Patient perspectives and priorities on access to medicines for rare conditions in Scotland
Annexes and References
Annex 1 – Recommendations from 2013 New Medicines Reviews

The role of the Scottish Medicines Consortium (SMC) - Routledge Review

Recommendation 1. SMC should meet in public so that members of the public, patients, patient group representatives, other health professionals and members of the pharmaceutical industry can attend to observe the appraisal process.

Recommendation 2. SMC should invite the manufacturer of the new medicine under consideration to give evidence at their main SMC appraisal meeting, in order to address any outstanding questions that SMC members have and highlight any outstanding issues of which they believe SMC should be aware prior to its advice being published.

Recommendation 3. SMC should be able to appraise any new medicines which the NHS in Scotland considers potentially of major importance to patient care, but which have not been submitted to SMC by the manufacturer within 12 weeks of launch. If necessary this appraisal may be conducted using such data as is already available in the public domain.

Recommendation 4. SMC should be able to have a temporary pause in the appraisal process at any stage in order to permit further dialogue with manufacturers on issues that would be likely to be central to the subsequent decision-making process.

Recommendation 5. SMC should develop a policy specifically relating to ultra orphan medicines to guide the process of consideration of all available evidence relevant to its advice on these medicines.

Recommendation 6. SMC, with the appropriate resource and in partnership with other relevant bodies in Scotland, should be encouraged to set up an engagement process such as a “Citizen’s Council” or “Citizen’s Jury” to explore views around specific societal issues of importance to the people of Scotland in relation to the availability of new medicines and the impact of these views on the existing processes for ensuring access to medicines.

Recommendation 7. SMC should explore other innovative approaches to increasing patient and public awareness of its role in ensuring timely access to clinically effective and cost-effective medicines in Scotland. Consideration should also be given to expansion of its role to support other aspects of safe, effective and cost-effective prescribing. SMC should produce a publicly available annual report of progress in this regard detailing its important contributions to this objective.

Recommendation 8. NHS Scotland should explore ways in which the expertise available within SMC might be used to support the process of Value Based Pricing (VBP).

Recommendation 9. A register of IPTR decisions in all Health Boards, suitably anonymised to protect patient confidentiality should be kept, and supporting information related to IPTRs shared between Health Boards.

Recommendation 10. There should be regular sharing of experiences between the IPTR panels and members of IPTR panel members across Scotland should meet at least annually for induction, feedback and training.
The role and remit of NHS Board Area Drug and Therapeutic Committees and Individual Patient Treatment Request arrangements – Swainson Review

Recommendation 1. Board ADTC should publish their local response to the SMC published advice within 30 days of the SMC advice, on the Board website and in a manner which is accessed easily by the public and patients (as required by CMO 1 2012). The response need not be definitive if further work is required but should indicate clearly the Board’s intentions; the final arrangements should be published within 90 days. Members of the public involved in the work of the ADTC (drawn from the members of the Board Patient and Public Forum (PPF) can assist with describing the processes in a way that is “user-friendly” for the general public, and act as a link with the wider PPF.

Recommendation 2. Board ADTC should publish their decisions and the reasons for their decisions in respect of SMC advice to be compliant with CMO (2012)1. These reasons should include the consequences for the local formulary, even if, in the case of novel medicines, this requires further deliberation and planning. Patients and the public should be signposted from the front page of the Board website to a link which will provide information about recent SMC decisions and subsequent formulary decisions and the overall formulary should be published alongside this information and updated as required.

Recommendation 3. Board ADTC should demonstrate the engagement of their PPF in the work of the ADTC. For preference, Board ADTC should have at least one member drawn from the PPF or demonstrate the connection between the PPF and the work of the ADTC.

Recommendation 4. NHS Scotland should consider a national meeting of all relevant specialists, organised by Healthcare Improvement Scotland (HIS), to agree a national implementation plan for some new medicines accepted by the SMC that meet agreed criteria. These criteria may include the introduction of novel, first in class medicines where there is considerable uncertainty of its place in therapy. The plan will apply to all patients covered by the SMC “accepted” advice and to all Boards to support equity of access. Further, HIS should continue to audit access to new medicines and compliance with CEL 17 (2012) and SGHD/CMO (2012) 1.

Recommendation 5. NHS Scotland should retain the existing ADTC to maintain alignment of patient and GP interests, safe prescribing and enable Boards to manage their costs. Regional clinical networks could have a role in agreeing equitable access to new medicines in relation to their populations.

Recommendation 6. All Boards should adopt the same IPTR paperwork and process, based on the examples from Greater Glasgow and Clyde, Lothian or Grampian. The application should contrast the clinical criteria appraised by the SMC where “not recommended” advice has been published with the patient’s disease and personal clinical characteristics so that the reasons for the IPTR are more easily assessed, and can be audited.

Recommendation 7. The IPTR arrangements in Boards should be audited by HIS to assess compliance with guidance and its consistency of application, and to publish the results.

Recommendation 8. Clinicians should be provided with basic training and guidance in the IPTR process locally. Clinicians who are uncertain or inexperienced should be able to access specialist advice and support (see recommendation 10).

