

A Systematic Review of the Regulatory Drug Approval Pathways in the European Medicine Agency and Other Regulated Markets

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ABSTRACT

Regulatory agencies have developed expedited drug approval pathways to accelerate patient access to therapies addressing unmet medical needs, particularly in oncology and rare diseases. The European Medicines Agency (EMA) has introduced several such pathways; however, their efficiency compared to other global regulators remains a subject of evaluation. This systematic review aimed to evaluate regulatory drug approval pathways within the EMA and compare them with other regulated markets, focusing on innovation, review timelines, regulatory productivity, and clinical outcomes in high-need therapeutic areas. A comprehensive literature search was conducted across PubMed, Web of Science, and ScienceDirect databases covering studies published between 2015 and 2025. A total of 320 records were identified, of which 28 studies met the inclusion criteria after screening. Data extraction and methodological quality assessment were performed using the AMSTAR 2 checklist. The EMA provides multiple expedited pathways, including PRIME, Accelerated Assessment (A. As), Conditional Marketing Authorisation (CMA), and Exceptional Circumstances Approval. Despite these initiatives, their utilization remains lower compared to programs offered by the U.S. Food and Drug Administration (FDA). Median review timelines under EMA expedited pathways range from 315 to 476 days, which are longer than FDA timelines (175-192 days). Oncology drugs within EMA pathways experience accelerated progression, reducing development timelines by approximately 2.5 years. However, limited uptake of PRIME, extensive post-marketing obligations, annual renewal requirements (particularly for CMA), and administrative complexities contribute to delayed approvals relative to the U.S. EMA expedited pathways play a critical role in facilitating early access to innovative therapies while ensuring robust evidence generation and regulatory oversight. However, their overall effectiveness is constrained by longer review timelines and regulatory complexities. Greater harmonization of global regulatory frameworks and optimization of evidence requirements may enhance the efficiency and impact of accelerated approval pathways worldwide.

Keywords: Breakthrough Therapy Designation, Drug approval pathways, EMA, Regulatory Productivity.

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INTRODUCTION

Regulatory approval of drugs is a very important process that guarantees safety, efficacy and quality of drugs prior to reaching the patients. The strict regulatory approval processes that are set by regulatory agencies like the European Medicines Agency (EMA) and other worldwide accepted authorities have led to the high standards of public health. There are several regulatory pathways available in the European Union (EU) for

the approval of medications. The centralized procedure, which was incorporated into EU legislation in 1993 and went into full operation in 1995, is one of the most significant routes. A single Marketing Authorization (MA) is granted through this process, enabling a medication to be sold in every EU member state.

Marketing Authorization Holder (MAH) must apply through either the Mutual Recognition Process (MRP) or the Decentralized Procedure (DCP) for medications that are meant to be marketed in many EU countries but do not fit inside the obligatory scope of the centralized procedure (Ebberts *et al.*, 2015).

The standard approval procedures can, however, be slow and costly, and this can delay patients' access to new therapies, especially in areas where the need is high, such as oncology and rare disorders (Pinto *et al.*, 2023).



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Addressing these issues, the regulatory authorities have worked to create new methods of approval, like Accelerated Approval (A. Ap), Priority Review (PR), and conditional marketing authorizations, to bring a breakthrough therapy to market more quickly, but without a reduced level of evaluation. Such mechanisms are designed to lessen administrative regulation, decrease the approval process, and lead to innovations in pharmaceuticals by motivating the discovery of medications to manage conditions affecting severe or life-threatening diseases (Pinto *et al.*, 2023; Alqahtani *et al.*, 2015). Despite their potential benefits, the implementation and effectiveness of these pathways vary across regulatory jurisdictions. Differences in administrative procedures, evidentiary requirements, and post-marketing obligations pose challenges for harmonization and global patient access (Alqahtani *et al.*, 2015). Understanding how these pathways operate, their impact on innovation, and the barriers to their efficient use is crucial for optimizing regulatory strategies worldwide. The objective of this systematic review is to evaluate and compare the effectiveness of innovative drug approval pathways with traditional approval routes in EMA and other regulated markets, focusing on timelines, regulatory productivity, pharmaceutical innovation, and associated challenges to provide evidence-based recommendations for optimizing global drug approval processes (Pinto *et al.*, 2023; Alqahtani *et al.*, 2015).

