

How Do Abbreviated HTA Submissions Impact Reimbursement? An SMC Case Study

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Background

- The Scottish Medicines Consortium (SMC) introduced new criteria for an abbreviated submission procedure in October 2020, enabling products in the same therapeutic class as an SMC-approved medicine to use the abbreviated pathway.¹
- Initially devised as an interim measure to manage the backlog of submissions during the COVID-19 pandemic, the new “therapeutic class abbreviated submission” (TCAS) pathway was made permanent in May 2023.²
- This study aims to assess the impact of this change on uptake of the abbreviated procedure and on the availability of medicines across a range of therapeutic classes in the National Health Service (NHS) in Scotland.

Methods

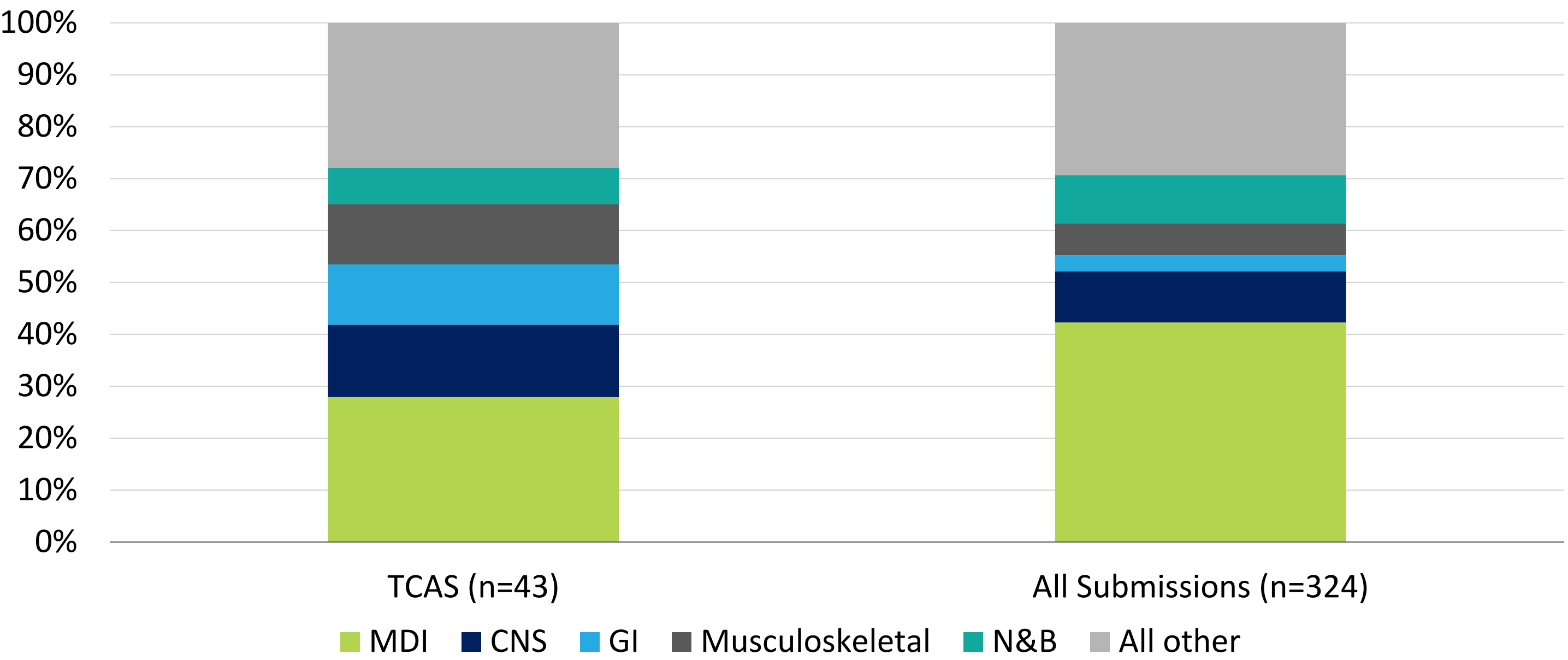
- All published SMC appraisals from 01 January 2014 to 01 June 2024 were analysed. The parameters considered were: submission type, publication date, SMC recommendation, and British National Formulary (BNF) chapter.
- Medicines were assigned to one of 15 BNF chapters based on the SMC’s categorisation. Where no categorisation was present, we assigned a BNF chapter or, in a small number of cases, a separate therapeutic tag.
- When examining the average annual throughput of submissions assessed by the SMC over the period 01 January 2014 to 01 June 2024, we excluded decisions published in 2020 as the disruption caused by the COVID-19 pandemic severely impacted the rate of publication of SMC decisions.

