Medicines data: NICE approvals and availability in England

Public Board Meeting

18th Sept 2025

NICE National Institute for Health and Care Excellence

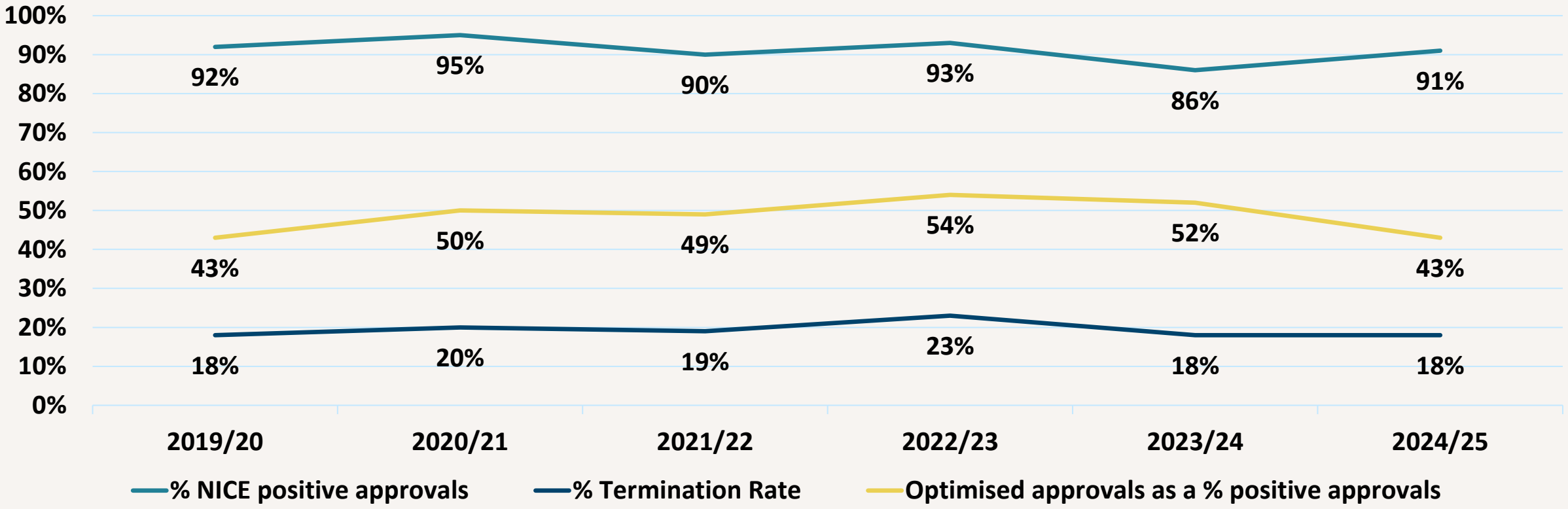
Executive Summary

1. Following publication of the 2024 EFPIA W.A.I.T. report on availability of medicines licensed in Europe 2020 – 2023, this update for information provides an analysis of NICE performance in supporting availability of branded medicines in England. This includes NICE domestic performance over time and in relation to European peers. The Board is asked to note key trends. Research by ABPI and NICE into reasons for appraisals terminated by industry is also attached as an Appendix.
2. NICE continues to consistently approve a high proportion of medicines that come to England for appraisal:
    - Over the last five years, we have approved 91% medicines that we appraised, with the latest figures for 2024/25 also standing at 91%.
    - Over this time, NICE data shows that terminations and optimised appraisals have been stable, supporting that NICE approach has been consistent over time – which is important for predictability.
3. Timeliness of NICE own processes is also improving. NICE is committed to further improve on this, as set out in the 10 Year Health and Regulatory Action Plans:
    - Last year (2024/25), the mean time between licence and guidance was cut by 26%, and when companies work with us to reduce timelines (via an 'optimal processes'), NICE guidance was published on average just 48 days after licence.
4. At the European level, this puts England in the top quartile in Europe – which is broadly consistent with previous years' performance:
    - On availability of medicines, England ranked 6th in Europe in the latest EFPIA data – up from 9th the previous year. This is a modest improvement on historic performance, where England was on average ranked 7th in Europe over the five previous reports.
    - On timeliness, this year England's position decreased one place to 7th, with a median time to access of 310 days (compared to 6th and 299 days last year). This is broadly consistent with historic performance, where, on average, England has ranked 7th amongst EU peers over five previous reports
    - A small number of medicines a year do not launch in the UK: NICE analysis of 212 medicines with EMA approval (Jan. 2021 – June 2025) found that 27 (13%) have not yet been licenced by the UK MHRA or assessed by NICE - ~6 medicines per year on average.

