Exploring the Impact of End-of-life Designation on Access to Oncology Therapies in the United Kingdom

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Introduction

- The Scottish Medicines Consortium (SMC) and National Institute for Health and Care Excellence (NICE) use different criteria and methodologies to appraise medicines with end-of-life (EOL) designation (Table 1), which could lead to divergent outcomes in the access of EOL medicines across the UK.[1,2]
- In Scotland, SMC can convene a Patient and Clinician Engagement (PACE) meeting if requested by sponsors to clarify aspects of value perceived by patients and clinicians, potentially giving patients a stronger voice in decision-making.[3]
- In England, the Cancer Drugs Fund (CDF) is a source of funding for cancer drugs. It allows for patient access, while uncertainty about a medicine's cost-effectiveness is assessed through data collection when EOL criteria are considered.[4]
- The aim of this study was to examine the differences between SMC and NICE criteria for assessing oncology therapies with EOL designation and understand how EOL status might impact decision-making.

	Treatment indication	Life expectancy	Extension to life
SMC EOL *criteria*	**Condition at a stage that usually leads to death**	**3 years**	**NA**
NICE EOL *criteria*	**Patients with a short life expectancy**	**Less than 2 years**	**Additional 3 months**

Table 1. SMC and NICE criteria for consideration of medicines as EOL

Methods

- Appraisals for oncology therapies assessed by SMC under the EOL process, published between May, 2020 and April, 2023, were reviewed and compared with NICE reports of the same treatments.
- The process was repeated for appraisals assessed by NICE during the same timeframe and cross-referenced to equivalent SMC appraisals.
- A data extraction tool captured decision details, EOL status, reimbursement restrictions/requirements, and how the PACE meeting and CDF could affect final recommendations.
- Withdrawn or terminated appraisals were excluded from the analysis.

Results

- During the timeframe studied, SMC assessed 35 oncology therapies and NICE assessed 29 oncology therapies meeting their respective EOL criteria (Figure 1).
- There were differences in EOL status between agencies, with only 66% (23/35) of therapies assessed by SMC also meeting NICE's EOL criteria. Regardless, the outcome of the majority of appraisals were aligned. Reimbursement was granted in 87% and 91% of appraisals by SMC and NICE, respectively, with decision-making aligning in 87% of recommendations (Figure 2).
- Among medicines with divergent outcomes, the agencies reported similar concerns about evidence submitted, including the degree of certainty around the clinical/cost-effectiveness and application of EOL criteria.
- Alpelisib and selpercatinib were accepted by NICE but not by SMC. For both drugs, SMC reported the submitting company did not present a sufficiently robust economic case to gain acceptance; for selpercatinib, they added that the health benefits demonstrated were not sufficient to justify the cost.
- Pralsetinib was accepted by SMC on an interim basis subject to ongoing evaluation, while rejected by NICE. NICE reported that a managed access agreement was not provided by the company to be included in the CDF while more data are being collected to resolve some uncertainty.

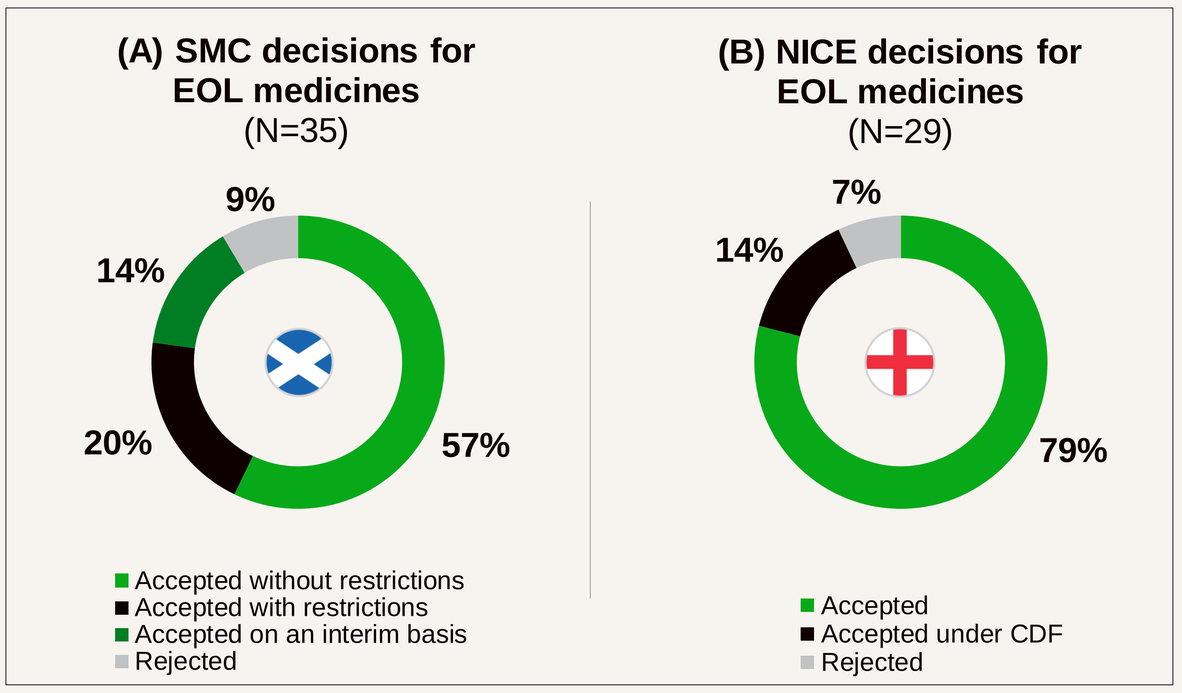


Figure 1. SMC (A) and NICE (B) decisions for EOL medicines over the entire study period