Results

Analysis of TCAS vs. All Submissions post-01 October 2020

- From 01 October 2020 to 01 June 2024, the SMC published 324 appraisals; 67 were abbreviated submissions, of which 43 were of the TCAS type.
- Assessments of medicines in five BNF chapters accounted for more than 70% of all submissions assessed via the TCAS pathway in the period from 01 October 2020 (i.e., following TCAS implementation) to 01 June 2024. The same overall percentage for the same five BNF chapters was seen across all submissions during the same period (Figure 1).
- A notable difference was seen in the largest category, “malignant disease and immunosuppression.” Around 27.9% of medicines assessed via the TCAS pathway in the period 01 October 2020 to 01 June 2024 were in this BNF chapter, compared with 42.3% across all 324 submissions (Figure 1).

Figure 1. SMC Assessments Published 01 October 2020 to 01 June 2024, by BNF Therapeutic Category and Submission Type

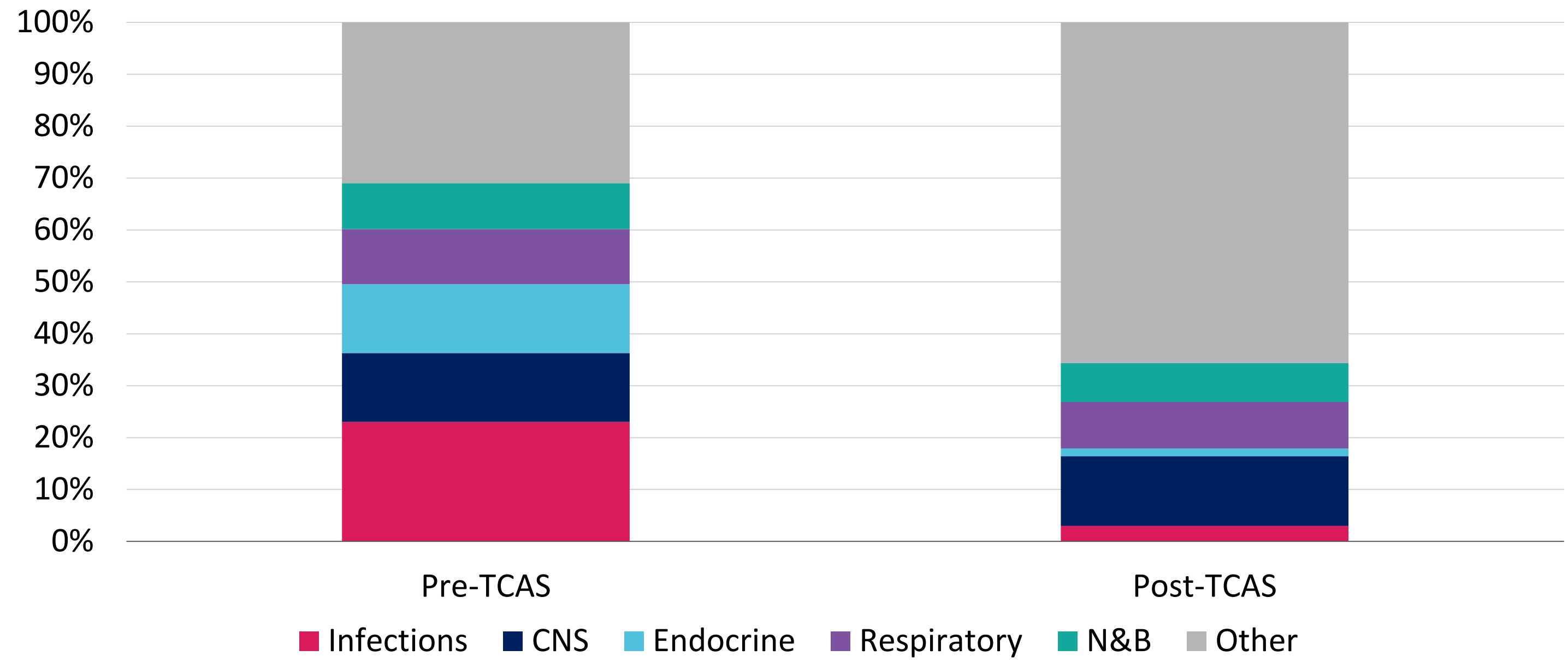


Abbreviations: CNS = central nervous system; GI = gastrointestinal; MDI = malignant disease and immunosuppression; N&B = nutrition and blood; TCAS = therapeutic class abbreviated submission

Analysis of Abbreviated Submissions before and after Introduction of TCAS

- In the period from 01 January 2014 to 30 September 2020 (“pre-TCAS”), the SMC published 113 abbreviated submissions. For these submissions, the most common BNF chapter was “infections” (23.0%) (Figure 2), while only 6.2% were for “malignant disease and immunosuppression.”
- The top five BNF categories for abbreviated submissions in the “pre-TCAS” period (“infections,” “central nervous system,” “endocrine system,” “respiratory system,” and “nutrition and blood”) accounted for 69.0% of all abbreviated submissions in this period, but these five categories accounted for just 34.3% of all abbreviated submissions in the period 01 October 2020 to 01 June 2024 (“post-TCAS”) (Figure 2).

Figure 2. Top 5 BNF Categories across All Abbreviated Submissions “Pre-TCAS” Compared with the Same Categories across All Abbreviated Submissions “Post-TCAS”