    Given the interest in medicines pricing, these data provide an important baseline against which we can understand any change in medicines access. Working with partners including MHRA and NHSE, NICE remains committed to supporting appropriate and timely access to clinically and cost-effective innovations. We will continue to regularly review such data to remain responsive to emerging trends.

NICE consistently approves a high proportion of medicines that we appraise

Over the last five years, NICE approved 91% medicines we appraised, with the latest figures for 2024/25 standing at 91%. The rate of optimised approvals and terminations remains broadly stable over the last 5 years – indicating a consistent and predictable NICE approach.



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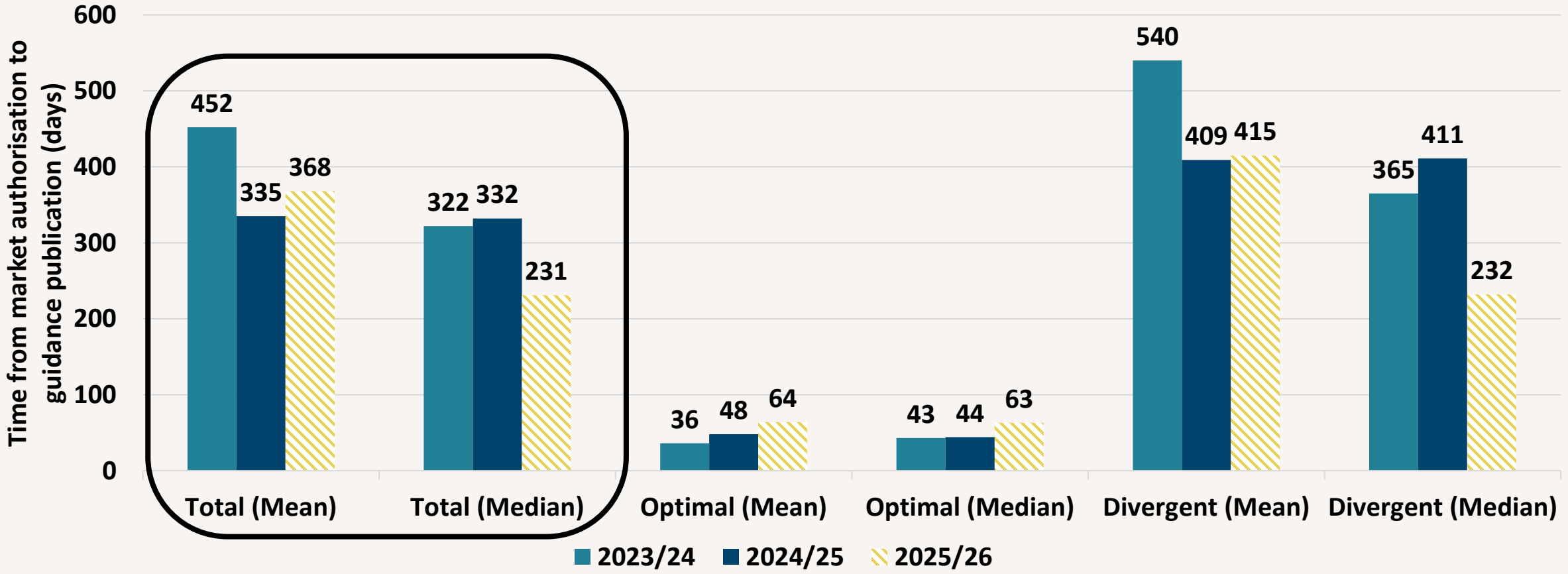
Data from NICE Medicines Sit-Rep Accessed 09/09/2025

Data includes both Technology Appraisals (including Cancer Drugs Fund) and Highly Specialised Technology Appraisals. Approval rate excludes terminations. Optimised recommendations are as a proportion of positive approvals

Note: From 2008/09 – 2018/19, termination rate was 10% on average, which increased to 19% following a 2019 policy change which required all Novel Active Substances and significant indications to come to NICE – resulting in topics coming to NICE that would not have otherwise come to NICE. This rate has since stabilised.

NICE has improved our timeliness and is committed to go further

Last year (2024/25), the mean time between licence and guidance was cut by 26% and when companies work with us to reduce timelines and support an optimal processes, NICE guidance was published on average just 48 days after licence. Incomplete data from 25/26 suggests NICE is on track to maintain and build on improvements.



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Notes:
Source: NICE SitRep data. Data is by financial year. Includes TA and HST.
2025/26* data is only partial year from 1st April 2025 to End August 2025

Optimal topics are defined as topics that publish within 90 days of market authorisation. Divergent topics are defined as topics that publish in over 90 days of market authorisation
Median figures are not the same as the EFPIA statistic on the next page due to the different periods used and because EFPIA data does not include license extensions

England's European ranking on access to new medicines is broadly stable

EFPIA WAIT data suggests access to new medicines in England remains broadly stable.