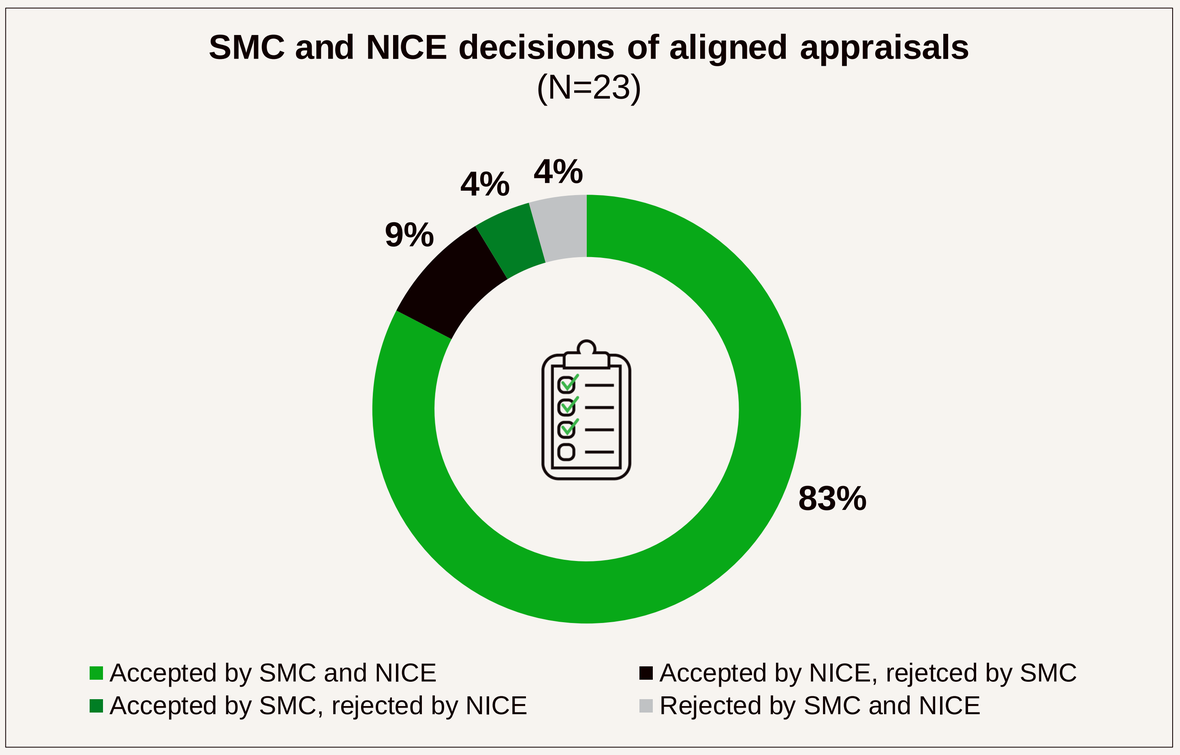


Figure 2. Alignment between SMC and NICE decision-making for EOL medicines over the entire study period

Conclusions

- SMC and NICE criteria for EOL designation differ, hence oncology therapies granted EOL status do not always overlap. However, nearly all appraisals identified resulted in reimbursement, meaning equitable access in Scotland and England.
- In Scotland, PACE meetings may enhance the implementation of patient-centred care, potentially leading to better health outcomes, while in England the CDF provides access to promising cancer drugs with uncertainty in their clinical evidence. However, it is not fully demonstrated how the PACE meetings and CDF in Scotland and England, respectively, could encourage access to EOL medicines.
- In rare cases of divergent outcomes, the reasons for opposing recommendations and contribution level of EOL designation in decision-making remain unclear. Detailed reporting on how decisions are reached by both agencies is not provided, and the assessment criteria are not uniform. Thus, increased transparency on how different factors are weighted, particularly when reimbursement is not approved, could help inform manufacturers as they prepare for future submissions.

Abbreviations

CDF=Cancer Drugs Fund; EOL=End-of-life; NA=Not applicable; NICE=National Institute for Health and Care Excellence; PACE=Patient and Clinician Engagement; SMC=Scottish Medicines Consortium; UK=United Kingdom

References

1. Scottish Medicines Consortium Update Report 2016. https://www.scottishmedicines.org.uk/media/2728/smc-update-report.pdf. Accessed October, 2023. 2. Bovenberg J et al. 10 Years of End-of-Life Criteria in the United Kingdom. Value in Health 2021. 24(5):691-698. 3. Scottish Medicines Consortium. Patient and Clinician Engagement (PACE) Meetings Overview. https://www.scottishmedicines.org.uk/media/7217/pace-overview-document-v36docx.pdf. Accessed October, 2023. 4. NHS England/ National Institute for Health and Care Excellence. Consultation on proposals for a new Cancer Drugs Fund (CDF) operating model: Q&A. 2016. https://www.engage.england.nhs.uk/consultation/cdf-consultation/supporting_documents/cdfqa.pdf. Accessed October, 2023.

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