

Scottish Medicines Consortium

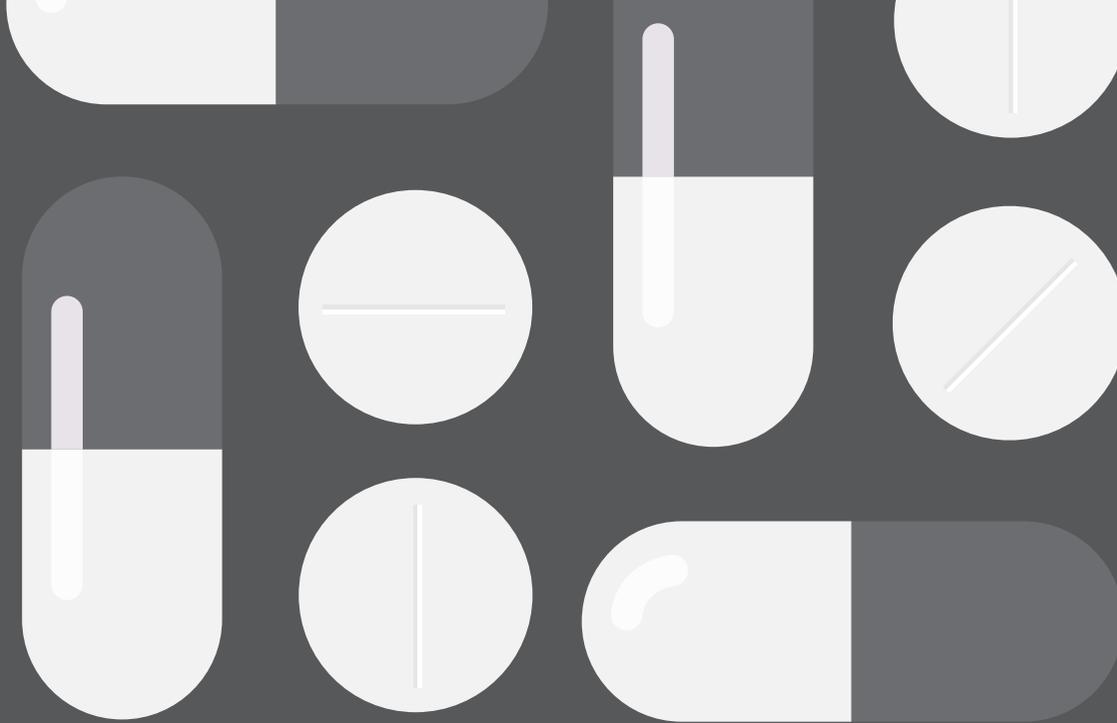
A Guide for Patient Group Partners



Advising on new medicines
for Scotland

www.scottishmedicines.org





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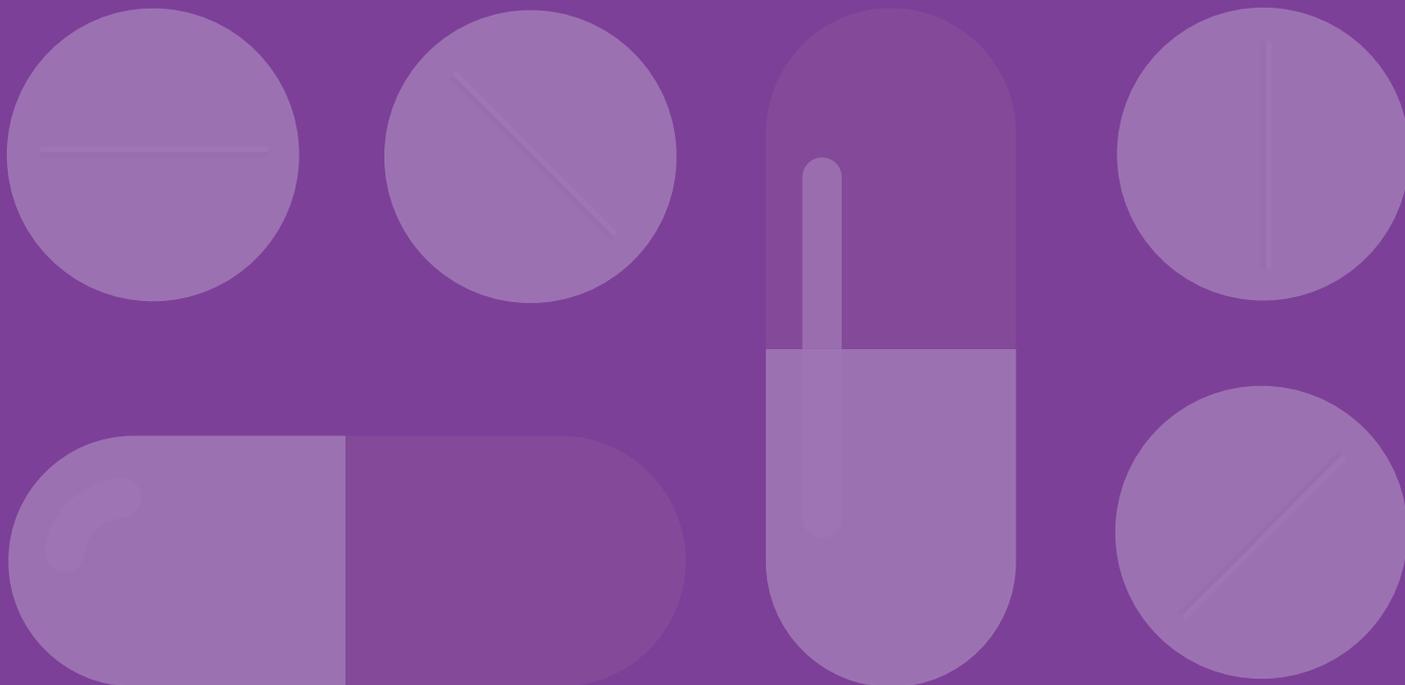
Introduction

About this guide

This guide is intended for use by patient groups who are submitting to the Scottish Medicines Consortium (SMC). It answers commonly asked questions which will help you understand what SMC does and how we work in partnership with patient groups to capture and present patient and carer experiences as part of our process.

Understanding the experiences of patients, their families and carers is a key element in the SMC decision-making process, and we need your help to collect this information. The time and effort you put into completing a submission is greatly appreciated. Your work gives us important information about what it is like for patients to live with a condition and to take specific medicines. Patient and carer input is essential, as we need to consider the opinions and experiences of those who will be directly affected by any recommendations we make.

If you have any more questions after reading the guide, the SMC Public Involvement Team can support you throughout the submission process. You can get in touch by emailing them at: **hcis.SMCPublicInvolvement@nhs.net** or by phoning: 0141 414 2403. Please do not hesitate to get in touch, as the team is here to help you.



The Scottish Medicines Consortium process

About the Scottish Medicines Consortium

The Scottish Medicines Consortium (SMC) is part of Healthcare Improvement Scotland. Our role is to provide advice to the NHS in Scotland about the clinical and cost-effectiveness of new medicines.

This includes:

- how well the medicine works
- which patients would benefit from receiving the medicine
- how safe it is to use compared to currently used treatments
- how taking the medicine affects the quality of a patient's life, and
- how much the medicine costs compared to the other treatment options.

We review new medicines as well as new formulations of, and new ways to use, established medicines. Most new medicines have to be approved by the SMC before prescribers are able to use them routinely in the NHS in Scotland.

The assessment process

Each assessment is carried out by our team of pharmacists, health service researchers and health economists, who evaluate the evidence provided by the pharmaceutical company that produces the medicine. This evaluation is then carefully looked at by our New Drugs Committee, which considers all of the clinical and economic evidence, which has been summarised in a draft Detailed Advice Document (DAD). This document and the supporting evidence is then closely examined and discussed further at the SMC committee meeting.

