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RESEARCH ARTICLE

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Do conditional marketing authorisations actually accelerate patient access? Time-to-access of conditional vs. standard marketing authorisations in Italy, Spain, and Germany

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ABSTRACT

Background: The European Medicines Agency (EMA) implemented 'fast-track' programmes, like conditional marketing authorisations (CMA), where the benefits of immediate drugs' availability outweigh the risks associated with incomplete evidence. However, payers in the European Union (EU) decide on medicines' coverage based on clinical benefits assessment, cost-effectiveness and/or budget impact. We investigated differences in the time-to-access of drugs approved via CMA vis-à-vis standard marketing authorisation (SMA) in Italy, Germany, and Spain.

Methods: CMA-licenced drugs from 2006 to 2022 were retrieved and matched with comparable SMA drugs. Collected data were as follows: marketing authorisation details, drug characteristics, pivotal trials' characteristics and national reimbursement decision dates. Data sources included European Public Assessment Reports, and country-specific databases (Farmadati®, Lauer-Taxe®, BIFIMED).

Results: CMA drugs take longer, in days, to reach reimbursement compared to SMA drugs both in Italy (CMA: median 523, mean 635, standard deviation (SD 364; SMA: median 455, mean 497, SD 242) and Spain (CMA: median 691, mean 779, SD 456; SMA: median 534, mean 568, SD 273). Cox regressions and Kaplan-Meier survival analyses corroborate these findings.

Conclusions: The EMA's intent to accelerate access to promising medicines may be offset by longer timelines to secure national reimbursement in major EU nations.

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KEYWORDS
Conditional marketing authorisation; fast-track pathway; EMA; health technology assessment; HTA; time-to-access

Background

Context

The process for licencing and reimbursing drugs can span multiple years, delaying patient access to new treatments. In this context, regulatory authorities, health technology assessment (HTA) bodies, and payers face pressure to accelerate this process. The European Medicines Agency (EMA) in the European Union (EU) and the Food and Drug Administration (FDA) in the United States (US) have introduced pathways to streamline marketing authorisation for treatments meeting specific conditions (e.g. unmet clinical needs, severe illnesses) (EMA, 2025b, 2025a, 2025c; FDA, 2025; MHRA, 2025). These accelerated pathways aim to shorten the time needed for new medicines to reach the market, offering patients earlier access to treatment options. See Supplemental Table S1 for details on EMA's 'fast-track' pathways.

A sub-set of these pathways allows drugs to be licenced with *less comprehensive data* at launch, requiring manufacturers to fulfil post-marketing obligations to resolve uncertainties about the risk-benefit ratio. In the EU, the conditional marketing authorisation (CMA) (EMA, 2025b), introduced in 2006 by Regulation

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(EU) 726/2004 (European Parliament and Council, 2004) and Commission Regulation 507/2006 (European Commission, 2006), applies to seriously debilitating or life-threatening diseases, emergency use, or orphan drugs (EMA, 2016b, 2025b; Lasch et al., 2025). These drugs may initially rely on smaller studies, shorter durations, or intermediate endpoints, with confirmatory post-authorisation data requiring longer-term efficacy endpoints, larger databases or extended study durations (EMA, 2016b). The rationale is to postpone the full evidentiary burden by granting provisional authorisation based on promising, yet incomplete, evidence, instead of delaying access until pivotal studies are completed, as in standard marketing authorisation (SMA).

The use of CMA has increased over time, from 27 approvals granted in the first decade (2006–2016), to 44 in the subsequent six years (until November 2022) (EMA, 2024; Manellari et al., 2023). Most of CMA authorisations relate to cancer treatments (Manellari et al., 2023). This growing utilisation of the CMA pathway likely reflects a convergence of regulatory strategy and therapeutic innovation. On one hand, the CMA pathway was deliberately designed to facilitate early access to therapies addressing serious or life- threatening conditions, especially where no satisfactory treatments exist, by allowing approval based on less comprehensive clinical data, provided robust post- authorisation commitments are met (Bellino & La Salvia, 2025; EMA, 2025b). On the other hand, biomedical advancements, particularly in certain therapeutic areas, have produced a large pipeline of targeted therapies that offer promising benefit signals at earlier stages, making them well-suited for such expedited pathways (Manellari et al., 2023).

Prior studies have investigated CMA drugs from different perspectives. One stream analysed the quality of evidence supporting risk-benefit assessments at launch. Banzi et al. reviewed CMA drugs approved from 2006 to 2015, finding limited evidence supporting the positive benefit-risk balance at the time of market launch (Banzi et al., 2015). Vokinger et al. used national health authority ratings, showing few CMA drugs had high added therapeutic value (Vokinger et al., 2022). Another study investigated surrogate endpoints, which accelerate drug development, revealing that pivotal trials for CMA mainly relied on non-validated surrogates (Schuster Bruce et al., 2019).

