SECTION 16 – MANAGED ENTRY OF NEW MEDICINES

BACKGROUND AND PURPOSE

The most common therapeutic intervention undertaken in the NHS, is the use of a medicine. Each year new medicines and formulations are developed by the pharmaceutical industry, and many of these provide new and novel therapeutic options for clinicians and patients.

The purpose of this section of the Code of Practice for the Management of Medicines is:

- To ensure that all healthcare professionals understand the NHS Ayrshire & Arran local policy and procedure for the managed entry of new, licensed medicines.
- To provide a fair, consistent and transparent process for patients.
- To ensure local compliance with NHS HDL (2003) 60 – "A Strengthened Role for the Scottish Medicines Consortium".
- To ensure local compliance with NHS HDL (2006) 29 – "SMC and Single Technology Appraisals from NICE"
- To outline a fair, consistent and systematic process for requests for medicines to be prescribed on a case by case basis for individual patients.
- To outline a fair, consistent and systematic process for requests for medicines to be prescribed on an exceptional circumstance basis for individual patients.
- To outline the arrangements regarding the appeals process that may be used to challenge decisions regarding access to medication of NHS Ayrshire & Arran.

This policy relates to medicines being used within the limitations of their marketing authority – i.e. the medicine has a licence for the indication being considered. Unlicensed medicines, or those intended for use out with their licensed indications are covered within Section 9 of the Code of Practice, and prescribers should be aware that where the resource implications are significant, applications to prescribe unlicensed and off label medicines may also have to be considered in the context of part 3 of this policy.

SCOPE

This policy applies to all prescribers acting on behalf of patients' resident within the NHS Ayrshire & Arran Area.

POLICY STATEMENT

New medicines will only be available for use in NHS Ayrshire & Arran where:

- They have been added to the Joint Formulary following a review of the place in therapy of each new medicine, taking into account local need, and information regarding clinical and cost effectiveness and where funding requirements have been identified and met in full. Formulary management procedures apply.

OR

- Where use in a case by case basis has been applied for, considered and approved.

OR

- Where use in an exceptional set of circumstances has been applied for considered and approved

PART 1 – MANAGED ENTRY OF NEW MEDICINES

The approved procedure for the managed entry of new licensed medicines into clinical practice is as follows:

1. THE LOCAL PROCEDURE FOR THE MANAGED ENTRY OF NEW MEDICINES INTO CLINICAL PRACTICE WILL APPLY IN THE FOLLOWING CIRCUMSTANCES :

1.1 Where a new medicine is granted a marketing authorisation within the United Kingdom and becomes available for use.

1.2 Where a new major formulation of an existing licensed medicine is granted a marketing authorisation within the United Kingdom and becomes available for use.

1.3 Where an established licensed medicine has an extension to the marketing authorisation to allow a major new indication.

1.4 The local process is graphically outlined in Appendix 1.

2. ROLE OF THE SCOTTISH MEDICINES CONSORTIUM (SMC)

2.1 The SMC have a remit to provide advice to NHS Boards and their Area Drug & Therapeutics Committees about the status of all newly licensed medicines, all new major formulations of existing medicines and major new indications of established medicines.

2.2 This advice will be made available as soon as practical after the launch of the medicine involved.

2.3 The SMC advice will take account of the clinical and cost effectiveness of each new medicine and the advice regarding the new medicine will be categorised as follows:

- Acceptable for General Use in NHS Scotland
- Acceptable for Restricted Use in NHS Scotland – the terms of the restriction may apply to specified patient groups and specified prescribers
- Not recommended for use in NHS Scotland

The SMC will also give further guidance regarding the context of the main recommendation; this advice is intended for local formulary use.

2.4 In accordance with NHS HDL (2003) 60 the SMC will specifically advise NHS Boards and their ADTCs when a particular medicine must be implemented within 3 months as part of a national implementation plan.