Recommendation 9. Boards should consider whether IPTR panels should include a member of the public drawn from the Board’s patient and public forum. Member(s) will require training and support.

Recommendation 10. All doctors considering an IPTR must be able to access consistent, knowledgeable support for their patients. National Services Division (NSD) should establish and maintain a register of approved specialists to support IPTR. One specialist may be sufficient for orphan and ultra-orphan diseases, but more than one specialist may need to be available for more common diseases, or variants, and on a regional basis. The model of the cancer networks is an example.
**Recommendation 11.** The Scottish Government and Boards should produce clear and concise documentation, available on national and local websites, that explains the roles of ADTC and IPTR, how the public and patients can be involved, and provide links to the reports recommended above and for ADTC.

**Recommendation 12.** The RCMF should focus on access to medicines for ultra-orphan diseases. Access should be supported where the SMC has published 'not recommended' advice after a full submission of the medicine, and after a successful IPTR or GPTR has been agreed.
Annex 2 – Patient Group Submission Forms

Patient Group Submission Form
The Scottish Medicines Consortium (SMC) is committed to working in partnership with patient groups to capture patient and carer experiences, and use them to inform decision-making.

Before you make a submission
Following a consultation with patient groups, we have changed the way you submit to SMC. You are now asked to complete a Patient Group Partner Registration Form before you make a submission. The registration form requests general information about your organisation. It only needs to be completed once and should save you time with any further submissions to SMC. If you have not already completed a registration form, please do this before you make your submission.

You can find the form here: www.scottishmedicines.org.uk/Public_Involvement

Name of medicine:

Indication (what the medicine is used for):

Submission date:

Name of organisation making submission:

Who is the main contact for submissions to SMC?

Name:

Position held in organisation:

Email address:

Phone number:

Postal address:

1. Please provide details of any individuals who have had a significant role in preparing your submission and who have an interest to declare.

2. Please tell us how you gathered information about the experiences of patients and carers to help inform your submission.

3. How does this condition affect the day-to-day lives of people living with it?

4. How well are patients managing their condition with medicines which are currently available in NHSScotland?

5. Would this medicine be expected to improve the patient’s quality of life and experience of care, and if so, how?

6. What kind of impact would treating a patient with this medicine have on the patient’s family or carers?

7. Are there any disadvantages of the new medicine compared to current standard treatments?
8. Please summarise the key points of your submission in no more than 200 words:

(The summary of your key points will be used in the published Detailed Advice Document (DAD) summary of Patient Group Submissions. It will also be used during the presentation at the SMC committee meeting. It is very important that you concisely capture the key messages of your submission.)

9. Do you consent for a summary of your submission to be included in the Detailed Advice Document for this medicine?

PACE Patient group/voluntary organisation statement
Please provide a brief summary of information you wish to be considered at the Patient and Clinical Engagement (PACE) meeting. This should cover information that may help determine the ‘added value’ of the medicine in the context of treatments currently available in NHS Scotland that may not be fully captured in conventional clinical and health economic analysis.

If you have already provided a patient group submission, this summary is optional and should be used to provide any additional information. It is not necessary to duplicate information.

Your summary should include details of severity of the condition the medicine treats and the need for the medicine, including the level of unmet need and how the medicine addresses it.

You should also focus on patient and carer quality of life issues, which could be improved by taking the medicine compared to current treatment options, such as:

1. The ability to continue work or education.
2. The management of symptoms such as pain and extreme tiredness.
3. Helping relieve psychological distress.
4. Convenience of how and where the treatment is received.
5. The ability to self-care or maintain independence and dignity.

Please do not exceed two pages.
References


12 Who We Are. Scottish Medicines Consortium, undated, available at: https://www.scottishmedicines.org.uk/About_SMC/Who_we_are

13 SMC Membership. Scottish Medicines Consortium, undated, available at: https://www.scottishmedicines.org.uk/About_SMC/Who_we_are/Membership/SMC_Membership


Clinical Experts. Scottish Medicines Consortium, undated, available at: https://www.scottishmedicines.org.uk/About_SMC/Who_we_are/Clinical_Experts


NDC Membership. Scottish Medicines Consortium, undated, available at: https://www.scottishmedicines.org.uk/About_SMC/Who_we_are/Membership/NDC_Membership


SMC Modifiers used in Appraising New Medicines. Scottish Medicines Consortium, June 2012, available at: https://www.scottishmedicines.org.uk/About_SMC/Policy_statements/SMC_Modifiers_used_in_Appraising_New_Medicines


Response to the Health and Sport Committee Inquiry into Access to New Medicines. Scottish Government, October 2013, available at:


51 Public Partners. Scottish Medicines Consortium, undated, available at: https://www.scottishmedicines.org.uk/About_SMCMembership/Public_Partners

52 Public involvement within SMC. Scottish Medicines Consortium, undated, available at: https://www.scottishmedicines.org.uk/Public_Involvement/SMC_explained/Public_involvement_within_SMC


62 Kathryn Fergusson, private communication, 14 January 2016.


64 Kathryn Fergusson, private communication, 14 January 2016.

65 Kathryn Fergusson, private communication, 14 January 2016.


67 Kathryn Fergusson, private communication, 14 January 2016.