We also gather information from patient groups and voluntary organisations about how people are affected by the condition and the impact of the new medicine on patients and their carers. This information is also presented and discussed at the SMC committee meeting.

The final Detailed Advice Document includes a summary of the key points from patient group submissions, and is published on the SMC website.

SMC members

SMC has around 40 members made up mostly of NHS clinicians and managers. Every NHS board area in Scotland is represented on either our New Drugs Committee or SMC Committee through doctors, pharmacists, and senior managers. There are also three public partner members as well as representatives from the Association of the British Pharmaceutical Industry (ABPI). The wide mixture of backgrounds helps to make sure that decisions are made from a broad perspective. SMC considers all the evidence and decides whether or not to accept the medicine for use in NHS Scotland and any conditions for use. The process usually takes around 20 weeks to complete.

How do patient and carer experiences add value to the review process?

It is important for SMC members to fully understand what kind of impact a new medicine has on the quality of life of patients and carers. This allows them to make a fully informed decision on whether or not to accept a new medicine. Patients, members of their families and carers can provide unique knowledge about what it is like to live with a condition. They can explain advantages and disadvantages of medicines that may not be available in the published literature or captured in any quality of life measures that have been explored during clinical trials.

Your efforts in collecting these experiences will provide valuable information for committee members to consider when making their decision on the medicine being assessed.

How to contribute to the SMC review process

We accept submissions from patient groups which are constituted: from small local support groups to large national voluntary organisations. We are unable to accept submissions from individuals.

A regularly updated list of the medicines we are assessing can be found on the SMC website. You can also sign up to our monthly newsletter which features details of medicines under review. Details can be found on the home page of our website, www.scottishmedicines.org.uk. Our Public Involvement Team also actively contacts relevant patient groups to tell them about forthcoming submissions.

Register as a Patient Group Partner

To take part in the SMC review process, first you need to register as an SMC Patient Group Partner. This is very straightforward to do. You complete a registration form, providing details about your patient group. It is your responsibility to ensure registration details are up to date each time you provide a submission. You can either register at the same time as you send your first submission, or in advance. The form can be found on the Public Involvement pages of our website.

Provide a Patient Group Submission

To provide a Patient Group Submission for a medicine, you complete a Patient Group Submission Form. The Patient Group Submission Form is a document that enables patient groups to provide suitable patient and carer input to the assessment of a particular medicine. Strong submissions provide clear facts, information and summaries of experiences to give a concise, accurate and balanced overview of a range of patients' and carers' perspectives.

The purpose of the submission is to identify important aspects of the medicine that:

- may not be represented in published literature
- may not be well captured in quality of life or other outcome measures used in clinical trials and other research studies
- may not be automatically understood by members of SMC.

The submission is also an opportunity to identify the priorities and preferences of patients and what the added value of a particular medicine maybe to them.

One representative per submitting patient group is able to participate at the SMC committee meeting, during discussions for the medicine for which they provided a submission. Their role is to answer questions from committee members, relating to patient and carer issues, and provide points of clarity relating to their Patient Group submission, as required. For further details please contact the Public Involvement Team.

How to access the Patient Group Submission form

You can find the Patient Group Submission form on the Public Involvement pages of our website. If you have any problems accessing the electronic version of the form, the Public Involvement Team can either email it to you, or send you a paper version in the post.

You will usually have between six to eight weeks from when the assessment is announced to complete and return your submission.

Your full submission will be provided to committee members as part of the meeting papers and a summary of it will be presented during the main SMC committee meeting by one of our Public Involvement Team.

A summary of your submission will also be included as part of the final Detailed Advice Document.

Available help and support

The SMC Public Involvement Team are able to guide you through the submission process, and can be contacted by email or phone. Face to face meetings can also be arranged if you feel you would benefit from this. They are also able to read over your draft submission and highlight any areas which could be strengthened.

Most submitting pharmaceutical companies provide us with a completed Summary Information for Submitting Patient Groups Form, which we can email to you. This provides background information about the medicine and the indication, which can help inform your submission.