2.5 Where such a national plan is not outlined, implementation is a matter for local decision making and planning.

3. LOCAL PROCESS FOLLOWING RECEIPT OF SMC ADVICE

3.1 The Area Drug and Therapeutics Committee (ADTC)

The NHS Board shall remit the discussion of the advice received from the SMC to the NHS Ayrshire & Arran ADTC, who will appraise each recommendation from the SMC and will recommend a course of action from the following options:

- That the medicine should be excluded from the NHS Ayrshire & Arran Joint Formulary
- That the medicine should be referred to the Formulary Management Group for further consideration.
- That the medicine should be referred to the Medicines Resource Group for further consideration.

3.2 The Formulary Management Group (FMG)

- The FMG will consider the recommendations from the ADTC based on SMC advice and, under a framework of delegated authority from the ADTC, will make decisions regarding the inclusion/exclusion within the formulary of new medicines from within a therapeutic area.
- In particular the FMG will decide on the formulary status of medicines where the formulary already contains suitable alternatives for clinical use.

3.3 The Medicines Resource Group (MRG)

- The MRG will review the decisions of the ADTC following its appraisal of SMC advice.
- The MRG will consider medicines approved for use by the ADTC where the resource implications associated with introduction are estimated to be significant.
- The MRG will make recommendations to NHS Ayrshire & Arran Board regarding the annual budget requirements associated with the managed entry of new and established medicines.
- NHS Ayrshire & Arran Board will make the final decisions regarding the resource allocation for new medicines.
- This budget requirement will include a figure for horizon scanning to enable the MRG and NHS Ayrshire & Arran to respond to new medicine developments in year.
- The MRG will use the allocation identified for horizon scanning to manage in year entry of new medicines.
- In year, the MRG will advise on the management of entry of new medicines into clinical practice on a case by case basis, against agreed clinical criteria/protocol (national, regional, local).

The local process for the managed entry of new medicines is shown in Figure 1.

