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The 90-day ambition: historical analysis of 200 NICE appraisals to assess proportion achieving final guidance within 90 days of MHRA approval

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BACKGROUND/INTRODUCTION

- In England, the National Institute for Health and Care Excellence (NICE) evaluates the clinical and cost-effectiveness of healthcare interventions
- Their aim is to publish final guidance within 90 days of a technology receiving marketing authorisation by aligning the first committee meeting with the date of Medicines and Healthcare products Regulatory Agency (MHRA) approval
- More recently, the MHRA / NICE aligned pathway was announced in mid-October 2025[1], allowing for the committee meeting to take place in public prior to marketing authorisation, supporting access at the time of marketing authorisation for appraisals satisfying certain criteria

OBJECTIVE(S)

- To analyse data for the 200 most recent NICE appraisals and establish the proportion currently achieving the objective of final guidance published within 90 days of MHRA approval

METHODS

- We assessed data from 200 NICE appraisals (TA868 to TA1067)
  - Cut-off date for publication of technology appraisal guidance was 4th June 2025
- Of these, we excluded 73, either because the MHRA date was redacted throughout or because the appraisal was terminated
- The following data were extracted for each appraisal:
  - Technology
  - Indication
  - Date of MHRA approval
  - Date of final scope
  - Date of publication of technology appraisal guidance
  - Final outcome
- Time to final guidance was defined as the number of days between MHRA approval and publication of the technology appraisal guidance on the NICE website

DISCUSSION

- Our analysis showed that less than one-fifth of technologies are currently appraised by NICE within 90 days of MHRA approval
- There is large variation in the time to final guidance, with some technologies being approved immediately after MHRA approval and others taking several years
- There are likely an array of contributing factors, including:
  - protracted negotiations
  - delays to company submissions
  - requirement for additional committee meetings

REFERENCES

1. NICE. Same time decisions on licencing and value – what pharmaceutical companies need to know. Available from: https://www.nice.org.uk/news/blogs/same-time-decisions-on-licensing-and-value-what-pharmaceutical-companies-need-to-know. Accessed 24 October 2025
2. Medicines and Healthcare products Regulatory Agency. MHRA and NICE invite early adopters to trial accelerated aligned pathway – six months ahead of schedule. Available from: https://www.gov.uk/government/news/mhra-and-nice-invite-early-adopters-to-trial-accelerated-aligned-pathway-six-months-ahead-of-schedule. Accessed 30 October 2025

RESULTS

- Of the 127 appraisals assessed, 20 (16%) received final guidance within 90 days of MHRA approval (**Figure 1**)
  - This included two appraisals (TA912 and TA956) where NICE approved the technology on the day of MHRA approval (**Table 1**)
- Half of the appraisals assessed received final guidance within 1 year of MHRA approval and 18% took more than 2 years
- The mean time to final guidance was 561 days (approximately 18 months) and the longest was 4331 days (almost 12 years) (**Table 2**)
- Of the 57 oncology appraisals included, 3 (5%) received final guidance within 1 year of MHRA approval, compared with 17 of 70 non-oncology appraisals (24%)

Figure 1 Time to final guidance in a sample of 200 NICE appraisals

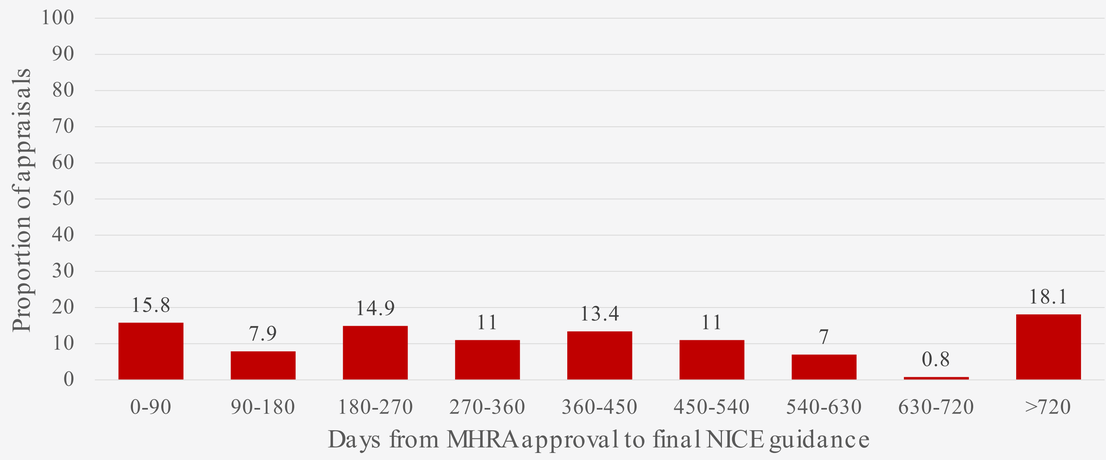

Table 1 5 appraisals with the shortest time to final guidance

TA	Technology	Date of MHRA approval	Time to final guidance (days)
TA956	Etrasimod for moderately to severely active ulcerative colitis in people aged ≥16 years	11/03/2024	0
TA912	Cipaglucoside alfa with miglustat for late-onset Pompe disease	15/08/2023	0
TA998	Risankizumab for moderately to severely active ulcerative colitis	21/08/2024	1
TA916	Bimekizumab for psoriatic arthritis	01/09/2023	33
TA913	Mavacamten for symptomatic obstructive hypertrophic cardiomyopathy	02/08/2023	35

Table 2 5 appraisals with the longest time to final guidance

TA	Technology	Date of MHRA approval	Time to final guidance (days)
TA1021	Crizotinib for ROS1-positive advanced non-small cell lung cancer	25/08/2016	3023
TA921	Ruxoltinib for polycythaemia vera	17/03/2015	3137
TA985	QuiremSpheres for unresectable advanced hepatocellular carcinoma	15/04/2015	3367
TA984	Tafamidis for transthyretin amyloidosis with cardiomyopathy	26/10/2012	4254
TA953	Fluocinolone acetonide intravitreal implant for chronic diabetic macular oedema	04/05/2012	4331

CONCLUSIONS

- NICE is currently achieving its objective of 90 days between MHRA approval and publication of final guidance for approximately 16% of appraisals
- NICE's proposed aligned pathway[1] should support an increase in this proportion over time
  - This pathway will bring together the MHRA's approval process and NICE's appraisal process, meaning that their decisions will be published simultaneously
  - The pathway has recently been opened to manufacturers of technologies designated for early access by NICE and the MHRA[2]
- Critically, achieving prompt access requires a commitment from all parties (i.e. the MHRA, NICE and manufacturers) to work closely to improve efficiency