IMPACT OF PATIENT AND CLINICIAN ENGAGEMENT (PACE) MEETING ON SCOTTISH MEDICINES CONSORTIUM RECOMMENDATIONS

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BACKGROUND

- The Scottish Medicines Consortium (SMC) provides an opportunity for pharmaceutical companies to request a Patient and Clinician Engagement (PACE) meeting when medicines intended for end-of-life or rare conditions receive a "not recommended" status in the initial assessment[1].
- This initiative was introduced in 2014 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[1].
- According to SMC, these may include but are not limited to the added value of the medicine for the patient, the added value of the medicine for the patient's family/carers and clinical issues such as unmet needs, severity of the condition, place in the treatment pathway, service/infrastructure changes/benefits as a result of using the medicine[1].

OBJECTIVE

- To evaluate the outcomes and impacts of PACE meetings on SMC final recommendations, particularly focusing on how these meetings influence patient access to treatments that were initially classified as "not recommended."

METHODS

- Health Technology Assessment (HTA) reports from January 2020 to June 2024 were downloaded from the SMC website[2].
- Reports with submission type "Abbreviated", "Collaboration", "Non-submissions" were excluded from our analysis. Additionally, reports labelled as "Ultra-orphan initial assessment" were excluded since no decision will be made on the medicine at initial assessment stage. Reports with the status "withdrawn/revoked" were also excluded.
- Reports for medicines intended for end-of-life and/or rare conditions were selected. These reports were further analysed in terms of the manufacturer's request to hold a PACE meeting, the inclusion of a patient access scheme (PAS), key discussion points at PACE meetings and the final decision made by the SMC.

RESULTS

- Out of the 222 reports analysed, 144 were classified as eligible for a PACE meeting and were subsequently included in the study. Between 2020 and the first half of 2024, manufacturers requested a PACE meeting in 117 cases, representing 81% of the eligible reports.
- The number of PACE meeting requests has remained relatively stable over the past five years, with annual figures ranging between 22 and 32 meetings (Figure 1).
- Among reports that underwent PACE meetings, 56 met the orphan drug criterion, while 18 pertained to end-of-life conditions. Notably, 43 reports satisfied both criteria. (Figure 2)

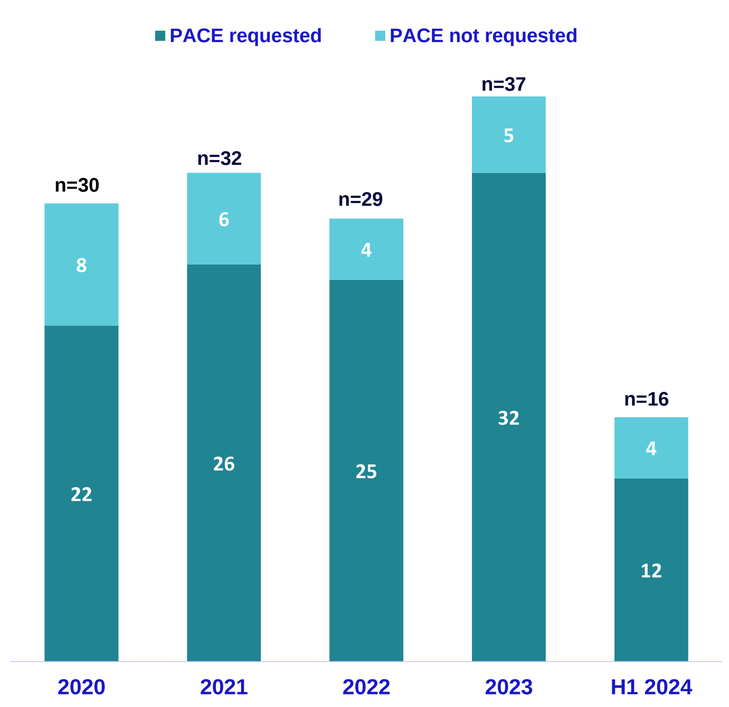

Figure 1. Number of requests for PACE meetings among all assessments of medicines intended for end-of-life or rare conditions (N=144) per year between 2020-H1 2024

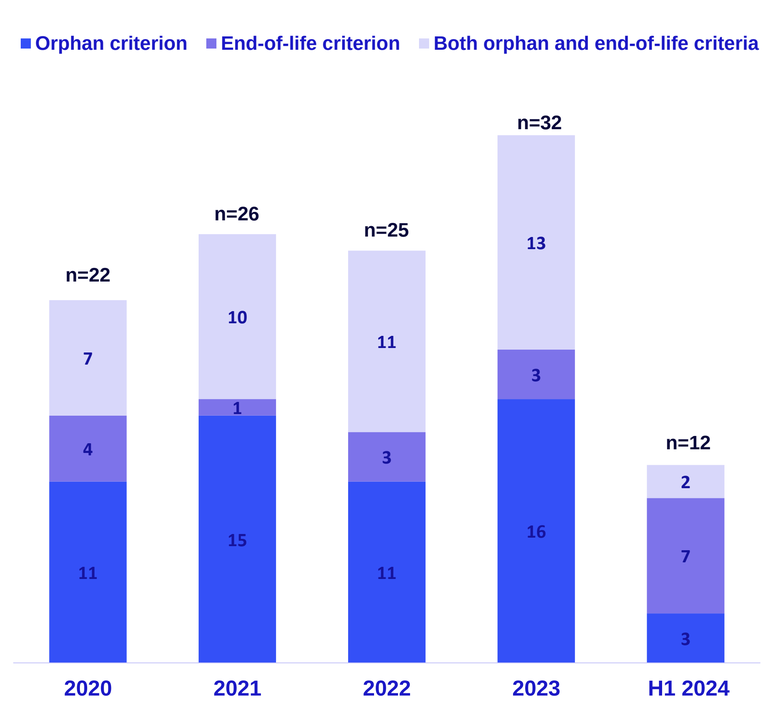

Figure 2. Eligibility criteria (Orphan and/or end-of-life) in SMC assessments involving PACE meetings (N=117) between 2020-H1 2024