A second stream investigated post-marketing obligations, noting no specific requirements for the types of endpoints to be used, leading many confirmatory studies to utilise surrogates (Schuster Bruce et al., 2019). In the US, some confirmatory studies imposed on marketing authorisation holders (MAH) are never completed (Naci et al., 2017). Regulatory guidelines remain unclear on how to handle unsuccessful or uncertain post-marketing studies (Gyawali et al., 2023).

A third stream examined the regulatory review times of expedited drug-approval programmes, showing their effectiveness in shortening times to a positive opinion and marketing authorisation (Da Costa Gonçalves et al., 2022). However, differently from the US, where FDA approval grants immediate patient availability, Europe's country-specific value assessment and price negotiations introduce additional factors. While the EMA evaluates clinical risk-benefits, national payers also assess clinical added benefits, cost-effectiveness and budget impact, possibly demanding different types and quality of evidence, making it unclear whether regulatory pathways influence actual access in the EU. Each EU member state follows, in fact, national processes for pricing and reimbursement (P&R) decisions, considering local needs, standard of care, and organisational factors, leading to heterogeneous outcomes (Casilli et al., 2023; Wolters et al., 2024). In the absence of robust evidence traditionally required by HTA bodies and payers, access may be delayed or restricted (Hutton et al., 2007; Walker et al., 2012). In this regard, tools like managed entry agreements, including coverage with evidence development schemes, provide conditional reimbursement while requiring further data collection (Daval & Kesselheim, 2023; Sachs, 2022).

Lastly, a fourth stream of research situates CMA within the broader global landscape of expedited and conditional drug-approval pathways (Matsushita et al., 2019; Murayama et al., 2021). Several studies have compared the European CMA with the US Accelerated Approval programme (FDA, 2025) and Japan's conditional early approval system (Murayama et al., 2021), identifying key differences in evidentiary requirements, reliance on surrogate endpoints, post-marketing obligations, and regulatory philosophies. For instance, a cross-sectional analysis of oncology drugs approved between 2006 and 2021 demonstrated divergence in trial designs and post-marketing commitments between FDA-Accelerated and EMA-CMA approvals (Xie et al., 2023). More recently, comparison of 'special regulatory pathways' in Japan and the US highlighted jurisdictional variation in how accelerated/conditional approvals are applied and in how regulatory designations overlap across regions (Kobayashi et al., 2025). Together, this comparative literature

frames CMA not as an isolated European instrument, but as part of a global trend towards conditional or accelerated authorisation.

Since CMAs have substantially increased recently, representing between 10 and 14% of all positive opinions in the last five years (EMA, 2024), and given the limited number of empirical studies on access dynamics for CMA drugs (a recent contribution is Mills et al. 2023), understanding whether CMAs may influence access to new drugs is relevant.

Objectives

This study examined the time-to-access of drugs with CMA compared to those with SMA, testing the hypothesis that accelerated regulatory authorisation does not necessarily ensure equally effective local access. The analysis focused on Italy, Germany, and Spain for three reasons. First, these countries have distinct HTA approaches. As of 2024, Italy has a single decision-making body, while Spain follows a two-tier system, with national value assessment followed by regional funding decisions. In Germany, new drugs launch without P&R approval, allowing free pricing for six months before an AMNOG-based (*Arzneimittelmarkt Neuordnungsgesetz*) reimbursement price applies. Before 2022, this period lasted 12 months. If the AMNOG price is significantly lower than the initial price, manufacturers may withdraw the product from the market. Reimbursement negotiations are guided by the assessed added clinical benefit, reflecting Germany's value-based pricing approach (Dintsios & Chernyak, 2022; Gandjour et al., 2020). Supplemental Table S2 details the P&R processes in each country. Second, these countries were selected for their data availability and accessibility. Finally, this study focuses on EU countries where the topic is currently unexplored, complementing prior work (Mills, 2023).