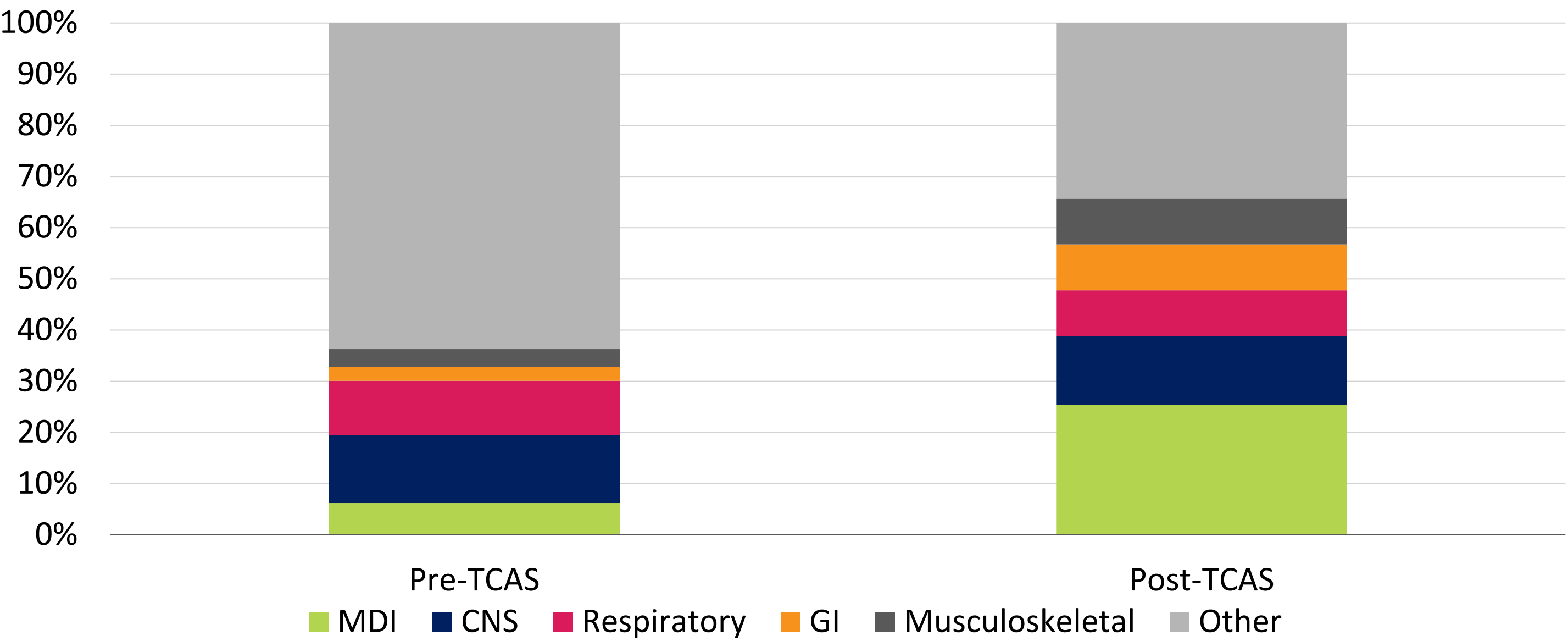


Abbreviations: CNS = central nervous system; N&B = nutrition and blood; TCAS = therapeutic class abbreviated submission

Results (cont.)

- For the 67 abbreviated submissions (including TCAS and other abbreviated submissions) published in the period 01 October 2020 to 01 June 2024, the most common BNF chapter was “malignant disease and immunosuppression” (Figure 3).
- The top 5 BNF categories for abbreviated submissions in the “post-TCAS” period (“malignant disease and immunosuppression,” “central nervous system,” “respiratory system,” “gastro-intestinal,” and “musculoskeletal”) accounted for 65.6% of all abbreviated submissions in this period, but these five categories accounted for only 36.3% of published submissions for the “pre-TCAS” period (Figure 3).

Figure 3. Top 5 BNF Categories across All Abbreviated Submissions “Post-TCAS” Compared with the Same Categories across All Abbreviated Submissions “Pre-TCAS”



Abbreviations: CNS = central nervous system; GI = gastrointestinal; MDI = malignant disease and immunosuppression; TCAS = therapeutic class abbreviated submission

Throughput of Assessments

- From 01 January 2014 to 31 December 2019, an average of 17.8 abbreviated submissions were published annually, increasing to an average of 21.6 per year from 01 January 2021 to 31 December 2023. In contrast, the SMC published 94.5 appraisals (all types) per year on average in 2014–2019, falling to 91.0 annually in 2021–2023.

Discussion

- The implementation of the TCAS pathway in October 2020 was correlated with a shift in the type of medicines undergoing abbreviated submissions, with a reduction in the share of submissions in the “infections” and “endocrine system” BNF categories and an increase in the share of submissions in the “malignant disease and immunosuppression” category.
