

Guidance to Manufacturers for Completion of Summary Information for Submitting Patient Groups Form

CONTENTS

PAGE

<u>General guidance</u>	3
1. Patient groups	3
2. ABPI Code of Practice	4
3. Deadline for submission	4
4. Size of submission	5
5. Formatting	5
6. <u>Guidance on completion of template</u>	
6.1 Front Page	5
6.2 What condition is this medicine used for?	5
6.3 How is this condition currently managed in Scotland?	6
6.4 How does the medicine work?	6
6.5 How effective is this medicine and is it different from other medicines currently available to treat this condition?	6
6.6 How is the medicine administered and how will this affect patients and carers?	6
6.7 What are the side-effects of this medicine and how are they managed?	6
6.8 What is the quality of life impact of this medicine on patients and their carers?	7
6.9 Space to provide signposting to further online information about this medicine which patient groups may find useful.	7
7. <u>Freedom of Information</u>	7

Appendix

Checklist for Completion of New Product Assessment Form	8
---	---

General Guidance

1. Patient Groups

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.

Understanding the experiences of patients, their families and carers is a core part of the SMC decision making process and helps SMC members to fully understand how a new medicine impacts the quality of life of patients and carers. Patients, members of their families and carers can provide information about what it's like to live with a condition and a real life view of the potential impact of a new medicine.

SMC works in partnership with patient groups to gather this information through our patient group submission process.

The SMC Public Involvement Team identifies patient groups for each appraisal, and encourages and provides support to them to provide a Patient Group Submission. For medicines that are designated as orphan, ultra-orphan, or for end-of-life, the patient group(s) may also be invited to participate in a Patient and Clinician Engagement (PACE) meeting to capture their input in greater detail. Therefore it is important that relevant patient groups have an informed and appropriate understanding of the medicine under review.

For this reason companies are required to provide a patient/public friendly version of their submission by completing the standard "Summary Information for Submitting Patient Groups" template available on the SMC website, together with the Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL). The SMC Public Involvement Team will forward these to any patient group making a patient group submission in connection with a new product submission.

Representatives of those groups may also wish to obtain information from the manufacturer about the treatment(s) under consideration.

Completion of the template has been added to the submission checklist. The template prompts companies to answer questions that are designed to help provide the type of information that patient groups have indicated would be of interest. Companies should avoid duplicating detailed clinical trial information provided in the SMC submission or replicating the Patient Information Leaflet.

Where relevant, information should focus on the impact and implications for patients such as:

- Severity of the condition
- Need for the medicine, including level of unmet need and how medicine addresses it
- Added value of medicine for patient and patient's carer/family including secondary trial end-points including those related to Quality of Life
- Key side effects and the impact on Quality of Life

General points regarding completion of the submission are detailed below.

2. ABPI Code of Practice

The [ABPI Code of Practice](#) for the Pharmaceutical Industry sets standards for the pharmaceutical industry including requirements for the provision of information to patients and the public as well as relationships with patient groups. The Code reflects and extends beyond UK and European law.

Individual companies will have their own compliance procedures relating to the Code, but Clause 26 prohibits the advertising of prescription only medicines to the public. Clause 26.2 and its supplementary information is of particular relevance to the completion of the “Summary Information for Submitting Patient Groups” template. It notes that information about prescription only medicines which is made available to the public either directly or indirectly must be factual and presented in a balanced way. It should represent fairly the current body of evidence relating to a medicine and its benefit/risk profile. The quality standards in Clause 7 of the Code apply to information to the public including the need to be able to substantiate information.

Clause 26 Supplementary Information also notes the following:

Clause 26.2 Health Technology Assessments

Companies may supply information to relevant patient organisations, the public or patients in relation to forthcoming health technology assessments by public national organisations such as NICE, AWMSG or SMC, provided the information is accurate, not misleading, not promotional in nature and otherwise complies with Clause 26.2.

Clause 1.2 includes that information supplied by pharmaceutical companies to national public organisations, such as the National Institute for Health and Care Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) and the Scottish Medicines Consortium (SMC) is exempt from the Code provided the information is factual, accurate and not misleading.

3. Deadlines for submission

The “Summary Information for Submitting Patient Groups” template should be submitted alongside submission of the New Product Assessment Form (NPAF), together with the SPC and PIL. The Product assessment timelines, including deadlines for receipt of company submissions to the SMC secretariat, are provided on a month-by-month basis on the [SMC website](#).