Methods

Definition of the concept of drug availability

For the purposes of this work, and in line with the approach used in other works (Mills, 2023), time-to-access is calculated as the number of days between the date of EMA's marketing authorisation and the date of a national reimbursement decision (namely, the decision to either reimburse or not to reimburse; drugs under evaluation that had not yet reached a reimbursement decision at national level at the time of the conduct of the study could not be considered and were excluded from analyses). The former is reported on the EMA website. In Italy, the date of the reimbursement decision is when the Italian Medicines Agency (AIFA) completes a value assessment process and assigns a reimbursement class. Class A includes drugs covered for outpatients; class H covers hospital drugs; class C includes out-of-pocket drugs not reimbursed by the national health system. Similarly, in Spain, this is the date of deliberation on the drug inclusion in the public reimbursement list, which is based on a prior therapeutic and economic evaluation. In Germany, drugs are granted reimbursement status immediately and automatically following EMA's marketing authorisation (although these can, in principle, be later withdrawn after completing the AMNOG process) (Staab et al., 2018).

Sample of drugs

All medicinal products licenced in the EU under the CMA pathway from 2006 (its introduction) to 2022 were initially considered. The new active substances approved under CMA were identified through the EMA's 10-year experience report (2006–2016) (EMA, 2016a) and subsequent annual reports (2017–2022) (EMA, 2024). In total, 80 new active substances received CMA during this period. Fifteen drugs were excluded because they were approved under unique circumstances ($N = 8$, COVID-19 drugs, which followed emergency procedures, and were managed through Joint Procurement Agreements across Europe), were seasonal influenza drugs ($N = 3$), or provided incomplete information ($N = 4$), resulting in a total of 65 CMA drugs.

A group of similar SMA drugs was identified and used as a comparator. Each SMA drug was chosen based on three hierarchical criteria: (i) only new active substances were considered (namely, drugs undergoing an evaluation for national reimbursement for the first time); (ii) drugs were selected based on the 4th-level

(chemical subgroup) Anatomical Therapeutic Chemical classification (ATC) equivalence (NIPH/WHO, 2025), or, when such correspondence could not be found, based on the 3rd-level (pharmacological subgroup) ATC equivalence; (iii) each drug in the control group was licenced by EMA within a maximum of ±1 year from its paired CMA counterpart. If no match was available within this timeframe, a longer period was considered while maintaining comparable distribution over time. The control group was validated by an experienced physician and a pharmacist to confirm that each CMA-SMA pair was appropriate in terms of indication, drug class and mechanism of action. Supplemental Fig. S1 reports a diagram with the drug selection process, and Supplemental Table S3 provides the full list of matched CMA-SMA drugs.

Data sources and data collection

For each drug, four macro-categories of data items were collected. First, information on the marketing authorisation process at the drug level was collected from the EMA website, and included the MAH, the date of EMA approval, the type of approval pathway, and other regulatory details, such as the accelerated assessment status (i.e. shortened review from 210 to 150 days for medicines of major public health interest) (EMA, 2025a) and the PRIME (priority medicine) review status (early, enhanced support for medicines addressing unmet medical need) (EMA, 2025c).

Second, drug characteristics at the time of market launch were also retrieved from the EMA website, and included commercial names, active substances, therapeutic areas (through ATC codes), orphan status, paediatric status, and ATMP (advanced therapy medicinal products, i.e. medicines based on genes, cells, or tissue-engineered constructs that are regulated under a dedicated EU framework) status.

Then, the characteristics of the pivotal studies used as basis for a drug application were retrieved from each drug's first European Public Assessment Report (EPAR). These included the number of pivotal studies, their status at the time of EMA assessment (completed or ongoing), the geographical scope (multicenter, multinational), and further details such as trial phase, design, blinding, type of control, and primary endpoint.

Lastly, country-level reimbursement decisions and dates were collected via national sources. For Italy, Farmadati® Gold was used to collect data on the reimbursement status and class. For Germany, the Lauer-Taxe® Drug Directory was used to retrieve the date of inclusion of each drug in the Statutory Health Insurance (SHI) reimbursement list. For Spain, the BIFIMED (*Buscador de la Información sobre la situación de financiación de los medicamentos*) platform was used, and the date of the national HTA decision (financing, financing with conditions, not financing) were retrieved; public minutes of the Interministerial Commission on Medicine Prices were consulted where required.

Data analysis

STATA SE (version 18.0) was used for statistical analyses. Regression models were employed to examine the association between study variables and both the type of marketing authorisation pathway (CMA versus SMA) and the time from EMA approval to national reimbursement (days). Drugs were included in the primary analysis irrespective of their subsequent regulatory status (e.g. later withdrawals by the EMA), given the objective of assessing the time taken by national authorities to reach an initial reimbursement decision based solely on the evidence available at the time of marketing authorisation. First, a descriptive overview of the drug sample was conducted, covering marketing authorisation details, drug characteristics, and reimbursement status by country. Time-to-access by approval pathway and country was also analysed using median days, with differences in medians assessed via the Kruskal-Wallis test (significance levels 5%).