Patient and Clinician Engagement

Patient and Clinician Engagement (PACE) is an additional part of the SMC submission process which can be used, when required, for medicines used at the end of life and for rare conditions (orphan medicines). Your patient group submission can be used to help inform the PACE meeting. More information about PACE can be found in the *Submission Process: guidance and forms* for patient groups section of our website.



Planning and completing a submission

Completing a submission takes some time and effort, but it is an opportunity for you to provide valuable information about patient and carer experiences. Putting in time to plan your submission can help you be more efficient in collecting the information needed and completing the form. During the planning phase, you should decide whether you need to gather new information from patients and carers, or whether you already have the necessary information to complete the submission form.

What information should you include in your submission?

We want to understand the experiences of those living with, and caring for people with, the health condition for which the medicine being assessed is used.

To help you provide the most useful information, this section offers suggestions on what to include in your submission and things to consider when presenting your information. It is helpful to look at the Patient Group Submission Form while reading this section.

Not all questions will be relevant to every submission. It is OK to leave a section blank, if appropriate.

It is important to report on the experiences of many of the individuals living with this condition, rather than exceptional cases. Focus on quality of life impact to patients and carers, rather than cost or clinical effectiveness, as these issues are both comprehensively covered by other parts of our appraisal process.

Please remember to be clear and concise. It is very important that the submission is balanced and acknowledges any shortcomings with the new medicine, as well as the advantages.

Try to include real life patient and carer experience quotes throughout your submission. This is particularly important for PACE medicines as quotes form the basis of the patient group presentation, which complements the PACE presentation given to SMC committee.

What to include in your submission

Section	Information which may be included, if relevant to your submission
Summary of Key Points	<p>This is the information that 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 here.</p> <p>Suggested format:</p> <ol style="list-style-type: none"> 1. Quality of life impact: The biggest challenges of living with this condition are... 2. Limitations of current treatments: Current treatments are inadequate because... 3. Benefits of new treatment: This new medicine is important to patients and carers because...
Please provide details of any individuals who have had a significant role in preparing your submission and who have an interest to declare.	<p>Interests to declare can include:</p> <ul style="list-style-type: none"> • whether the individual is a shareholder or director of the pharmaceutical company who manufacture the medicine • if the individual has received payments of any kind from the submitting company • whether it relates to clinical trial work for the medicine under consideration, or • whether the interest relates to the specific medicine under consideration.
Please tell us how you gathered information about the experiences of patients and carers to help inform your submission.	<ul style="list-style-type: none"> • Information may have been gathered from focus groups, online forums, one to one discussions, telephone helplines, published or unpublished research or user-perspective literature.

Question	Information which may be included, if relevant to your submission
<p>1. How does this condition affect the day-to-day lives of people living with it?</p>	<ul style="list-style-type: none"> • A brief description of the condition (one or two sentences). • Likely outcome of condition. • Aspects of the condition that are most challenging (for example symptoms, loss of ability to work, loss of confidence to go out, inability to drive, social exclusion). • Activities that patients find difficult or are unable to do. • Aspects of the condition that are the most important to control (for example symptoms that limit social interaction or ability to work, such as difficulty breathing, pain, fatigue, incontinence). • Support required for daily living (physical or emotional). • Types of patients that are most affected by the condition (for example men, women, children, ethnic groups). • Challenges in managing this condition when patients also have other medical conditions. • Financial impact, such as loss of earnings or cost of travelling to appointments. • Any psychological distress commonly experienced.
<p>2. How well do medicines which are currently available in NHSScotland help patients manage this condition?</p>	<ul style="list-style-type: none"> • Main treatments currently used by patients for this condition (for example tablet, injection, physiotherapy, hospital check-ups) and how they are given (for example at home, in hospital) dose and frequency, and ease of access. • Extent to which current treatments control or reduce the most challenging aspects of the condition. • The most important benefits of current treatments. • The burden of therapy on daily life (for example impact at different stages of disease, interruption to work, stigma, clinic visits to receive infused medicines, need for weekly blood tests or describe a typical episode of therapy over a week or period of treatment). • Side effects from treatments which are difficult to tolerate. • Concerns about long-term use of current therapy. • Challenges in taking it as prescribed (for example swallowing the pill, self-injecting, use of a device to deliver the medicine, taking after food). • Ways in which the dosing is modified compared to what is prescribed (for example dividing the dose to avoid unwanted side effects, missing doses to fit into daily life).

