SECTION 16.3 - MANAGED ENTRY OF NEW MEDICINES - APPEALS

BACKGROUND and PURPOSE

The purpose of this section of the Code of Practice for Medicines Governance is to outline the processes required to submit and manage an appeal against a decision of an individual patient treatment request panel.

This section must be read in conjunction with Sections 16.1 – Managed Entry of New Medicines and 16.2 – Individual Patient Treatment Requests.

APPEALS AGAINST IPTR DECISIONS

1.1 Where an IPTR panel has decided that a particular medicine should not be made available for an individual patient, then that patient or their representative, with the support of their clinician, has the right to appeal that decision.

1.2 Appeals may be made on the following grounds:
   - The IPTR panel has failed to act fairly (where it is felt that due process has not been followed)
   - The IPTR panel has reached a decision which cannot be justified in light of the evidence submitted

1.3 An appeal will not be accepted solely because the patient or clinician does not agree with the decision reached.

1.4 An appeal can be submitted only where the clinician supports the patient / patient representative’s decision to appeal.

1.5 Appeals should be submitted with 14 days of receipt of the IPTR panel decision.

NOTE: Where new evidence for the medicine emerges or if the original decision was based on a factual inaccuracy, this should not routinely be considered as part of an appeal but a resubmission through the initial process.

2. Lodging an appeal

2.1 The appeal should be lodged in writing to the Chief Executive, NHS Ayrshire & Arran.

2.2 The patient or their representative seeking to appeal a decision regarding availability of a medicine should specify the grounds for the appeal and this may include a brief statement of the case to be made, together with any supporting documentation available at this time.
3. Consideration of the appeal

3.1 The Chief Executive and a Non Executive member of the NHS Board will consider the request for the appeal and will inform the patient or their representative within 5 working days whether an appeal will be heard.

3.2 When it is determined that a Medicines Appeal Panel (MAP) hearing will be heard, the Chief Executive will inform the Associate Director of Nursing (PFPI) that such a hearing will be required. The Chief Executive will give the Associate Director of Nursing (PFPI) an indication of the clinical urgency associated with the requirement to arrange the MAP hearing.

3.3 Appeals will be heard within a maximum 28 days of the receipt of the written appeal, and will be commensurate with the clinical urgency of the appeal.

4. The medicine appeals panel (MAP)

4.1 Where an appeal is granted a MAP will be established as detailed below. This panel will not include any individual who considered the original IPTR.

- Non Executive Director of the NHS Board, nominated by the NHS Board on an annual basis (each April), who will act as the Chair of the MAP. All Non Executive Directors of the NHS Board will be briefed, on an annual basis, by the Director of Pharmacy, on the background and procedures associated with consideration of an appeal against a decision regarding availability of a medicine. This will allow urgent appeals to be held due where the main nominee is absent or unavailable.

- Chief Executive of NHS Board

- External expert, for example, chair of another NHS Board’s Area Drug & Therapeutics Committee. The Chair of the MAP will select the external expert to reflect the matter being considered. Officers of NHS Ayrshire & Arran will provide support in this regard.

- A member of the public, identified from a list maintained and updated annually by the Associate Director of Nursing (PFPI) (the membership will be drawn from established lay groups – Public Partnership Forums and the Patients’ Council). All members of the public who have agreed to participate in a MAP will be briefed, on an annual basis, by the Director of Pharmacy, on the background and procedures associated with consideration of an appeal against a decision regarding availability of a medicine.

**NOTE:** The Chair of the NHS Board may provide temporary nominations to the MAP if unacceptable delays would be caused by absence of members of the MAP.

4.2 The Associate Director of Nursing (PFPI) or their delegated representative will be responsible for the organisation of the arrangements for the MAP hearing. This will include forming the MAP at an appropriate time and venue and distribution of all necessary paperwork and documentation to facilitate discussion at the hearing.
5. Patient advocacy and support

5.1 NHS Ayrshire & Arran recognise that the process of application, preparation and participation in appealing decision made about availability of medicine may be challenging for a patient or their representatives.

5.2 When a patient or their representative indicates that they wish to appeal a decision regarding availability of a medicine they will be allocated a dedicated patient support officer by the Associate Director of Nursing (PFPI). In addition the patient and/or their representative will be offered access to independent advocacy.

5.3 The role for the patient support officer is to be the main point of contact within NHS Ayrshire & Arran prior to the MAP hearing. The patient support officer will offer support to guide the person seeking to appeal a decision regarding availability of a medicine through the process of preparation for the MAP hearing. The patient support officer will not offer specific advice regarding the specific details associated with the decision under appeal.

6. Prior to the appeal

6.1 Details of the procedures of the appeal hearing shall be supplied to the patient or their representative by their dedicated patient support officer. This will include verbal and written advice as to the right to be represented at the hearing and to call experts, if necessary. The patient or their representative will also be given written and verbal advice as to who they may consider to be their advocate at the appeal hearing. This shall be done as soon as possible after receipt of the appeal.