Wider NICE analysis of 212 medicines with EMA approval (Jan. 2021 – June 2025) found that 27 (13%) have not yet been licenced by the UK MHRA, therefore not assessed by NICE: 6 medicines per year on average[1].

EFPIA WAIT annual reports compare access to new medicines across >30 European countries. The latest report, published 7th May 2025 is based on data on medicines authorised between 2020-2023 and considered available as of January 5th 2025[2].

Measure	Latest performance		Change from previous years
Rate of availability: % of all EMA authorised medicines on central reimbursement list	6th (65% available)	↑	Improvement of 3 places from 9th (56% available) (2023 report). Improvement on average rank of 7th across previous 2019 – 2023 reports.
Time to availability: median days from local (MHRA) authorisation to inclusion on reimbursement list.	7th (310 days)	↓	Decrease from 6th (299 days[3]). On par with average rank of 7th across previous 2019 – 2023 reports.
Full vs restricted availability	57% available medicines with no restrictions 37% full availability of all EMA authorised medicines	↑	6 pp increase in unrestricted availability 9 pp increase in full availability of all EMA authorised meds

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1) "Medicines" as defined by EMA medicines approval. Excludes hybrid and generic medicines, biosimilars, and prophylactic vaccines. Medicines with EMA marketing authorisation between 1 Jan 2021 (post-Brexit cut-off date) to 1 Jul 2025 were included in the analysis. MHRA approval assessed up to 10 Sept 2025 – those with no MHRA licence and not available via IRP.

2) Source: EFPIA WAIT report 2024 (published May 2025). Rankings exclude countries which submitted timeliness data for a very small selection of medicines which distorts the reporting. In the recent 2024 report, this included Malta (1 medicine), North Macedonia (9 medicines), Cyprus (15 medicines). Of 5 prior reports 2019 – 2023, only 4 median timeliness data points reported. Rank for restricted availability not tracked as this is not readily compared.

3) Not the same as the median figures quoted on the previous page due to the different periods used and because EFPIA data does not include license extensions

Appendix – ABPI/NICE research on reasons for appraisals terminated by industry

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Appendix – ABPI/NICE research on terminated appraisals

NICE and ABPI conducted an interview-based review of reasons stated by industry for terminating appraisals with 10 companies which had the highest number of terminated appraisals in recent years. NICE data shows that terminated appraisals increased in 2019/20 (from 10% to 19% on average) and stabilised with no increasing trend thereafter. This followed NICE's 2019 VPAS commitment to review all new active substances and significant indications. This required industry to submit topics which might otherwise not have been in NICE's work programme. Research sought to more closely understand the reasons behind termination decisions:

1. **Characteristics: Terminations are most prevalent in medicines with multiple indications and combination therapies**, driven by challenges in being considered cost effective. Only a minority of terminations discussed related to new medicines (New Active Substances) (20%); almost 80% relate to licence extensions. Companies reported that just over half (101, 55%) of terminated potential indications are available across Germany, France, Italy and Spain, with 21% (39) unavailable. Data was not available for 24%.
2. **Reasons for termination: companies primarily choose to terminate appraisals because they considered the product/indication would likely not be found clinically and cost effective by NICE (32, 70% of indications).** Companies cited an inability to meet NICE's cost-effectiveness threshold at floor price, a lack of indication-based pricing, uncertainty around commercial flexibilities, issues with combination therapies, appraisal comparators and with clinical data as key reasons.
3. **The second most commonly stated reason was commercial reasons** (14, 30% of indications). Companies cited difficulty obtaining a commercial return in smaller indications after the costs of an appraisal had been factored in. Where a lack of indication-based pricing (IBP) was an identified as an issue, companies outlined that in many instances getting a follow-on indication reimbursed would result in a loss of revenue.
4. **NICE appraisals have good predictability**: companies expressed confidence in their decision making on terminations before or at the scoping stage.

Overall, terminations have remained stable for several years and reflect that not all products/indications will likely be clinically and cost effective. NICE will continue to monitor terminations with a view to best continuing to support access to clinically and cost-effective medicines for patients in England. **Work has progressed to ensure support for appropriate flexibilities for multi-indication medicines – which, together with combination therapies have highest terminations**. A 2024 Competition and Markets Authority ruling that provides new opportunities for companies to work together on combination therapies; in addition, an updated NHSE commercial framework clarified commercial flexibility on indication-based pricing. In addition, the 10 Year Plan committed to further work to streamline approvals for multi-indication medicines across NICE and NHSE.