Question	Information which may be included, if relevant to your submission
3. Have you been able to consult with patients who have used this medicine?	<ul style="list-style-type: none"> It is recognised that there are many reasons why you may not have been able to consult directly with patients, such as: double blinded trials, trial not open in Scotland or lack of capacity.
4. Would this medicine be expected to improve the patient's quality of life and experience of care, and if so, how?	<ul style="list-style-type: none"> Potential improvements to quality of life. Convenience of treatment, such as fewer or shorter hospital/GP visits, easier to tolerate administration of medicine (for example tablet instead of IV, shorter treatment duration/frequency, or smaller dose). Potential improvements to health outcome, such as extended survival or bridge to cure. Level of improvement patients would like to see. Financial implications (for example travelling costs or days off work). The level of side effects that patients would tolerate for a given benefit. Groups of patients who might particularly benefit or who might benefit less from the new medicine than others. Aspects of patients' needs or expectations that it is hoped the new medicine will address (explaining specific issues for particular stages of disease).
5. What kind of impact would treating a patient with this medicine have on the patient's family or carers?	<ul style="list-style-type: none"> Potential reduced dependency. Emotional and psychological impact. Potential improvements in quality of life.
6. Are there any disadvantages of the new medicine compared to current standard treatments?	<ul style="list-style-type: none"> It is very important that the submission is balanced and mentions any negatives about the medicine compared to current medicines. For example, side effects, or how the medicine is administered and by whom.
7. Is there any additional information you think may be useful for the SMC committee to consider?	<p>This section is optional and can be used for any additional information relevant to your submission.</p>

What not to include in your submission

Not needed	Reason
Clinical or scientific evidence	As part of the process for assessing the medicine, the assessment team conducts a thorough and systematic search and analysis of the available clinical evidence about the medicine; therefore, you do not need to provide this information.
Summarised or reworded information from sources other than patients or caregivers (such as clinicians or other healthcare providers, manufacturers)	The purpose of the Patient Group Submission Form is to collect information from both patients and their carers. Information and feedback from clinicians and pharmaceutical manufacturers is received separately.
The same messages repeated under different headings	Sometimes it may be difficult to assign information to only one section of the Patient Group Submission Form. Please make sure that you are answering each specific question and not repeating information to 'fill up the space'. We want to make sure that you provide only the most relevant information to guarantee the best recommendations possible for the medicine being assessed.
It is not helpful to use language which is overly emotive or critical of the SMC decision-making process	This detracts from your key points and may be detrimental to your submission.

How to collect the required information

The type of information you collect will depend on the questions you want to answer. Information can be grouped into two categories: quantitative (numerical information) and qualitative (descriptive information).

Quantitative information is input that is either counted or measured, such as:

- How much time do you spend getting to your appointments?
- How long does the treatment work for?
- How many treatments have you been on?

One common way to collect this type of information is by using closed questions within surveys, where answers are selected from a predetermined set of responses, for example using ratings on a numbered scale or multiple choice. You can then report the average response or how many times a particular response is chosen.

It is also important to collect the thoughts, opinions, stories, and feelings of patients and carers. This input is described as **qualitative information** (descriptive information) and answers questions, such as:

- What challenges have you encountered while managing the side effects of the person you are caring for? For example, it is difficult to get to a hospital or that special equipment or specialists are required that are only available in particular centres.
- Why is it difficult to access your current treatment?
- Can you describe how the treatment would improve your quality of life?

There are many ways to collect qualitative information. Some are very simple and quick to do, for example posting a question on a social networking website, such as Twitter or Facebook, or online discussion forums. Electronic questionnaires can also be an easy and convenient way to collect key information. You can also use group discussions, interviews or open-ended questions in surveys. These allow participants to explain their experiences in their own voice.