6.2 The Executive Medical director or named deputy on the original IPTR panel will provide the IPTR decision record to the Associate Director of Nursing (PFPI) together with any supporting documentation.

6.3 The patient or their representative shall be invited to submit, to the Associate Director of Nursing (PFPI), a brief statement of the background to the decision under appeal, together with any supporting documentation. This statement and/or supporting documentation may be produced by the patient’s clinician as required.

6.4 If either party wishes to take advantage of the opportunity to submit further written information, this should take place, where practicable within 7 days of lodgement of the appeal.

6.5 At least 7 days notice of the hearing of the MAP shall be given. Such notice shall include copies of any papers submitted by the parties. If there is a requirement for a hearing of the MAP to be heard at short notice due to the decision having potentially significant effects on outcome for the patient’s treatment then the limit of 7 days notice may be waived by the Chief Executive of the NHS Board.

6.6 If either party intends to submit or refer to any further documentary evidence then this should be in hands of the Associate Director of Nursing (PFPI) prior to
the hearing. The Associate Director of Nursing (PFPI) shall ensure, where practicable, copies are available at the hearing and that parties are notified of the intention to submit or refer to this further documentary evidence.

7. **Procedures at the Hearing**

7.1 The person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative shall be present at all times during the hearing of the appeal.

7.2 Person or persons acting in an advisory capacity only to person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative may also be allowed to be present at the hearing, provided such persons are made known to the MAP prior to the appeal commencing.

7.3 The person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative shall put forward the detail of the appeal in the presence of the officer of NHS Ayrshire & Arran who made the decision or delegated representative and call such experts as agreed prior to the appeal commencing.

7.4 The officer of NHS Ayrshire & Arran who made the decision or delegated representative shall have the opportunity to ask questions of the experts supporting the person seeking to appeal a decision regarding availability of a medicine but not of the person themselves.

7.5 Members of the MAP shall have the opportunity to ask questions of the person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative or expert.

7.6 The person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative shall have the opportunity to ask further questions of the expert, to make points of elucidation arising from questions from the officer of NHS Ayrshire & Arran who made the decision or delegated representative and members of the MAP.

7.7 The members of the MAP shall then have the opportunity to ask questions of the officer of NHS Ayrshire & Arran who made the decision or delegated representative.

7.8 The officer of NHS Ayrshire & Arran who made the decision or delegated representative shall have the opportunity to ask further questions of the expert representing the person seeking to appeal a decision regarding availability of a medicine, to make point of elucidation arising from questions from expert and members of the MAP.

7.9 The person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative and the officer of NHS Ayrshire & Arran who made the decision or delegated representative shall have the opportunity, if they wish to sum up the information presented in the appeal, introducing no new material.
7.10 The officer of NHS Ayrshire & Arran who made the decision or delegated representative, the person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative and any witnesses/experts if present shall withdraw from the meeting.

7.11 The MAP shall then deliberate in private, only recalling the person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative and officer of NHS Ayrshire & Arran who made the decision or delegated representative, to clarify points of uncertainty on evidence already given. If recall is necessary, both parties are to return notwithstanding only one is concerned with the point giving rise to doubt.

7.12 The MAP shall recall the person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative and officer of NHS Ayrshire & Arran who made the decision or delegated representative and announce their decision on the appeal, which will be confirmed in writing.

7.13 For the assistance of parties to the appeal, a procedure note has been prepared and is attached below. This note is an abbreviated version of the detailed procedures set out above.

8. Procedures following the appeal

8.1 The Chief Executive of NHS Ayrshire & Arran shall give to the person seeking to appeal a decision regarding availability of a medicine and the officer of NHS Ayrshire & Arran who made the decision written confirmation of the decision taken by the MAP. This must include reasons for the decision. The response to the appellant will indicate that if they remain not satisfied then the only further option open is to seek legal advice. This shall be effected within 5 working days of the hearing of the appeal at which the decision was taken.
9. Procedure notes

Person or Representative
Statement explaining grounds of appeal, including submission of supporting documentary evidence and the calling of experts

Questions by the officer of NHS Ayrshire & Arran who made the decision or representative

Officer of NHS Ayrshire & Arran who made the decision
Statement detailing the reasons for the decision of MRG/NHS Ayrshire & Arran regarding introduction of new medicine, and answering the grounds of the appeal including the submission of documentary evidence and calling experts as appropriate

Questions by Person or representative

Members MAP
Questions for either party

Officer of NHS Ayrshire & Arran who made the decision
Sum up

Person or Representative
Sum up

Adjournment
MAP will decide whether they wish to adjourn in order to consider the appeal submitted and the representations made, in which event all parties shall withdraw

Decision
The MAP will re-convene and the decision shall be intimated to all parties