1. **Introduction**

In response to a request from the Scottish Government, with effect from 1 June 2018, Healthcare Improvement Scotland is co-ordinating the National Review Panel as part of the revised Peer Approved Clinical System (PACS) Tier Two.

2. **Role and remit**

- The National Review Panel will be advisory and not make ‘decisions’ or ‘instruct’ NHS board decision-making.

- The findings and recommendations of the National Review Panel will be issued to the NHS board Chief Executive. If required, the NHS board will convene a new PACS Tier Two Panel to revisit its original decision, taking into account the National Review Panel reasoning as to why it considered either the original decision unreasonable in light of the evidence submitted and/or that due process had not been followed.

- The National Review Panel will accommodate requests on either of the following grounds:
  - the NHS board has failed to follow due process and the situation cannot be resolved locally, and/or
  - the NHS board has reached a decision which could be deemed unreasonable in light of the evidence submitted.
The National Review Panel will refer to the following decision-making criteria used by the local NHS board PACS Tier Two Panel.

1. The clinician can demonstrate that a reasonable attempt, or appropriate consideration, has been made to treat the patient in the first instance with medicines currently accepted by the Scottish Medicines Consortium (SMC) for routine use in NHS Scotland for this condition and for the patient in question that these medicines are deemed unsuitable or have been found to be ineffective.

2. The clinician can present an evidence-based case to demonstrate the potential that the patient will achieve a measurable clinical benefit at least comparable to if not better than that experienced by the population considered by SMC.

Provide independent advice to the local NHS Board PACS Tier Two Panel to support consistency in decision making across NHS Scotland in relation to individual requests to use a medicine (other than ultra-orphan) for a patient that:

- is a medicine for an indication that has been considered and not recommended for use in NHS Scotland by the Scottish Medicines Consortium (SMC), or

- is a medicine accepted for restricted use by SMC but the intended use is outwith SMC restrictions, or

- is a medicine which has been submitted to and is awaiting/undergoing evaluation by the SMC.

The National Review Panel will only review submissions where the clinician has provided a full and appropriate completed submission. Paperwork that is incomplete or has been completed incorrectly will be returned to the requesting clinician and will not be considered by the National Review Panel. This should be pursued through a resubmission to the NHS board’s PACS Tier Two review process for local resolution.

Where a review is requested because the clinician and patient consider that the NHS board has failed to follow due process then the National Review Panel will only accommodate a review in the event where this cannot be resolved locally.

In circumstances where new evidence emerges or the local NHS Board PACS Tier Two Panel decision was made on a factual inaccuracy, this should be pursued through a resubmission through the NHS Board PACS Tier Two process for local resolution.
3. Governance arrangements

Healthcare Improvement Scotland

National Review Panel Steering Group

Internal Group

National Review Panel

The National Review Panel will be governed within the Code of Corporate Governance of Healthcare Improvement Scotland.

Healthcare Improvement Scotland is responsible for any judicial review in relation to the processes of the National Review Panel and its advice.

Dr Brian Robson, Executive Sponsor, will report on the work of the National Review Panel to the Quality Committee as directed by the Board requirements.

4. Membership

Each National Review Panel will have four members:

<table>
<thead>
<tr>
<th>Chair of National Review Panel</th>
<th>Representative of Scottish Association of Medical Directors</th>
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<tbody>
<tr>
<td>Senior Pharmacist</td>
<td>Representative of Directors of Pharmacy within NHS Scotland</td>
</tr>
<tr>
<td>Local PACS Tier Two panel member</td>
<td>Representative from ADTC/PACS Tier Two networks</td>
</tr>
<tr>
<td>Public Partner</td>
<td>Healthcare Improvement Scotland</td>
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The proceedings of the Panel will be observed by a second Public Partner.

Panel members will not consider cases from a clinician within the same NHS board or where the patient is being treated within the same NHS board in which the panel member works. The National Review Panel will therefore require a pool of members to allow it to replace a member in these circumstances. There may be more than one member from the same NHS board.
In the event that a conflict of interest is identified, a replacement panel member will need to be found. Conflicts specific to the National Review Panel will arise where:

- a member of the panel has been involved in the SMC committee that made the decision on the medicine being submitted to the National Review Panel, or has been involved in an SMC committee that has considered a comparator medicine to the medicine being submitted in the last three years, and
- a panel member will not consider cases from a clinician within the same NHS board or where the patient is being treated within the same NHS board in which the panel member works.

The National Review Panel will be supported operationally by the National Review Panel Clinical Leads (Pharmacy and Medicine) who will have expertise in critical appraisal of submitted evidence. The Clinical Leads will attend each panel meeting to provide wider context and support to panel members. The Clinical Lead will not be involved in the decision-making processes of the panel.

5. Members’ roles and responsibilities

All members of the panel have shared responsibility for the discharge of the functions of the National Review Panel to ensure they are open, transparent and robust. The Chair of the panel is responsible for preserving order, promoting openness and debate between members of the panel.

All members of the panel will participate in discussions to reach a consensus on the outcome of the panel. The Chair of the panel will have the final ruling in circumstances where consensus cannot be reached.

6. Secretariat

Healthcare Improvement Scotland will provide the secretariat for the National Review Panel.

7. Decision-making

The National Review Panel will follow the same decision-making criteria as the local NHS board PACS Tier Two Panel which are laid out in the guidance issued by Scottish Government on 29 March 2018.

The National Review Panel will agree its advice on the day that it meets and inform the Chief Executive of the NHS board within one working day of the panel meeting in line with the guidance issued by Scottish Government on 29 March 2018.

8. Meetings

The National Review Panel will be convened on a monthly basis. Meetings can be held electronically (WebEx/video and teleconferencing) to support the rapid turnaround of appeals and to ensure flexible availability for panel members from different geographical areas.

Ad hoc meetings of the National Review Panel will be convened when the clinical urgency of the case dictates that this is necessary.

The team will meet for a briefing from the clinical lead(s) at the start of each panel.
9. Reviews

The National Review Panel will consider the same evidence that was considered by the local NHS board PACS Tier Two Panel. This evidence will be presented on the nationally standardised PACS Tier Two paperwork. In order to maintain the privacy of the patient and in line with data protection requirements:

- personal identifiers within the PACS Tier Two paperwork will be redacted at source by the NHS board clinician before submission to the National Review Panel
- data minimisation will be in line with *Data Redaction & Standardised Adverse Event Review Reports*, Healthcare Improvement Scotland (December 2014), and
- all National Review Panel information will be managed in line with Healthcare Improvement Scotland information governance and records management policies.

The submission to the National Review Panel requires that no new evidence is presented.

The requesting clinician will be given the opportunity to present the case to the National Review Panel (virtually or in person).

The Chair of the original NHS board PACS Tier Two Panel will be given the opportunity to present the considerations which led to the original NHS board decision (virtually or in person).

10. Confidentiality

Information may be of a sensitive or confidential nature. It is vital that all members understand their responsibility to treat as confidential, information which may be available to them, or obtained by them, or which may be derived whilst working on the National Review Panel.

Individuals must not breach this duty of confidence by disclosing, or using in an unauthorised manner, confidential information, or providing access to such information by unauthorised individuals or organisations.

11. Conflicts of Interest

All members of the National Review Panel will be asked to declare, at the beginning of each meeting of the panel, any conflicts of interest using the Declaration of Interests template.

Conflicts of interest will be recorded at each meeting of the panel.

12. Communication of outcomes

The National Review Panel will provide a response to the NHS board Chief Executive within one working day of the panel meeting.

The response will specify the action to be taken by the NHS board PACS Tier Two Panel with immediate effect.