Next, a Kaplan-Meier survival analysis was performed to assess the relationship between the market authorisation pathway and the time from EMA authorisation to national reimbursement across the analysed countries. The event of interest was the national reimbursement decision (to reimburse, to reimburse with conditions, or not to reimburse).

Building on this, sequential multivariate Cox regression (proportional hazards regression) models explored associations between collected variables and time-to-access (days) for CMA versus SMA drugs. After verifying the proportional hazard assumption, independent variables were categorised into three

groups: (i) marketing authorisation details (approval pathway, accelerated assessment, PRIME status); (ii) drug characteristics (cancer, orphan, ATMP status); and (iii) trial characteristics (phase, design, blinding, primary endpoint). Model 0 (reference case) only included the type of pathway (CMA versus SMA). Using a stepped-wedge approach, Model 1 added marketing authorisation details, Model 2 incorporated drugs' characteristics, and Model 3 included pivotal trial characteristics. All models included country fixed effects (FE), with Germany as reference country. If multiple pivotal trials were available in EPAR documents, the trial with the highest phase was used. Robustness checks included additional Cox regressions considering only positive reimbursement decisions (excluding drugs with denied national reimbursement, Supplemental Table S12) and excluding drugs withdrawn from the EU market (EMA status: 'withdrawn', 'expired', or 'revoked' at the time of analysis, Supplemental Table S13). Supplemental Table S4 outlines the expected impact of each regressor on the time from EMA authorisation to national reimbursement.

Results

Overview of the study sample

Table 1 reports a descriptive overview of the drug sample used in the study.

Table 1. Descriptive overview of the drug sample.

	Total sample $N = 127$		CMA $N = 65$		SMA $N = 62$	
	N	%	*N*	%	*N*	%
A. Marketing authorisation details						
AA	16	13%	8	12%	8	13%
PRIME	13	10%	9	14%	4	6%
B. Drugs characteristics						
Cancer	89	70%	46	71%	43	69%
Orphan	52	41%	30	46%	22	35%
ATMP	10	8%	6	9%	4	6%

Abbreviations: AA: accelerated assessment; ATMP: advanced therapy medicinal products; CMA: conditional marketing authorisation; PRIME: priority review status; SMA: standard marketing authorisation.

Supplemental Table S5 reports aggregated data on the reimbursement status by country. In Germany, most drugs ($N = 113$, 89%) are reimbursed under the SHI (although drugs that were initially funded under the SHI, and that have been later withdrawn, were counted as missing for Germany). In Italy, 82% of the drugs in the sample are or have been reimbursed under the NHS, with the majority being hospital drugs (Class H; $N = 97$, 76%). As for Spain, 100 drugs (76%) are or have been included in the national reimbursement list. Details at the drug level are available in Supplemental Table S6.

Comparing time-to-access by pathways

Table 2 reveals country-specific differences in time-to-access (days), from EMA authorisation to national reimbursement (further details by country, and by marketing authorisation and drugs characteristics in Supplemental Table S7). In Italy, the median access time for CMA drugs is 523 days, compared to 455 days for SMA drugs, suggesting faster access for standard approvals. In Germany, median access times are substantially shorter overall, with CMA and SMA median times at 43 and 39 days, respectively (only attributable to administrative and/or procedural steps). In Spain, median access times are longer, 691

Table 2. Time-to-access (days) by market access pathway.