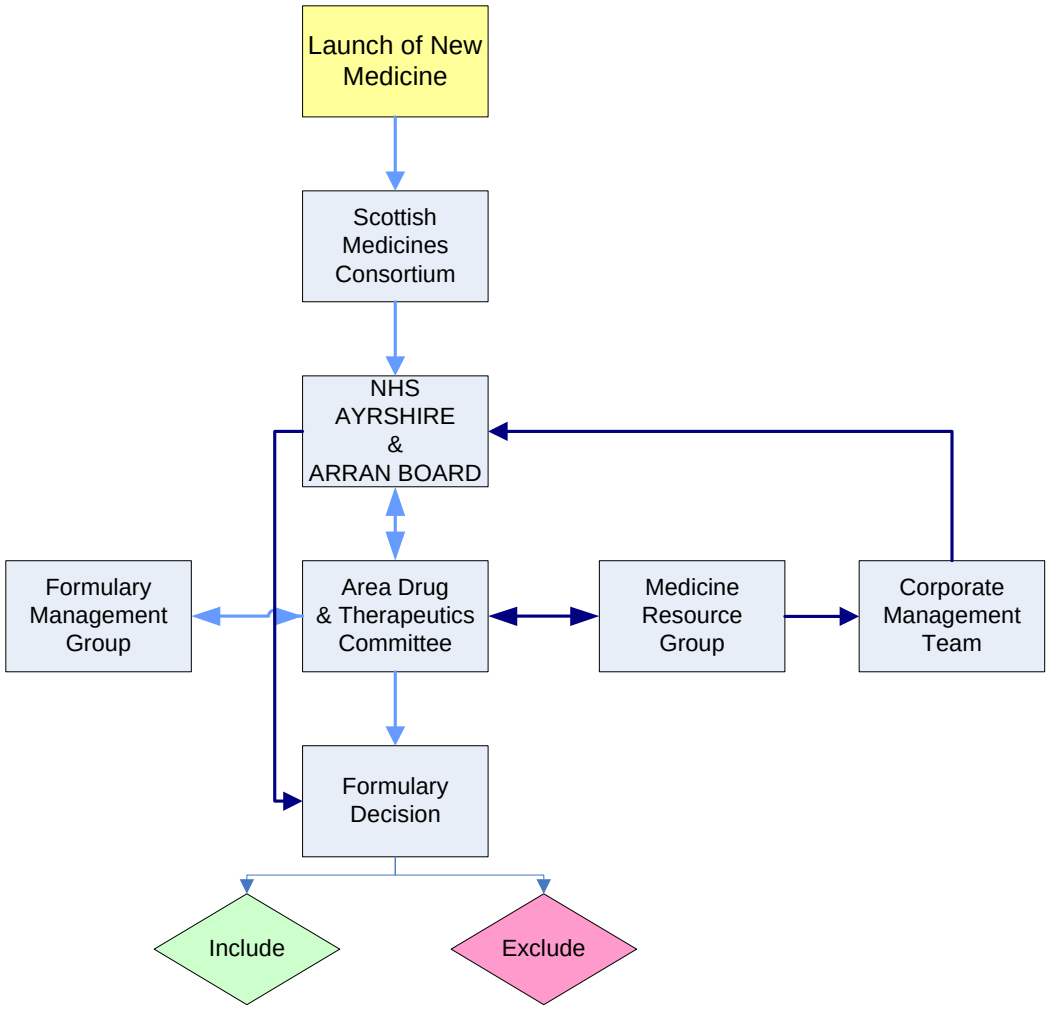

Launch of New Medicine
Scottish Medicines Consortium
NHS AYRSHIRE & ARRAN BOARD
Formulary Management Group
Area Drug & Therapeutics Committee
Medicine Resource Group
Corporate Management Team
Formulary Decision
Include
Exclude

Figure 1

4. OUTCOME OF LOCAL CONSIDERATION OF SMC ADVICE

4.1 The following decisions regarding the introduction of new medicines are possible

- Medicine is excluded from the Joint Formulary
- Medicine is included within the Joint Formulary on an unrestricted basis
- Medicine is included within the Joint Formulary under a restricted basis and in line with a locally or regionally developed protocol
- Medicine is approved for use within NHS Ayrshire & Arran and is being managed on a case by case basis, pending the allocation of recurring funding.

5. COMMUNICATION OF DECISIONS TO CLINICIANS

5.1 The local decision will be made within four weeks of the SMC decision being placed within the public domain.

5.2 Information on decisions made by the ADTC and MRG will be communicated to all clinicians on a monthly basis via Joint Formulary Bulletin.

6. JOINT FORMULARY REVIEW

6.1 The formulary will automatically undergo a regular review, by therapeutic group, as part of an agreed rolling programme.

6.2 Where an individual clinician or a group of clinicians identify, that substantive new evidence is available which may change the original decision regarding the availability of the medicine within NHS Ayrshire & Arran then they may ask the ADTC via the FMG to reconsider the decision in light of the new evidence.

7. CASE BY CASE AVAILABILITY OF MEDICINES

7.1 Where a medicine is approved for use within NHS Ayrshire & Arran but is awaiting allocation of recurring funding, an individual clinician can apply to use that medicine for an individual patient on a case by case basis.

7.2 The process for case by case applications is detailed in Part 2 of this policy.

8. EXCEPTIONAL CIRCUMSTANCE AVAILABILITY OF MEDICINES

8.1 Where a medicine is not approved for use, either on a general or restricted basis, an individual clinician can apply to use that medicine on a named individual patient basis if they believe there are exceptional circumstances associated with the case.

8.2 The process for exceptional circumstance applications is detailed in Part 3 of this policy.

9. APPEAL OF DECISIONS

9.1 Where NHS Ayrshire & Arran, having considered all of the available information, has decided that a particular medicine should not be made available for an individual patient, then that patient has the right to appeal that decision.

9.2 The process for appeals is detailed in Part 4 of this policy.

PART 2 – CASE BY CASE APPLICATIONS

Where a medicine is approved for use within NHS Ayrshire & Arran, but is awaiting allocation of recurring funding, an individual clinician can apply to use that medicine for a named individual patient.

