is restricted to licensed medicines in licensed indications which have been judged by the regulatory authority to have proven clinical efficacy. Therefore, by definition, all requests imply that the patient will derive some benefit from the medicine, in the opinion of the applicant. It would be impossible for panel members to refuse any application in these circumstances.

  Proposal:

  This is central to the fundamental question raised above. The key principles of the current IPTR policies are (1) utilisation of SMC advice as a point of reference, (2) determination of whether the individual patient differs from the ‘not recommended cohort’ and (3) judgement of whether this difference will confer additional clinical benefit. Your wording above appears to equate to clinical freedom, calling the purpose of the SMC and the individual patient review process into question. We urge reconsideration.

- **Where there is a degree of uncertainty and the panel opinion is split about the evidence of benefit, the views of the submitting clinician and Lead Clinician should be influential in the IPTR decision reached.**

  We believe this is consistent with the existing wording in the GGC policy, in relation to how we are exercising flexibility in decision making at both Directorate and Board levels.

  Proposal:

  We support this as an element of interim policy.

The current GGC Policy was revised from 11th December ‘13, subject to consultation during January ‘14 and implemented on 3rd February ‘14. It seeks a balance between the extant IPTR guidance and the proposed principles of the PACS process. It has been operational for 1 month only, so it seems premature to draw conclusions on its strengths and weaknesses. We believe that it embraces ‘flexibility in decision making’ and that we can point to cases which have recently been approved following refusal under previous arrangements. However, while access has been improved, our panels retain the authority to decline specific requests based on the individual patient circumstances. This raises the risk of challenge from individual patients, specialists, politicians and colleagues from the pharmaceutical industry. It is vital that SGHD and NHS Boards have a united front in these circumstances.
In light of the above, we have made further changes to the NHS GGC interim IPTR / PACS policy (attached) but we urge caution with any further dilution of the extant policy in the absence of a viable alternative which can be applied equitably across NHS Scotland.

We hope this is a useful contribution to the ongoing discussion.

Thank you.

Yours sincerely

Dr Jennifer L Armstrong

Dr Alison Graham

Dr Iain Wallace

Dr Peter Murdoch

Professor Norman Lannigan
Acting Head of PPSU
Medical Directors and Directors of Pharmacy
NHS Greater Glasgow & Clyde, Lanarkshire, Ayrshire & Arran & Forth Valley