DO MANUFACTURERS STILL SEE A VALUE IN SUBMITTING EVIDENCE FOR A NICE APPRAISAL IN ENGLAND?

COMPARING AND CONTRASTING TERMINATED APPRAISALS BETWEEN ONCOLOGY AND NON-ONCOLOGY AND MONOTHERAPIES AND COMBINATION PRODUCTS

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Introduction/Objective

- Since 2018 NICE has stated it will evaluate all new active ingredients and major new indications.[1] Significantly increasing the number of evaluations conducted by NICE. Additionally, in 2018 they introduced a fee for these assessments. The fee was £126,000 when first charged in 2019, and now stands at £142,800.[2]
- A positive NICE assessment is key to obtaining reimbursement on the NHS in England and Wales. If manufacturers fail to submit an evidence package to NICE, it results in a "terminated appraisal", actively foregoing access to the market.
- This research aimed at identifying trends in terminated appraisals in relation to therapeutic area, monotherapy vs combination regimen, and date of termination.

Methods

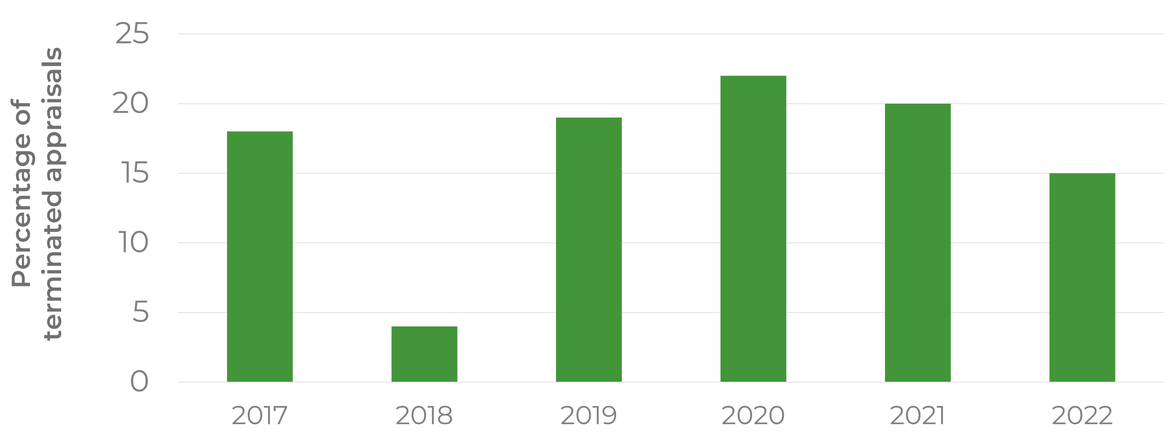
- This study reviewed Single Technology Appraisals (STAs) and Highly Specialised Technologies (HSTs) published on the NICE website between January 2017 to May 2022.
- Appraisals listed as "Terminated appraisal – non-submission" were identified and data were extracted on disease area, active substance, (monotherapy vs combination drug), and date of termination.
- A comparison of the number of terminated appraisals between non-oncology and oncology products and between monotherapies and combination drugs was made.

Results

- A total of 358 NICE STAs and HSTs between January 2017 and May 2022 were identified and included in the analysis.
- Of these, 60 (17%) were terminated appraisals due to non-submission (Figure 1).
- All terminated appraisals were STAs.
- Figure 2 breaks down the percentage of terminated appraisals per year. The annual percentage of non-submissions was generally between 15% to 22%, except in 2018 where only 4% of appraisals were terminated.