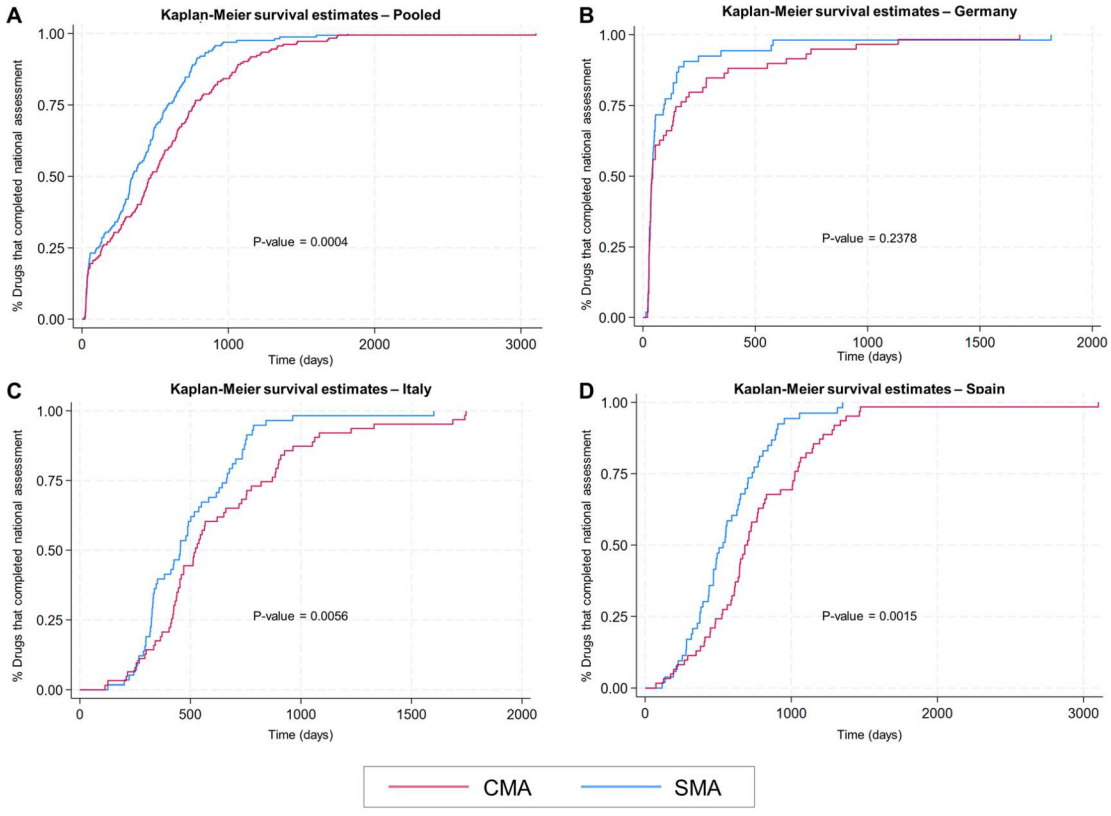
	CMA						SMA						Kruskal-Wallis
	N	Mean	SD	Min	Median	Max	*N*	Mean	SD	Min	Median	Max	*p*-value
Italy	63	635	364	114	523	1,747	58	497	242	127	455	1,601	0.0276
Germany	59	182	312	20	43	1,677	54	115	263	0	39	1,817	0.3355
Spain	59	779	456	74	691	3,102	52	568	273	116	534	1,352	0.0039

Abbreviations: CMA: conditional marketing authorisation; SD: standard deviation; SMA: standard marketing authorisation.

days for CMA drugs and 534 days for SMA drugs. The Kruskal-Wallis test highlights significant differences in access times between CMA and SMA in Italy and Spain.

Survival analysis of the time from centralised MA to national reimbursement decisions

Figure 1 presents Kaplan-Meier survival curves for time-to-access from EMA authorisation to national reimbursement. In the pooled sample (Figure 1(a)), a significant difference between CMA and SMA drugs is observed. SMA drugs reach reimbursement faster, as shown by the steeper initial slope, while CMA drugs take longer on average. This overall trend suggests a systematic delay for CMA drugs compared to SMA drugs across the included countries. In Germany, there is no statistically significant difference between CMA and SMA drugs, as both types of drugs have similar timelines to reimbursement (Figure 1(b)). In Italy, a significant difference exists between CMA and SMA drugs. SMA drugs are reimbursed more quickly, whereas CMA drugs experience a more gradual timeline (Figure 1(c)). In Spain, there is also a significant difference in time-to-access between CMA and SMA drugs (Figure 1(d)).



Abbreviations: **CMA**: conditional marketing authorization; **SMA**: standard marketing authorization.

Figure 1. Kaplan-Meier graphs of national decisions time (days) for both CMA and SMA drugs. Abbreviations: CMA: conditional marketing authorisation; SMA: standard marketing authorisation.

Multivariate regression analysis to examine drivers of time-to-access

Results of the multivariate models are presented in Table 3, showing only country FE, as this specification performed best. Concordance metrics indicate incremental model improvements with each successive model, with Harrell's C rising from 0.7311 (Model 0) to 0.7487 (Model 3). Supplemental Table S8 reports average marginal effects of predictors. However, to support robustness testing and further explore these relationships, additional models with both year and country FE, and without any FE, are reported in the Supplemental Tables S9 and S10, respectively. Sensitivity analysis results, where the Cox regression analysis considered only pooled data from Italy and Spain (namely the countries where statistically significant

Table 3. Multivariate cox regression models investigating time-to-access (days) from EMA approval to national reimbursement decision in Germany, Italy, and Spain.

