

Has the new NICE appraisal process for oncology drugs delivered faster patient access to innovative treatments?



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Introduction/objective

- Since 29 July 2016, the National Institute for Health and Care Excellence (NICE) has employed a new fast-track appraisal process for oncology drugs. The aim of this process is to provide patients earlier access to new, more effective medicines.
- The new approach aims for draft guidance to be published prior to European Medicines Agency (EMA) market authorisation (MA) in the form of an Appraisal Consultation Document (ACD), and a Final Appraisal Determination (FAD) to be published within 90 days of MA.
- This study investigates the extent to which these targets have been met for cancer drugs receiving MA post-July 2016, in order to determine whether NICE's new process is translating into faster patient access in practice.

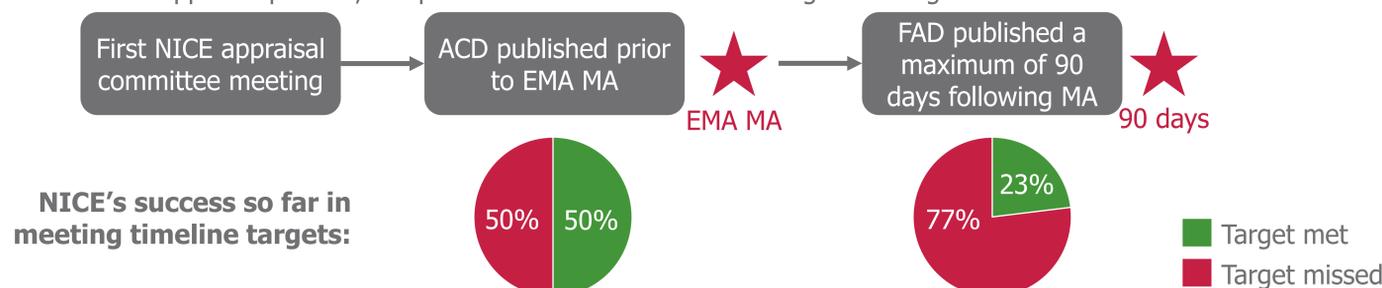
Methods

- Publicly available sources were utilised to identify cancer drugs assessed through the new NICE oncology appraisal process (data cut-off 24 April 2018).
- The following information was collected for each drug:
 - The publication dates of the ACD and FAD by NICE
 - The EMA MA date for the indication assessed by NICE in the ACD and FAD.
- The number of days between the MA date and ACD / FAD publication dates were then calculated, and compared to the target timelines set by NICE.
- Multiple-technology appraisals, drugs with MA prior to 29 July 2016, and transition drugs from the old Cancer Drugs Fund were excluded.

Results

- A total of 13 oncology drugs were identified that received MA from the EMA between 29 July 2016 and 24 April 2018. The FAD publication dates were identified for all 13 drugs, while the ACD publication dates were identified for 12 of the 13 drugs. No ACD was issued for olaratumab + doxorubicin for treating advanced soft tissue sarcoma – ACDs are only produced if initial assessment identifies significant uncertainty or concludes a drug should not be recommended for use. This suggests that the initial submission for olaratumab + doxorubicin provided sufficient data to enable NICE to make a final recommendation, without the need for an ACD.
- For the drugs where ACDs had been published, 50% were published post-MA, missing NICE's target. In addition, in 77% of cases, NICE missed its 90-day FAD publication target. An overview of the key timeline targets in NICE's CDF appraisal process, compared to NICE's success in meeting these timelines, is shown in Figure 1.

Figure 1: Timeline targets in NICE's CDF appraisal process, compared to NICE's success in meeting those targets



- For drugs whose ACD publication target was met, the ACD was published a median of 19 days prior to MA. For those drugs for which the ACD publication target was not met, the ACD was published a median of 52 days after MA (see Figure 2). In two cases, the ACD was published >200 days after MA.
- The median time from MA to FAD was 123 days, ranging from 30-337 days. For three drugs, the FADs were published >180 days after MA, more than twice NICE's target (see Figure 3).

Figure 2: Working days between ACD publication and MA, based on appraisals of oncology drugs between July 2016 and April 2018