METHODOLOGY

This systematic review was done per guidelines outlined in the Preferred Reporting Items for Systematic Reviews (PRISMA). The review aimed to synthesize evidence on regulatory drug approval pathways in the EMA and other regulated markets, with a particular focus on innovative pathways, timelines, regulatory productivity, and outcomes in therapeutic areas like oncology and rare diseases. Duration of the study were 2015 to 2025.

Search Strategy and Study Selection

The extensive literature search that was done in PubMed, Web of Science, and ScienceDirect databases resulted in the identification of 320 records. Systematic research work follows PRISMA focus to identify the study and thereafter its interrogation of suitability and inclusion. The database searches led to 320 retrieved records (PubMed $n=126$, Web of Science $n=98$, ScienceDirect $n=96$). Out of 440 records, 48 duplicate records were removed leaving behind 272 records that were screened. At the screening phase, 25 records have been excluded because of the lack of abstracts ($n=9$), the absence of full texts ($n=5$), or other reasons ($n=11$).

The count of full-text reports that were searched in the retrieval process was 247, with 8 of them not accessible. Then, 239 reports were checked against their eligibility. Out of those, 219 reports were excluded, most of them due to not pertaining to regulatory drug approval pathways ($n=74$) or not addressing EMA or

other regulated markets ($n=111$). Lastly, 34 studies fulfilled the inclusion criteria and they were used in the qualitative synthesis.

In Figure 1, the PRISMA flow diagram elucidates the systematic manner in which the process of identification, screening, and, ultimately, inclusion of studies takes place, which guarantees transparency and the reproducibility of review method.

Eligibility Criteria

Studies were included if they:

- Focused on drug approval pathways in EMA or other regulated markets.
- Reported empirical data, comparative analyses, or regulatory outcomes.
- Were published in peer-reviewed journals in English.

Studies were excluded if they were unrelated to regulatory approval pathways, did not pertain to EMA or other regulated markets, were review/commentary/editorial articles without empirical data, or were conference abstracts lacking sufficient detail.

Data Extraction

Independently extracted data from the included studies, retrieving information like PubMed ID, publication year, journal, authors, study type (RCT-based or NRSI-based), whether the review was Cochrane or non-Cochrane, and the count of citations. Any disagreements were resolved by consensus or by consulting a third reviewer (Lifeng Lin).

Quality Assessment using AMSTAR 2

The quality of the included studies was assessed utilising the AMSTAR 2 (A Measurement Tool to Assess Systematic Reviews 2) checklist, independently evaluated each included study using the online AMSTAR 2 tool. Discrepancies were resolved after consulting the original AMSTAR 2 publication, supplemental materials, and relevant Cochrane Handbook chapters.

The AMSTAR 2 tool comprises 16 domains, including 7 critical and 9 non-critical domains. Each domain was rated as “Yes,” “Partial Yes,” or “No.” Domains marked “No” were considered weaknesses. The overall confidence rating was categorized as high, or moderate, or low, or even critically low per the count of critical along with non-critical weaknesses.

- **High Quality:** Contains no weaknesses or only one minor, non-critical issue.
- **Moderate Quality:** Includes multiple non-critical issues but lacks any major flaws.
- **Low Quality:** Has one major flaw, possibly along with minor issues.

- **Critically Low Quality:** Involves more than one major flaw, with or without additional minor weaknesses.

RESULTS

Timelines for Drug Approval in Innovative vs. Traditional Pathways

Regulatory agencies provide expedited programs like the FDA's Fast Track (FT) and Breakthrough Therapy Designation (BTD) in the U.S. and the EMA's PRIME in Europe to speed up drug progression for severe conditions having unmet medical needs. These pathways enable early regulatory interactions, rolling submissions, and flexible utilisation of preliminary data, thereby shortening progression and review timelines. Traditional clinical progression for new drugs and vaccines typically spans 10-15 years from early discovery through regulatory approval, with prolonged Phase 2 and Phase 3 trials contributing significantly to overall timelines (Gyawali *et al.*, 2023). However, expedited regulatory pathways like FDA A.Ap, PR, and BTD, and EMA's A. As and CMA substantially shorten both progression and review durations.