Figure 1: Proportion of all STAs and HSTs that were terminated appraisals from 2017 to 2022

Figure 2: Percentage of terminated appraisals per year

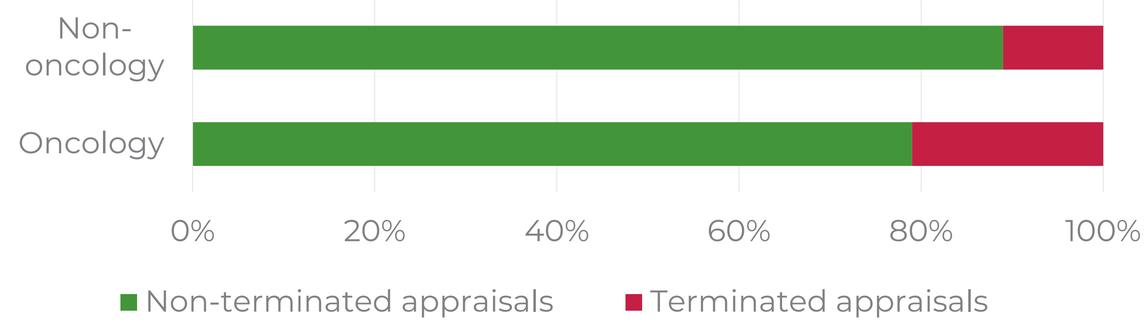


- Figure 3 illustrates the characteristics of terminated appraisals included in the analysis.
- 72% of terminated appraisals were for oncology products, and 35% were for combination drugs.
- All of the terminated combination drugs appraisals were oncology products.

Figure 3: Characteristics of terminated appraisals

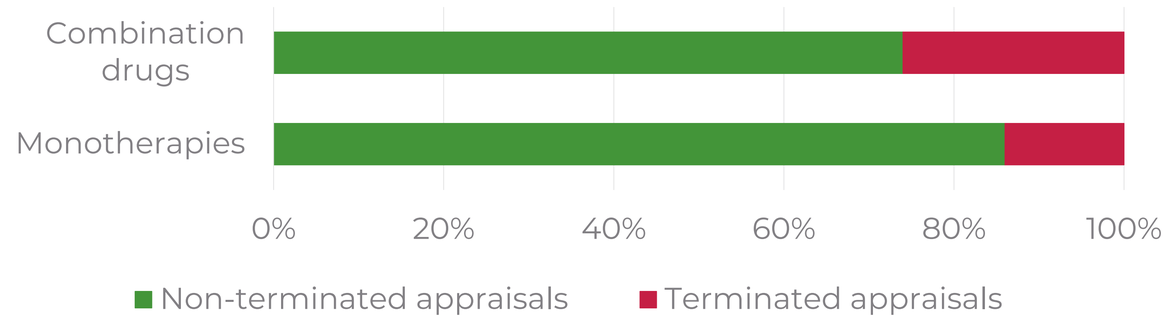
- Compared with appraisals for non-oncology products, oncology products were almost twice as likely to result in a terminated appraisal (11% vs 21%) (Figure 4).

Figure 4: Proportion of terminated appraisals for oncology and non-oncology drugs



- **As illustrated in Figure 5, a similar situation was also observed for monotherapies and combination drugs (14% vs 26%).**

Figure 5: Proportion of terminated appraisals for monotherapies and combination drugs



Discussion and Conclusion

- High acquisition cost coupled with high levels of uncertainty in the clinical data may reduce the likelihood of a product being deemed cost-effective, especially in oncology. Manufacturers may therefore be choosing not to commit the necessary resources to develop a submission, where the chance of success at the desired price point is low.
- In addition, oncology products are often approved for multiple indications. It is possible that manufacturers are choosing not to submit indications that would pull down the cost-effective price of higher-value indications. It would be interesting to determine what proportion of non-submissions are for products that already have NICE approval in a different indication.
- Given the need to include both the price of the new product and the price of the existing 'backbone' treatment there are significant challenges in demonstrating cost-effectiveness for combination treatments. It is therefore highly likely that combination products are less likely to be cost-effective than monotherapies and companies may be choosing not to submit to NICE when the clinical benefit of adding their therapy to existing therapy cannot justify the additional cost.

Abbreviations: HSTs: Highly Specialised Technologies; STAs: Single Technology Appraisals

References: 1 - https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/charging *[Accessed 19/10/22]*
2 - NICE, Guide to the processes of technology appraisal. Available at: https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/technology-appraisal-processes-guide-apr-2018.pdf *[Accessed 19/10/22]*

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