	Model 0 HR (SE)	Model 1 HR (SE)	Model 2 HR (SE)	Model 3 HR (SE)
Dependent variable: Days from EMA approval to national deliberation on reimbursement				
A. Marketing authorisation details				
CMA	0.670*** (0.073)	0.656*** (0.072)	0.605*** (0.070)	0.707* (0.122)
AA		1.572** (0.256)	1.341 (0.223)	1.440* (0.264)
PRIME		1.292 (0.237)	1.775** (0.373)	1.811* (0.464)
B. Drug characteristics				
Cancer			1.467** (0.186)	1.221** (0.350)
Orphan			1.254 (0.148)	1.221 (0.171)
ATMP			0.429**(0.107)	0.482* (0.153)
C. Trial characteristics				
Status completed				1.760*** (0.258)
Multicenter				0.984 (0.517)
Multinational				0.821 (0.265)
Phase				1.179 (0.234)
Design (multiple arms randomised)				0.242** (0.104)
Blinding				1.345 (0.483)
Control-Active control				3.531** (1.511)
Control-Different posology				2.271* (0.923)
Control-Placebo				2.834 (1.537)
Endpoint				1.257 (0.192)
Number of observations	348	348	348	328
Concordance (Harrell's C)	0.7293	0.7382	0.7395	0.7472
Country FE	Yes	Yes	Yes	Yes

Abbreviations: AA: accelerated assessment; ATMP: advanced therapy medicinal product; CMA: conditional marketing authorisation; EMA: European Medicines Agency; FE: fixed effects; HR: hazard ratio; PRIME: priority medicine review; SE: standard error

Notes: Results are pooled across all countries. Model 0 is a baseline case only controlling for the type of approval pathway (CMA = 1, conditional marketing authorisation; CMA = 0, standard marketing authorisation), with country FE. Additional covariates were sequentially added: further marketing authorisation details (Model 1), drugs' characteristics (Model 2), and pivotal trial characteristics (Model 3). Statistical significance is set as: *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

differences between CMA and SMA drugs were observed), only positive decisions, and excluded drugs that have been withdrawn from the market by EMA, are shown in Supplemental Tables S11, S12 and S13, both confirming prior findings.

Marketing authorisation details (Model 0 and Model 1)

Model 0 serves as a baseline model, focusing solely on the impact of the CMA status, to establish an initial benchmark. The hazard ratio (HR) for CMA (HR = 0.670, SE = 0.073) suggests that CMA drugs have a lower rate of reaching reimbursement at any given time compared to SMA drugs and generally take longer, on average, to reach reimbursement than standard approvals.

In Model 1, additional aspects of the marketing authorisation pathway are incorporated, including accelerated assessment (AA) status, and PRIME designation. While CMA shows a statistically significant association with a slower pace to reimbursement, AA and PRIME effects are less consistent; PRIME is significant in later models, indicating a possible but variable influence on the speed of reimbursement approval.

Drug characteristics (Model 2)

Model 2 introduces drug-specific characteristics, namely therapeutic area (cancer vs. other), orphan designation, and ATMP status. The HR for oncology drugs (HR = 1.467, SE = 0.186), suggests that they are associated with a higher rate of reaching reimbursement compared to non-oncology drugs, and faster reimbursement timelines. The HR for ATMP status, by contrast (HR = 0.429, SE = 0.107), indicates that ATMP drugs on average have a slower rate of reaching reimbursement than non-ATMP drugs.

Trial characteristics (Model 3)

Model 3 incorporates the characteristics of the clinical trials supporting the drug, including trial completion status, multicenter and multinational design, phase, study design, blinding, and type of control. Some trial characteristics show associations with faster reimbursement timelines, such as those trials whose status was completed at the time of market launch, which were significantly associated with a faster rate of

reimbursement compared with ongoing trials. By contrast, multiple arms randomised study designs are on average associated with longer reimbursement outcomes (HR = 0.242, SE = 0.104). A similar pattern is observed for certain types of control groups, as trials using active comparators or different posology controls also tend to be associated with slower reimbursement.

Discussion

This study examined the impact of the CMA pathway on the time to achieve national reimbursement in Italy, Germany, and Spain, compared with SMA drugs, considering new active substances authorised from 2006 to 2022. Results suggest that CMA drugs are associated with longer times to reimbursement than those with standard approval. This may reflect the increased difficulties raised by CMA drugs' *less-than-comprehensive data* to proceed to drug evaluation and appraisal, and the increased uncertainty of decisions. Findings underscore the nuanced roles of regulatory pathways, drug characteristics, and trial design in shaping reimbursement timelines across member states under analysis. In this regard, oncology drugs and certain trial characteristics, like trials completed at the time of authorisation, or the presence of active controls, seem to be associated with faster reimbursement.