- The implementation of the TCAS pathway was also correlated with an increase in volume of abbreviated submissions assessed by the SMC annually, while the overall number of medicines assessed annually has not increased, suggesting that the new criteria may have allowed more companies to utilise the abbreviated rather than full submission procedure.
- Further research is required to determine the impact of the TCAS pathway on assessment times and on time to reimbursement for new medicines in Scotland.
- This study has a number of limitations.
 - The SMC does not explicitly state whether a drug has been through the TCAS pathway. We judged 43 of 67 abbreviated submissions since 01 October 2020 to be of the TCAS type, but there may be others in the TCAS category that we were unable to identify from the available data.
 - We were not able to control for how medicines would have been assessed had the TCAS pathway not been implemented. Accordingly, our findings are illustrative and cannot show causation.

Conclusions

The implementation of the TCAS pathway from 01 October 2020 was correlated with an increase in the average annual number of abbreviated submissions assessed by the SMC compared with the “pre-TCAS” period, suggesting that the new criteria may have enabled more companies to take advantage of the streamlined assessment process. The introduction of the TCAS pathway was also correlated with a shift in the type of medicines assessed via the abbreviated submission pathway, with more oncology products utilising the abbreviated procedure under the new criteria.

References

- Scottish Medicines Consortium. Streamlining SMC processes for medicines that clearly offer good value to NHS Scotland. Accessed 25 October, 2024. <https://scottishmedicines.org.uk/about-us/latest-update/streamlining-smc-processes-for-medicines-that-clearly-offer-good-value-to-nhsscotland/>
- Scottish Medicines Consortium. Accessed 30 October 2024, <https://scottishmedicines.org.uk/about-us/latest-update/streamlining-smc-processes-for-medicines-that-clearly-offer-good-value-to-nhsscotland/>

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