1. THE FOLLOWING CONDITIONS FOR CONSIDERATION OF CASE BY CASE ACCESSIBILITY TO MEDICINES APPLY:

1.1 Access to a medicine on a case by case basis shall be considered for individual patients only.

1.2 Only clinicians with direct clinical responsibility for an individual patient can submit an application to access a medicine on a case by case basis.

1.3 Access to a medicine on a case by case basis shall be considered in NHS Ayrshire & Arran when the MRG following advice from the ADTC/SMC has considered that the medicine is approved for use but recurring funding is not yet allocated.

2. PROCESS FOR CONSIDERATION OF CASE BY CASE ACCESSIBILITY TO MEDICINES

2.1 Applications to use a medicine on a case by case basis for an individual patient will be made in writing by the requesting clinician, using the Case by Case Application Form (Appendix 2).

2.2 The application must include a statement that the patient meets eligibility criteria established for use of the particular medicine agreed by the MRG/ADTC.

2.3 It is the responsibility of the prescribing clinician to complete the application form in full. Documentation that is incomplete will be returned for completion prior to consideration.

2.4 Case by case applications should be sent to the Director of Pharmacy.

3. CONSIDERATION OF REQUESTS FOR ACCESS TO A MEDICINE ON A CASE BY CASE BASIS

3.1 The Director of Pharmacy will consider case by case applications.

3.2 The Director of Pharmacy will have the authority to approve case by case requests, where they are confident that the individual patient has met the pre-specified eligibility criteria agreed by the MRG/ADTC for access to this medicine.

3.3 The Director of Pharmacy will have the right to discuss the facts of the case with appropriate colleagues.

3.4 In exceptional circumstances where an application requires to be considered and a decision taken and the Director of Pharmacy is unavailable then the Senior Prescribing Adviser, Specialist in Pharmaceutical Public Health or the Principal Pharmacist Medicines Information will act as designated deputies for the Director of Pharmacy.

3.5 The Director of Pharmacy or deputy may request additional supporting information from the requesting clinician if required.

4. COMMUNICATION OF THE DECISION

4.1 The Director of Pharmacy will give written confirmation of their decision to the requesting clinician, within a maximum of 20 working days of receipt of the written request.

4.2 The Director of Pharmacy will assess each application in terms of clinical urgency and will ensure that an appropriate response time is maintained.

4.3 Where a case by case application is rejected, the Director of Pharmacy must outline the rationale for the decision in the written response to the clinician.

5. APPEALS AGAINST A CASE BY CASE DECISION

5.1 Where the Director of Pharmacy, having considered the information supplied by the requesting clinician decides that the case in question does not meet the pre-specified eligibility criteria, then the requesting clinician can apply to use the medicine on an exceptional circumstance basis, as laid out in part 3.

6. MONITORING OF CASE BY CASE ACCESSIBILITY TO MEDICINES

6.1 The Director of Pharmacy will report the number and type of case by case requests and decisions to the MRG on an annual basis as part of the budget setting process.

6.2 The MRG will monitor the situation to ensure that wider performance management of prescribing allocations take account of use of medicines on a case by case basis.

PART 3 – EXCEPTIONAL CIRCUMSTANCES

Where a medicine is not approved for use, an individual clinician can still apply to use that medicine, for a named individual patient where the clinician believes there are exceptional circumstances associated with case. (Figure 2)

1. **THE FOLLOWING CONDITIONS FOR CONSIDERATION OF EXCEPTIONAL CIRCUMSTANCE ACCESSIBILITY TO MEDICINES APPLY:**

1.1 Access to a medicine on an exceptional circumstance basis shall be considered for individual patients only.

1.2 Only clinicians with direct clinical responsibility for an individual patient can submit an application to access a medicine on an exceptional circumstance basis.

1.3 Access to a medicine on an exceptional circumstance basis shall be considered in NHS Ayrshire & Arran:

- Where a medicine is available within the United Kingdom and licensed for the indication under consideration, but has not yet been considered by the SMC
- Where a medicine is available in accordance with the restrictions specified by the SMC and incorporated into a local protocol, but where the patient, or their condition, does not meet the specified inclusion criteria
- Where the medicine is not approved for use following advice from the SMC that the drug is not recommended for use in NHS Scotland
- Where the medicine is unlicensed, or is being used outside the terms of the Marketing Authorisation, the requirements of Section 9 of the Code of Practice must also be met in terms of Clinical Governance.