Figure 1 contrasts the traditional drug and vaccine progression model (Panel A) with an emergency outbreak model, like that used during the COVID-19 pandemic (Panel B). In the traditional model, drug progression spans 12-17 years, progressing sequentially through discovery, preclinical studies, and phased clinical trials (Phases 1-3), followed by marketing authorisation and Phase 4 monitoring. Conversely, in emergency contexts, the progression timeline is compressed to less than 2 years by combining discovery and preclinical phases and conducting

overlapping clinical trials (Phases 1/2/3), culminating in CMA and expedited regulatory review (Jong *et al.*, 2024).

Expedited pathways like the FDA's A.Ap and PR, and the EMA's CMA and A. As, shorten drug progression and review timelines compared with standard routes (Gyawali *et al.*, 2023). For oncology drugs, clinical progression time drops from about 6.7 years to 4.5 years. Median review times are faster in the U.S. (≈ 175 -179 days) than in Europe (≈ 400 -476 days), meaning FDA approvals often occur months earlier. Under the EU's centralised procedure, a single EMA application, if approved, allows marketing across all EU and EEA countries, with CHMP conducting the scientific evaluation (Joppi *et al.*, 2020). Figure 2 compares FDA and EMA expedited pathways, highlighting mechanisms like FT, BTD, A.Ap, PR, PRIME, Conditional Approval, A. As, and Exceptional Circumstances, all designed to provide faster access to innovative therapies.

Expedited approval pathways shorten oncology drug progression from ~ 6.7 years to ~ 4.5 years, with FDA reviews (median 201 days) being faster than EMA (337 days), giving a 136-day U.S. advantage. In 2022, 71% of FDA approvals were expedited versus 10% at EMA, leading to faster U.S. access (≈ 175 -179 days vs. 400-476 days). From 2004-2023, the FDA was first to approve 84 anticancer drugs, often via A.Ap, while EMA led in only 5 cases and never used conditional marketing for first approvals. Approval gaps averaged 2.4 years and exceeded 5 years for some drugs, with only 16 drugs approved by all four regulators within a year. These results highlight faster U.S. access due to FDA pathways and emphasize the need for global regulatory alignment to reduce delays in life-saving treatments.

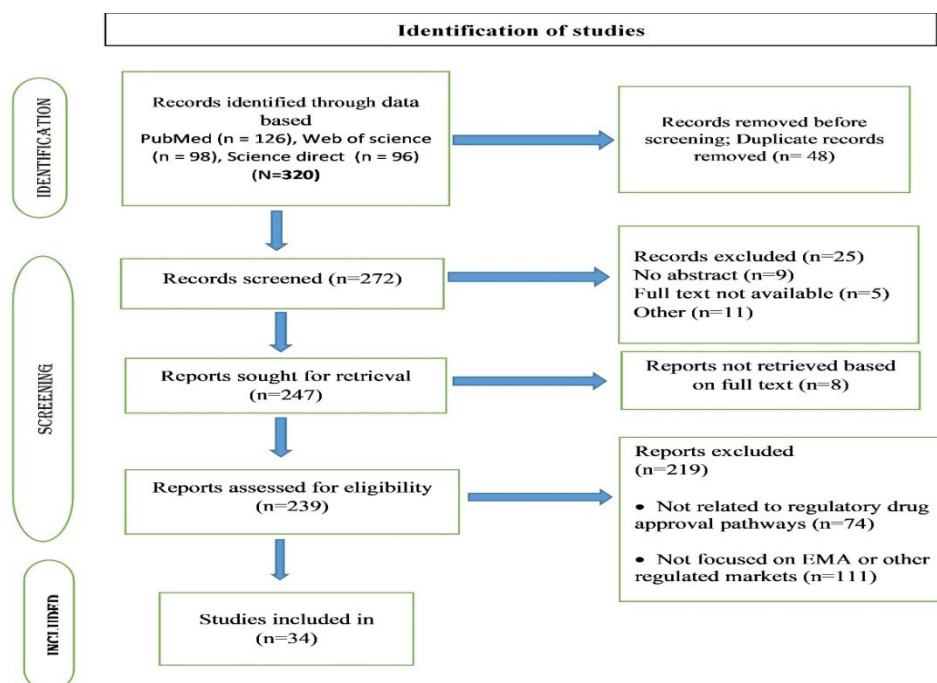


Figure 1: Illustrating the identification, screening, eligibility assessment, and final inclusion of studies in the systematic review, in accordance with PRISMA guidelines.