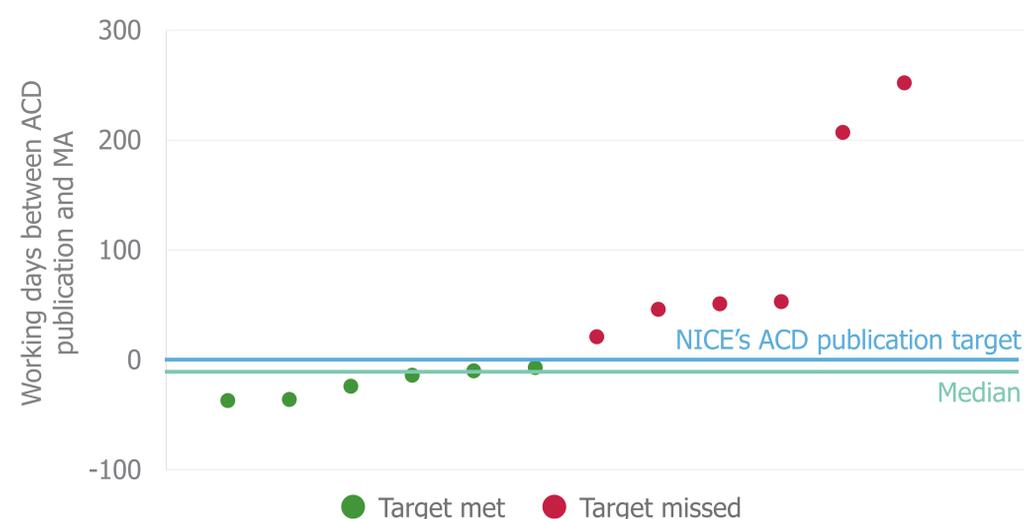
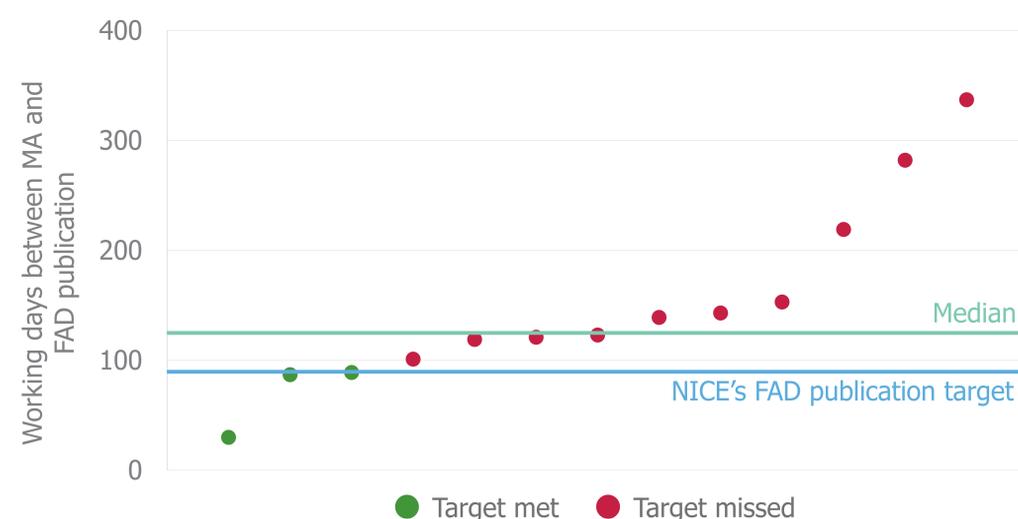


Figure 3: Working days between MA and FAD publication, based on appraisals of oncology drugs between July 2016 and April 2018



Discussion and conclusion

- The modified NICE oncology appraisal process aims to enable fast-track appraisals, allowing patients earlier access to new treatments. In practice, ACDs were published prior to MA for only 50% of oncology drugs receiving MA between July 2016 and April 2018. Furthermore, FAD publication is taking 33 days longer on average than the 90-day stated target.
- However, an analysis of NICE appraisals conducted from 2001-2010 indicate that single technology appraisals (STAs) for cancer drugs took >25 months on average¹ (>500 working days). This suggests that the new fast-track process has significantly reduced the time to publication of NICE guidance.
- NICE have previously reported that their FAD targets were met in 100% of cases in 2017/18, for appraisals that meet the following criteria: the product must be identified sufficiently early; the appraisal must follow the standard NICE process; there must be no changes to the regulatory schedule; there must be no requests for further evidence submission after initial evidence submission; and there can be no appeals.² However, a Freedom of Information request* submitted to NICE revealed that NICE consider that only one appraisal (TA492 for Atezolizumab) met these criteria and hence, was able to receive recommendations within the 90-day target. This is in contrast to the results presented here, which assumed that 3 appraisals met NICE targets – this discrepancy is likely due to differences in methodology. Overall, it is clear from both information provided by NICE and from our analysis, that target timelines are likely to be met in only a minority of cases and under strict conditions.
- The delays that were identified in NICE's publication of ACDs and FADs could potentially be due to: NICE resource constraints; the complexity of appraisals; health economic insufficiencies; manufacturer delays or the large number of innovative medical treatment submissions.
- Manufacturers should therefore adapt their market access strategy and pharmaceutical pricing to accommodate the expedited appraisal process. Later publication of NICE guidance delays reimbursement, and ultimately patient access.

1. Ford J et al. NICE guidance: a comparative study of the introduction of the single technology appraisal process and comparison with guidance from Scottish Medicines Consortium. *BMJ Open*. 2012;2(1):e000671; 2. Prescott J. Roadmap for the life sciences: a new approach to NICE technology appraisals. Presented at NICE Annual Conference, 2018; *Requested as per the Freedom of Information Act 2000