2. PROCESS FOR CONSIDERATION OF EXCEPTIONAL CIRCUMSTANCE ACCESSIBILITY TO MEDICINES

2.1 Applications to use a medicine on an exceptional circumstance basis for an individual patient will be made in writing by the requesting clinician using the Exceptional Circumstance Application form (Appendix 3)

2.2 It is the responsibility of the prescribing clinician to complete the application form in full. Documentation that is incomplete will be returned for completion prior to consideration.

2.3 The application must include a statement regarding the evidence base for clinical use, and must include a full description of the factors relating to the individual case, which make the case in question exceptional.

Only evidence of clinical need should be taken into consideration. Factors such as gender, ethnicity, age, lifestyle or other social factors such as employment or parenthood will not be considered on the grounds of equality.

The fact that the treatment might be efficacious for the patient is not, in itself, grounds for exceptionality.

2.4 Exceptional circumstance applications, for patients being treated within NHS Ayrshire & Arran should be sent to the Medical Director.

3. CONSIDERATION OF REQUEST FOR ACCESS TO A MEDICINE ON AN EXCEPTIONAL CIRCUMSTANCE BASIS

3.1 The Executive Medical Director or named deputies (Associate Medical Directors) will consider exceptional circumstance applications.

3.2 The Executive Medical Director or named deputies (Associate Medical Directors) will have the authority to approve exceptional circumstance requests, seeking further advice and clinical input where appropriate.

3.3 The Executive Medical Director or named deputies (Associate Medical Directors) will have the right to discuss the facts of the case with appropriate colleagues.

3.4 Where an application requires to be considered and a decision taken and neither the Executive Medical Director or named deputies (Associate Medical Directors) are available then the Director of Pharmacy (or designated deputy) will consider the case following discussion with either the Medical Director's deputy on the ADTC or the Chair of ADTC. The designated deputies for the Director of Pharmacy in this regard will be the Senior Prescribing Adviser, the Specialist in Pharmaceutical Public Health or the Principal Pharmacist Medicines Information.

3.5 Where the Executive Medical Director or named deputies forms the view that exceptionality has not been demonstrated in the information submitted they will allow the applying consultant a further opportunity to outline what they consider to be circumstances which make the case exceptional.

4. COMMUNICATION OF DECISION

4.1 The Executive Medical Director or named deputies (Associate Medical Directors) will give written confirmation of their decision to the requesting clinician, within a maximum of 20 working days of receipt of the written request.

4.2 The Executive Medical Director or named deputies (Associate Medical Directors) will assess each application in terms of clinical urgency and will ensure that an appropriate response time is maintained.

4.3 The Executive Medical Director or named deputies (Associate Medical Directors) must outline the rationale for each exceptional circumstance decision in their written response to the clinician. The rationale for the decision must be outlined in full, irrespective of the nature of the decision.

4.4 A copy of the letter outlining the decision of the Executive Medical Director or named deputies (Associated Medical Directors) will be sent for information to the patient's GP where this is clinically appropriate.

4.5 Where an application is rejected, the Executive Medical Director or named deputies (Associate Medical Directors) will include in the response to the clinician information for the patient on the process that can be used to appeal against the decision.

5. APPEALS AGAINST EXCEPTIONAL CIRCUMSTANCE DECISIONS

5.1 Where the Executive Medical Director or named deputies (Associate Medical Directors) having considered all of the available information has decided that a particular medicine should not be made available for an individual patient, then that patient or legal guardian has the right to appeal that decision.

5.2 Appeals should be submitted with 14 days of receipt of the decision as outlined in Part 4.

6. MONITORING OF EXCEPTIONAL CIRCUMSTANCE ACCESSIBILITY TO MEDICINES

6.1 The Executive Medical Director or named deputies (Associate Medical Directors) will report the number and type of exceptional circumstance requests and decisions to the MRG on an annual basis as part of the budget setting process.