What to do if you have unanswered questions about the medicine

Submitting pharmaceutical companies are invited to provide a Summary of Patient Information as part of their SMC submission. If the company has provided SMC with this information, we are able to pass it on to you.

If you have any specific unanswered questions about the medicine, please get in touch with our Public Involvement Team, who can contact the company on your behalf, to seek an answer for you.

Does the information have to be from Scottish patients and carers?

Ideally, it is best to focus on gathering information from people in Scotland who may benefit from receiving the new medicine. However, we realise that for some medicines, especially those used to treat rarer conditions, this is not always possible. If you are unable to gather information from the local population, it is fine to include information from a wider pool of patients and carers from outside Scotland. Please mention in the submission form if your information is not from the Scottish population.

How to summarise information for the submission form

The way you present this information will depend on the types of questions that you asked. Remember that the SMC committee is looking for an overview of experiences or themes. The way you present quantitative information (closed-ended questions in surveys) is different from how you should present qualitative information (descriptive, open-ended questions in surveys, and interviews).

It is important to be as clear and concise as possible when you are reporting so that your submission has maximum impact.

Quantitative information

The quantitative information you collect will mostly come from closed questions used in your survey. To summarise data, it is helpful to combine responses as averages, frequencies or counts (number of people), or proportions (percentages). It is best to keep the statistics simple.

Example	Those who completed the survey ranked 'infections' as the most important, with 71.8% (total number participants = 22) rating it as 10, a 'very important' aspect of controlling xxx cancer. 'Infections' were followed by 'kidney problems', 'pain', 'mobility', 'neuropathy', 'shortness of breath', and 'fatigue'. In all cases, more than 50% of respondents rates these aspects as a 10, 'very important' to control. In all cases, the rating average was greater than 8, which meant that all listed symptoms were considered important.
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Qualitative information

Regardless of how you collected your information, patient and carer experiences need to be summarised. A good way to present descriptive information is to include quotes from participants. Before you choose quotes, it is important to analyse all of your qualitative information as a whole. If you begin by selecting random quotes you may not realise that there are specific themes that a majority of participants collectively discussed. Qualitative information can come either from:

- responses collected through interviews or social networking websites; or
- open-ended questions asked in your surveys.

The findings should be in the voice of the participant, for example what participants expressed, reported, said or described. You should make it clear that this result was taken directly from the participant's experiences, rather than the opinions of your patient group.

Use quotes to support any themes, which you are highlighting in your submission.

Example	"Currently I have to visit the hospital for an entire day every second week, and get my treatment through a drip. We dread these visits. My husband has to take a day off work every two weeks and I get extremely upset and anxious at the thought of more needles. A new medicine which works just as well and is a pill that I could take at home would have a massive positive impact on both our lives right now".
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Please don't identify patients or carers by their full names. Instead use initials or first names only. Please remember when writing your submission that a number of its readers will be either non specialist in the area or condition, or lay members of SMC. Use plain English and avoid technical language, whenever possible.

Useful resources

Health Technology Assessment International (HTAi) provides a variety of educational and learning tools for helping patient groups capturing patient and carer experiences.

Find out more at: www.htai.org/index.php?id=744

The Scottish Health Council's Participation Toolkit provides a number of tried and tested tools for engaging with patients, carers and the public. Although aimed at the NHS, it is also very relevant to patient groups.

Find out more at: www.scottishhealthcouncil.org/toolkit.aspx



You can read and download this document from our website. We are happy to consider requests for other languages or formats. Please contact our Equality and Diversity Advisor on 0141 225 6999 or email contactpublicinvolvement.his@nhs.net



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The Healthcare Environment Inspectorate, the Improvement Hub, the Scottish Health Council, the Scottish Health Technologies Group, the Scottish Intercollegiate Guidelines Network (SIGN) and the Scottish Medicines Consortium are part of our organisation.