4. Size of submission.

The quantity of information provided in the “Summary Information for Submitting Patient Groups” template should be sympathetic to the fact that many patient groups have limited resources and may only comprise a few individuals, who are not used to reviewing information relating to a product submission. Succinct and relevant information is required with questions answered using plain English rather than being overly technical. Information should be concise, but also complete and comprehensive. The submission would not be expected to be more than 5-10 pages including any references.

5. Formatting

The boxes in the “Summary Information for Submitting Patient Groups” template will expand with the text. Page numbering will also alter with the text and the page-numbering format within the template. Splitting the document into sections other than those inherent in the template may disrupt page numbering. When completing the template, please do not alter the template format.

An electronic version of the template should be provided in Word or compatible format.

6. Completion of “Summary Information for Submitting Patient Groups” template

6.1 Front page

The template should include the approved and proprietary name of the product, the submission date for the NPAF and the name of the company making the submission.

Please include the name and position of the person who is the main contact for patient groups. This may be different to the contact details provided for the NPAF, but should be the appropriate person responsible for liaising with patient groups. It need not be someone who can directly answer enquiries, but the contact person should have sufficient knowledge to be able to relay enquiries to the appropriate person within the company.

6.2 What condition is this medicine to be used for?

Give a brief overview of the condition and the target population, focusing on the submitted indication. Whilst this can include the exact wording of the licence, an explanation in plain English would also be helpful. It may be relevant to use the wording from the PIL.

If the submission positions the medicine for use in a sub group of the licensed indication, explain the relevant sub group and why it has been selected.

6.3 How is this condition currently managed in Scotland?

Please give an outline of the current patient pathway and in particular the current treatment(s) likely to be displaced by the medicine under review, which may include non-drug treatment options. Consider the severity of the condition and the implications for patients.

6.4 How does the medicine work?

Please don't use overly technical language, but if appropriate include how the medicine might be different and why this might be relevant to the way patients are managed.

6.5 How effective is this medicine and is it different from other medicines currently available to treat this condition?

Please detail any unmet need and how the medicine addresses this. Try to summarise the clinical trial results as briefly and simply as possible, rather than giving too much detail. Highlight the outcomes that are likely to be most important to the patient. What are the advantages and any disadvantages from a patient perspective compared to current treatment(s)? As mentioned in section 2, information should be factual and presented in a balanced way. It should represent fairly the current body of evidence relating to a medicine and its benefit/risk profile. Manufacturers should be mindful of not appearing disparaging of other treatments.

6.6 How is the medicine administered and how will this affect patients and carers?

Please include details such as: form, frequency, handling and self-administration/or otherwise. Consider the impact on patient care, such as avoiding the need for hospital visit.

6.7 What are the side-effects of this medicine and how are they managed?

Include the main side effects that are likely to be experienced. Use this question to explain the implications for patients and how they are managed. For a full list of side effects reference can be made to the PIL instead of listing them here.

6.8 What is the quality of life impact of this medicine on patients and their carers?

Focus on what is likely to be most important for the patient and patient's carer/family. What is the added value of the medicine for patients and carers compared to current treatment(s)? This might include secondary trial end-points including those related to quality of life. However, secondary endpoints should be set in the context of primary endpoints.

6.9 There is space to provide signposting to further online information about this medicine which patient groups may find useful.

This might include reference points, resources or published clinical trial data. There may be other publicly available regulatory documents regarding this medicine, including the Public Assessment Report and a Risk Minimisation Document (where relevant). Patient groups may also find it useful to know what experience there has been of the medicine in Scotland and the rest of the UK. For example, local clinical trial centres and early access programmes. Are there patient information materials and websites that may be helpful?

7. Freedom of Information

The SMC secretariat and core functions sit within Healthcare Improvement Scotland, a public authority covered by the Freedom of Information (Scotland) Act 2002. Information on how to make a freedom of information request, and on your information rights, can be found [here](#).

Appendix

Checklist for Completion of New Product Assessment Form

The checklist for the submission of the New Product Assessment Form (NPAF) has been updated to prompt companies to also provide a completed Summary Information for Submitting Patient Groups template. Companies are requested to provide this at the same time as the main submission.

All sections of NPAF completed	
Signed electronic copy of full NPAF and appendices enclosed	
Electronic Summary of Product Characteristics enclosed	
References provided in a RIS formatted file with a copy of all references (pdfs) provided either via email and contained in zipped files or on a CD ROM along with the NPAF	
Summary Information for Submitting Patient Groups enclosed	

Guidance notes:

All steps in the above checklist should be completed before the NPAF is submitted to SMC. Failure to complete any of these may delay processing of the submission.