6.2 The MRG will monitor the situation to ensure that wider performance management of prescribing allocations will take account of use of medicines on an exceptional case basis.

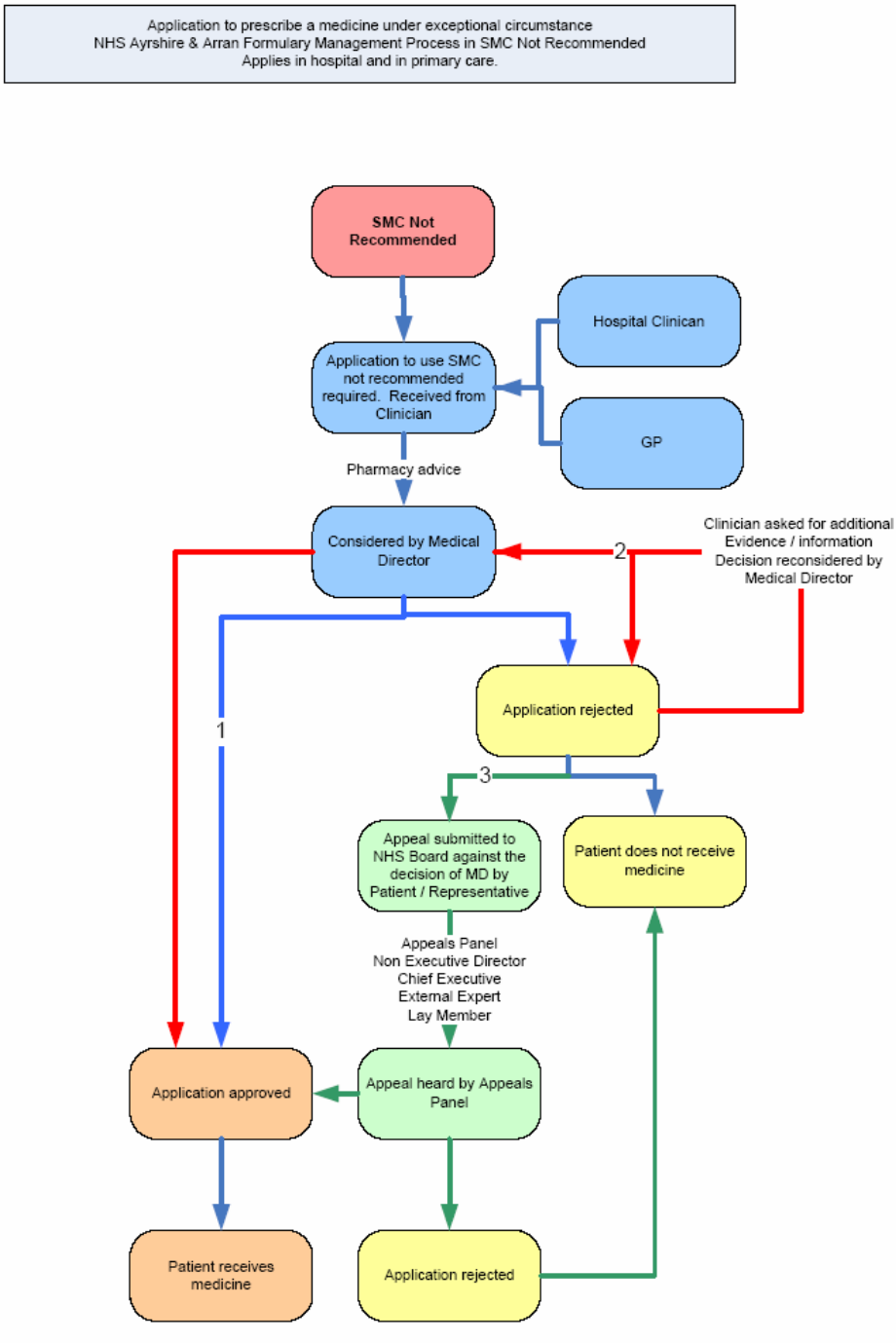
7. ONGOING EVALUATION OF EXCEPTIONAL CIRCUMSTANCE REQUESTS

7.1 Part of the approval process for exceptional circumstance requests includes a requirement for on going monitoring and formal feedback regarding treatment outcomes.