- Among the 117 assessments that included PACE meetings after an initial negative opinion, the SMC recommendation changed to positive (defined as accepted, interim acceptance or restricted) in 86% of cases. Conversely, 14% (16/117) of assessments remained negative. Reasons for these negative recommendations included both high costs and a lack of sufficiently robust evidence in 63% of cases (10/16 assessments), insufficient evidence alone in 31% (5/16), and high costs alone in 6% (1/16). (Figure 3)

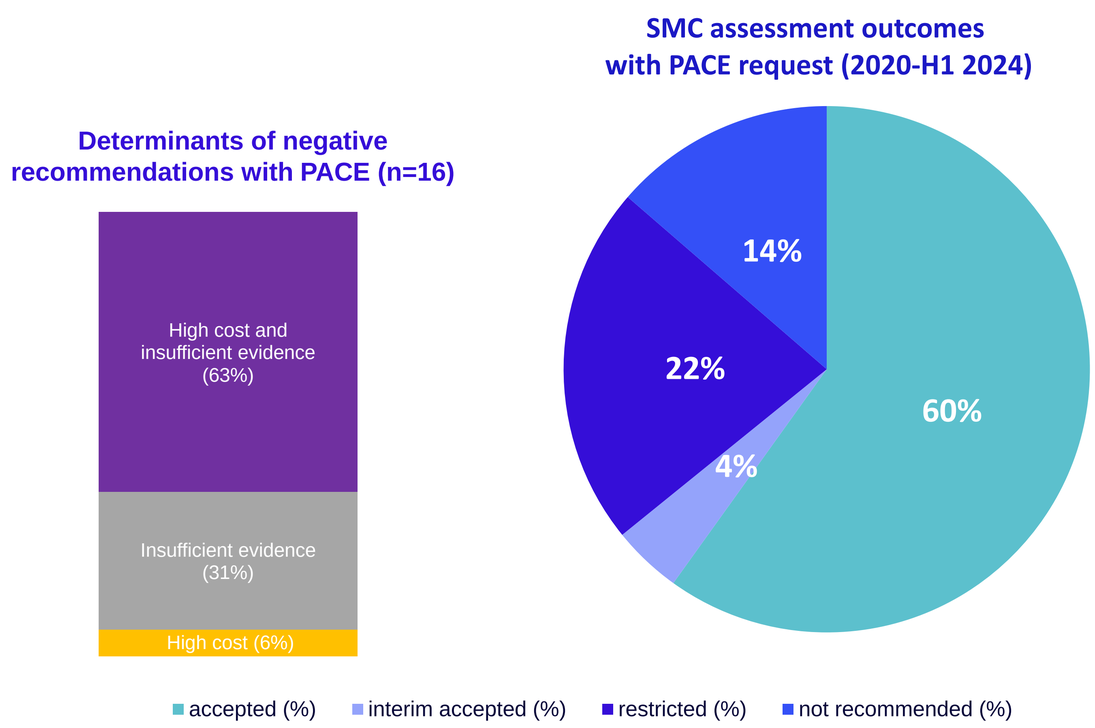

Figure 3. Results of HTA Assessments by SMC with PACE meetings (2020- H1 2024)

- In assessments where a PACE meeting was held, the company did not submit a Patient Access Scheme (PAS) in only 2 assessments. For the remaining dossiers, a PAS was assessed as acceptable for implementation in NHS Scotland in over 99% of cases and was not accepted in only one case (axicabtagene ciloleucel, Yescarta®) leading to a negative recommendation by SMC despite demonstrating significant clinical benefits.
- During the PACE meetings, patients and clinicians highlighted several key topics, including the clinical and additional benefits of the drug (100% of cases), the disease severity and burden for patients (98% of total cases), and the unmet need for new therapeutic options (85% of cases). In contrast, discussions regarding the burden on family/caregivers were less emphasized (37% of cases).

CONCLUSIONS

- **PACE meetings appear to be effectively achieving the SMC's objective of providing a platform for patient groups and clinicians to highlight the disease burden experienced by patients and the drug added value that may not be adequately reflected in standard assessments.**
- **A noticeable improvement was observed in the SMC recommendations after a PACE meeting following an initial negative recommendation. However, PACE may not be the sole driver of a change from a negative recommendation to a positive one. Changes to pricing which can be delivered through Patient Access Schemes (PAS) along with the perceived quality of evidence, likely play significant roles as well.**

REFERENCES

1. Scottish Medicines Consortium Patient and Clinician Engagement (PACE) Meetings Overview. Available at: https://scottishmedicines.org.uk/media/8208/working-with-smc.pdf Last accessed: 05/11/2024
2. Scottish Medicines Consortium website. Retrieved October 22, 2024, from https://scottishmedicines.org.uk/