In Italy and Spain, where drugs undergo formal HTA evaluations, CMA drugs faced significantly longer times to reach national reimbursement compared to SMA drugs. By contrast, in Germany, where drugs are automatically included in the SHI before evaluation, both CMA and SMA drugs experienced similarly short timelines to reimbursement. To note, the variability of time-to-access in Germany suggests that the time to filing for reimbursement procedure by MAHs may also explain differences in timings.

The differences in median times reflect that the evidentiary requirements for assessing new drugs remain highly variable across EU member states (Wolters et al., 2024). While this was documented in prior works on time-to-access for drugs in general (Feltmate et al., 2015; Mela et al., 2025; Newton et al., 2024; Salek et al., 2019), our findings on time-to-access for CMA drugs are particularly noteworthy. CMA is indeed intended for drugs that address unmet medical needs, which are approved in the interest of public health (EMA, 2025b), suggesting an expectation of timely access. Notably, different approaches are increasingly proposed to accelerate patient access. Pricing and payment schemes are considered viable solutions to sustain timely patient access, while handling the clinical and economic uncertainties around new drug launches (Ardito et al., 2025; European Commission/EXPH, 2018; Vogler et al., 2017). Horizon scanning programmes have also been established to generate early insights into forthcoming technologies (Marangi et al., 2019; Oortwijn et al., 2018; Vogler, 2022). 'Fast-track' regulatory pathways are also expected to act as practical tools in this regard, although this study highlighted that CMA drugs are instead associated with longer reimbursement times.

Our findings extend prior research, yet are very limited, on reimbursement delays for conditionally approved drugs, particularly the analysis by Mills (2023), which examined HTA barriers across England, Scotland, France, and Canada, and attributed such delays to the more pronounced clinical uncertainties raised during national HTAs (Mills, 2023). Our study quantitatively measured the impact of CMA on time-to-access using a duration model (Kaplan-Meier survival analysis and Cox proportional hazards regression). Unlike the logistic regression approach, which models the probability of delay as a binary outcome, our model allowed us to account for the actual time until reimbursement, capturing differences not just in whether a delay occurs, but also in how long it lasts. This distinction is critical in contexts where timing is a key policy concern, as in the case of patient availability to CMA drugs, which are intended to accelerate patient access (EMA, 2016b, 2025b; Lasch et al., 2025). Beyond methodological differences, our study also expands the geographic scope by analysing reimbursement delays across three EU countries, Italy, Germany, and Spain, whereas Mills focused mostly on non-EU markets (Mills, 2023). Our results highlight that, in Italy and Spain, CMA drugs experience significantly longer reimbursement delays than SMA drugs, aligning with Mills' assertion that national payers perceive higher clinical uncertainty for CMA products (Mills, 2023). However, our study reveals that in Germany, where immediate access is granted prior to price negotiations, no significant delay exists for CMA drugs compared to SMA drugs. Interestingly, the recent introduction of a single decision-making body in Italy in March 2024 (the technical and scientific committee) seems positively associated with faster reimbursement decisions (AIFA, 2025). This highlights a key

limitation in prior analyses that did not account for how country-specific reimbursement structures shape HTA outcomes.

Our study's results should also be interpreted in the broader context of similar expedited approval pathways, such as the FDA's accelerated approval programme. In the US, drugs granted accelerated approval become in principle immediately available to patients without an additional formal health technology assessment (HTA) process. The FDA's assessment focuses solely on the risk-benefit profile (FDA, 2023), leaving coverage and pricing negotiations to individual payers. This raises the question of whether accelerated approval pathways, like CMA, achieve their intended purpose only when no later-stage evaluation occurs (as in the US) or when HTA criteria align with regulatory decisions (as should be the case in the EU). The US approach ensures faster patient access, but have faced criticism for prolonged post-marketing confirmatory study timelines (Naci et al., 2017) and instances where drugs remain on the market despite failing to demonstrate clinical benefits (Frank et al., 2022; Gyawali et al., 2021). Meanwhile, EU member states impose stricter access controls, preventing the widespread use of drugs with high uncertainty, but at the cost of delaying potentially life-saving treatments. A potential lesson for the EU is to enhance coordination between the EMA and HTA bodies, ensuring that the evidentiary requirements for conditional approval align better with what payers need to make timely reimbursement decisions. A question that many will seek to address in the coming years is whether the Joint Clinical Assessment, introduced under the HTA Regulation 2021/2282 (European Parliament and Council, 2021), will succeed in its intent to accelerate (and standardising) time-to-access across member states (Schuster, 2024). Conversely, the US could benefit from integrating elements of the EU's HTA framework to ensure that reimbursement decisions reflect both clinical and economic value, thereby reducing the risk of prolonged market access for drugs with unconfirmed benefits. Ultimately, a balanced approach that combines early access with robust post-market evaluations and risk-sharing mechanisms could optimise patient access while safeguarding healthcare system sustainability.

