



# 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 standard SMC submission form and the medicine is evaluated by the New Drugs Committee (NDC) in the usual way. If the 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 New Drugs Committee (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 usually take place on the afternoon of the second Tuesday of each month in the SMC premises in Glasgow with up to three PACE meetings held in an afternoon. This process adds an additional one to three months onto the assessment timelines.

Each PACE meeting is tailored to the medicine under consideration. The meeting is chaired by an NDC vice-chair or someone 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 it is important that all attendees are aware of the importance of not breaching confidentiality. Additionally the completed PACE statement should be treated in confidence until presented at the SMC committee meeting.

## Declarations of Interest

All meeting participants are required to adhere to the SMC policy on declarations of interest which can be found on the SMC website.

## 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, 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, out of pocket expenses.

## 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, out of pocket expenses, impact on family life, and impact on the carer's ability to work.

## 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 group members. The resulting PACE meeting statement is included in the SMC meeting papers for the medicine alongside the NDC detailed advice document, company comments, patient group submission(s) and any new or revised Patient Access Scheme (PAS) submission. The output from the PACE meeting is a major factor in the SMC decision.

# 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 submitting company provides adequate justification.*

- Orphan medicine: a medicine with European Medicines Agency (EMA) designated orphan status (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 an EMA orphan designation for the condition and this is maintained at time of marketing authorisation,
  - the condition is chronic and severely disabling, and
  - the condition requires highly specialised management.

*\*For ultra-orphan medicines SMC uses the description of the condition within the European Medicines Agency's (EMA) Orphan Maintenance Assessment Report (OMAR) as a reference (or the description within the original orphan designation if the OMAR is not available).*