7.2 Clinicians gaining access to medicines on an exceptional circumstance basis will be required to provide regular updates regarding treatment outcomes as specified at the time of approval.

7.3 Where treatment is unsuccessful the clinician is required to advise the Medical Director or named deputies (Associate Medical Directors) of this outcome.

Figure 2: Process for applying for Medicine not recommended by SMC



PART 4 – MEDICINE APPEALS

Where the Executive Medical Director having considered all of the available information has decided that a particular medicine should not be made available for an individual patient, then that person or their representative has the right to appeal that decision.

In such cases a Medicine Appeals Panel (MAP) will be established. The remit of the MAP is to provide an opportunity to appeal a decision regarding availability of a medicine for a particular person where it can be demonstrated that:

- Important facts may not have taken into account when considering this request and/or
- The officer of NHS Ayrshire & Arran making the decision did not follow reasonable process or the principles of their remits

Formal appeals may only be made by an individual or their delegated representative and not directly by the attending clinician. However, in the interest of the individual, the attending clinician may assist in the appeals application.

Information will be provided on lodging and appeal to the clinician and the patient by the Executive Medical Director. A patient information leaflet is available for this purpose (Appendix 5)

1. LODGING AN APPEAL

1.1 If a person affected by a decision, or their delegated representative, believe that they have reasonable grounds to appeal a decision regarding availability of a medicine then a formal appeal may be submitted.

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

1.3 The person seeking to appeal a decision regarding availability of a medicine or his/her delegated representative 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..

2. Consideration of the Appeal

2.1 The Chief Executive and a Non Executive member of the NHS Board will consider the request for the appeal and will inform the person seeking to appeal a decision regarding availability of a medicine within 5 working days whether a MAP hearing will be heard.

2.2 When it is determined that a MAP 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.

2.3 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.

3. THE MEDICINE APPEALS PANEL

3.1 Where an appeal is granted a MAP will be established as detailed below.

- Non Executive Director of the NHS Board, will act as the Chair of the MAP. All Non Executive Directors of the NHS Board will be briefed, as part of their induction, by the Director of Pharmacy, on the background and procedures associated with consideration of an appeal against a decision regarding availability of a medicine.
- 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.

3.2 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.

4. Patient Advocacy and support

4.1 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.

4.2 When a patient or their legal guardian 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.

4.3 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.

5. PRIOR TO THE APPEAL

5.1 Details of the procedures of the appeal hearing shall be supplied to the person seeking to appeal a decision regarding availability of a medicine by their dedicated patient support officer. This will include verbal and written advice regarding availability of additional support during the appeal. The person seeking to appeal a decision regarding availability of a medicine 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.

5.2 The officer of NHS Ayrshire & Arran who made the decision or delegated representative shall be invited to submit, to the Associate Director of Nursing (PFPI) organising the MAP hearing, a brief statement of the background to the decision under appeal, together with any supporting documentation.

5.3 The person seeking to appeal a decision regarding availability of a medicine or their representative shall be invited to submit, to the Associate Director of Nursing (PFPI) organising the MAP hearing, 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 expert witness if required.

5.4 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.

5.5 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 NHS Board.

5.6 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) organising the MAP hearing prior to the hearing. The Associate Director of Nursing (PFPI) organising the MAP hearing 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.

6. PROCEDURES AT THE MAP

6.1 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. The person seeking to appeal the availability of a medicine may wish to bring along a friend or relative for personal support at the MAP.

6.2 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.

6.3 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.

6.4 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.

6.5 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.

6.6 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.

6.7 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.

6.8 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.

6.9 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.

6.10 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.

6.11 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.

6.12 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.

6.13 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.

7. PROCEDURES FOLLOWING THE APPEAL

7.1 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..

7. 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