Limitations

The findings of this study should be interpreted in light of its limitations. First, the evidence presented here is observational and does not allow us to establish a causal relationship; we only document that CMA drugs take longer to reach reimbursement compared with SMA drugs. This descriptive evidence should therefore be complemented with further research to explore underlying causes. The metric used for time-to-access was chosen as it allows easy comparability across countries, in line with other studies (EFPIA, 2023; Mills, 2023). However, it only reflects the timeframe from EMA authorisation to national reimbursement. The time saved in the clinical development for CMA products is not quantified, so that the final outcome in terms of overall time-to-access of each pathway is not estimated.

Also, we did not account for the actual use or uptake of drugs following nation-specific logics. Doctors' prescription habits may differ, possibly due to differing levels of trust in CMA-SMA drugs.

The external validity of the findings might be influenced by the chosen SMA control group, and the associated level of uncertainty. Although we matched products to achieve similarity between the samples of SMA and CMA products, conditional approval is conceptually granted to selectively expedite the access to products that are intended to treat severe diseases with unmet needs holding a plausible clinical benefit, so that any matching will only be partially able to ensure actual similarity. Thus, a formal matching procedure was not conducted, also due to the relatively small number of new active substances authorised each year in each relevant therapeutic area. Since the efforts required to collect data on all SMA drugs from different therapeutic areas were deemed likely not to lead to valuable comparisons, and we applied an approach that was also used in a comparable study (Mills, 2023). The matching quality was however verified with an experienced physician and a pharmacist with vast background in clinical pharmacology.

Furthermore, country-specific nuances may not be fully captured or compared due to national differences in reimbursement procedures and specificities of local data structures (e.g. we did not account for eventual reimbursement changes after the conclusion of the AMNOG process in Germany).

Lastly, the results should also be viewed in the context of manufacturers' common practice of strategically selecting in which countries to initiate pricing and reimbursement procedures (i.e. 'launch sequence'), which

often leads to prioritising countries expected to grant higher prices. This approach can itself contribute to observed delays and should be considered when interpreting the findings.

Conclusions

This study suggests that EMA's CMA drugs encounter more challenges at the national stage compared to SMA drugs, in terms of time taken by HTA bodies to formulate reimbursement decisions. Conditionally approved drugs generally present a weaker clinical evidence profile, which likely leads to greater clinical and economic uncertainties during the HTA assessment. Delays in reimbursement decisions may therefore counterbalance some of the time saved in earlier regulatory phases through the CMA pathway. In this context, different approaches, such as pricing and payment schemes, are increasingly leveraged as viable solutions to sustain timely patient access, while handling the clinical and economic uncertainties around new drugs' launches.

Abbreviations

AA	Accelerated Assessment
ATC	Anatomical Therapeutic Chemical Classification System
ATMP	Advanced Therapy Medicinal Product
CMA	Conditional Marketing Authorisation
EMA	European Medicines Agency
EPAR	European Public Assessment Report
EU	European Union
HR	Hazard Ratio
HTA	Health Technology Assessment
ILAP	Innovative Licencing and Access Pathway
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
MAH	Marketing Authorisation Holder
MHRA	Medicines and Healthcare Products Regulatory Agency
PRIME	Priority Medicine review
RCT	Randomised Controlled Trial
SD	Standard Deviation
SE	Standard Error
SMA	Standard Marketing Authorisation
UK	United Kingdom
US	United States of America

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Data availability statement

Data will be made available by the corresponding author upon reasonable request.

Author contributions

Vittoria Ardito: Conceptualisation; Data curation; Formal analysis; Methodology; Validation; Writing – original draft; Writing – review & editing. Lasse Falk: Data curation; Validation; Writing – review & editing. Montserrat Gasol Boncompte: Data curation; Validation; Writing – review & editing. Caridad Pontes: Methodology; Supervision; Validation; Writing – review & editing. James Robinson: Methodology; Validation; Writing – review & editing. Jonas Schreyögg: Conceptualisation; Methodology; Supervision; Validation; Writing – review & editing. Oriana Ciani: Conceptualisation; Funding acquisition; Methodology; Supervision; Validation; Writing – review & editing.

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