

Patient and Clinician Engagement (PACE) Meetings Overview

Introduction

For medicines used to treat end of life and/or rare conditions, the Scottish Medicines Consortium (SMC) offers the submitting company the opportunity to request a Patient and Clinician Engagement (PACE) meeting which gives patient groups and clinicians a stronger voice in SMC decision making. This document outlines how the meetings work. Please see appendix 1 for the SMC definition of end of life, orphan and ultra-orphan medicines.

How does the process work?

End of life and orphan medicines

A submission is made using the New Product Assessment Form (NPAF) form and the medicine is evaluated by the New Drugs Committee (NDC) in the usual way. If the draft advice for the medicine is 'not recommended' following NDC, the pharmaceutical company can choose to request that SMC convenes a PACE meeting.

Ultra-orphan pathway

A PACE meeting is not convened during the initial ultra-orphan assessment as no decision will be made on the medicine at that time. Following the data collection period, and subsequent submission to SMC, the medicine will be evaluated by the NDC. If the advice for the medicine is 'not recommended' following NDC, the pharmaceutical company can choose to request that SMC convenes a PACE meeting. More information on the ultra-orphan pathway can be found in the *How we decide* section of the SMC website.

PACE meetings

PACE meetings are held virtually using Microsoft Teams. This process adds an additional one to three months onto the assessment timeline.

Each PACE meeting is tailored to the medicine under consideration. The meeting is chaired by an NDC vice-chair, SMC vice-chair or someone else with specific experience of the SMC process and supported by SMC staff. An SMC public partner participates in the PACE meeting to provide public scrutiny of the process. Representatives are sought from patient groups and clinicians from the relevant specialty (identified by Managed Clinical Networks and regional Cancer Networks). The company can also submit a brief statement for consideration by the PACE group.

Confidentiality

The paperwork provided in relation to the PACE meeting and any information discussed at the meeting is confidential and attendees are made aware of the importance of not breaching confidentiality. Additionally, the completed PACE statement is treated in confidence until presented at the SMC committee meeting.

Declarations of interest

All meeting participants are required to adhere to the Healthcare Improvement Scotland Evidence Directorate policy on declarations of interest which can be found on the Healthcare Improvement Scotland website.

Having a conflict of interest **does not** preclude clinicians or patient group representatives from participating in a PACE meeting. Declarations of interest will be collected and included in SMC paperwork.

Capturing a medicine's benefits

The aim of the PACE meeting is to describe the added benefits of the medicine, from both patient and clinician perspectives, that may not be fully captured within the conventional clinical and economic assessment process.

These may include, but are not limited to:

Added value of the medicine for the patient

For example: impact on quality of life such as the ability to work or continue in education/function with any associated financial impact, symptoms such as fatigue, pain, psychological distress, also factors such as convenience of the treatment, whether it allows self-care or the ability to maintain independence and dignity.

Added value of the medicine for the patient's family/carers

For example: time for accompanied visits for treatment, requirement for assisting the patient with personal care and support, impact on family life, and impact on the carer's ability to work and any associated financial impact.

Clinical issues

For example: unmet need, severity of the condition, place in the treatment pathway, service/infrastructure changes/benefits as a result of using the medicine.

PACE meeting output

A PACE template is completed during the meeting and the content agreed by participants. The resulting PACE statement is included in the SMC meeting papers for the medicine alongside the NDC detailed advice document, company comments, collated clinical expert responses, patient group submission(s) and any new or revised Patient Access Scheme (PAS). The output from the PACE meeting is a major factor in the SMC decision.

Resubmissions for PACE eligible medicines

If the SMC committee is unable to accept a PACE eligible medicine for use in NHSScotland despite the added flexibility of PACE, then the company has the option of resubmitting to SMC. If the company resubmits within six months of the PACE meeting being held then the original PACE statement will be used for the resubmission. If the resubmission is received more than six months later then SMC staff will contact the original participants to establish if the previous PACE statement is still valid in terms of capturing the potential added value or if an updated PACE statement or a further PACE meeting is required.

Appendix 1

Definitions for end of life, orphan and ultra-orphan medicines

- End of life medicine: a medicine used to treat a condition at a stage that usually leads to death within 3 years with currently available treatments.

The definition of end of life medicine may be based on a sub-population of the licensed indication where the submission is positioned for use in this subgroup and the submitting company provides adequate justification.

- Orphan medicine: a medicine with a Great Britain (GB) orphan designation at the time of marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) (i.e. conditions affecting fewer than 2,500 people in a population of 5 million) or a medicine to treat an equivalent size of population irrespective of whether it has designated orphan status.

The definition of orphan medicine is based on the full population of the licensed indication relevant to the submission, irrespective of whether or not the company wishes SMC to consider the product when positioned for use in a sub-population of the licensed indication.

- Ultra-orphan medicine: all criteria listed must be met
 - the condition* has a prevalence of 1 in 50,000 or less in Scotland,
 - the medicine has GB orphan designation at the time of marketing authorisation,
 - the condition is chronic and severely disabling, and
 - the condition requires highly specialised management.

** typically a recognised distinct disease or syndrome. SMC uses the description of the orphan condition within the MHRA Orphan Register.*