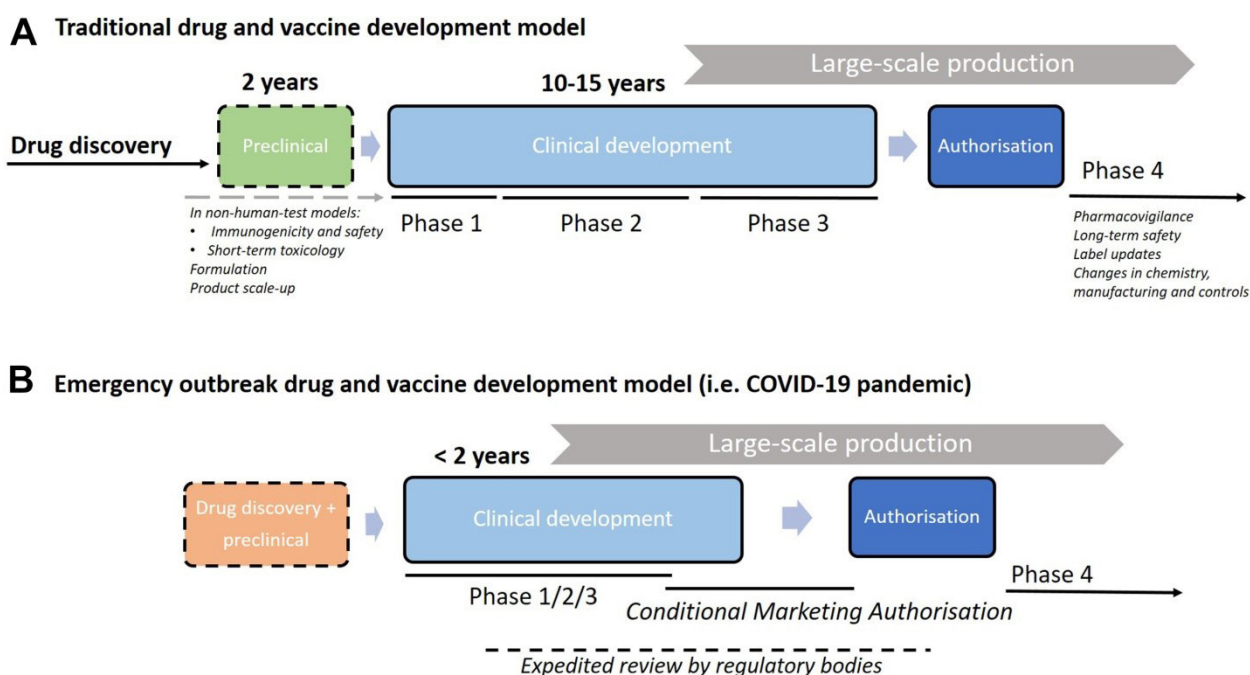


Figure 2: Schematic comparison of standard drug development and approval timelines with expedited regulatory models implemented during public health emergencies or for serious and life-threatening conditions (Jong *et al.*, 2024).

Between 2015 and 2017, the FDA approved 113 new drugs, of which 66 were subsequently licensed in Europe. The median review time was consistently shorter at the FDA compared with the EMA, particularly for drugs reviewed under FDA expedited programs, while the same drugs underwent standard procedures at the EMA, resulting in longer timelines. Differences in supporting evidence between the two regulators were observed for only seven drugs, indicating that later access to new medicines in Europe is primarily due to the FDA's greater utilisation of expedited programs and additional administrative steps at the European Commission, rather than substantial differences in evidence requirements (Gonçalves *et al.*, 2022). The comparison of clinical progression times for new anticancer drugs shows that the utilisation of expedited regulatory approval pathways significantly shortens timelines in the United States compared with standard processes. Drugs that underwent minimum one expedited program like FT, BT, or A. Ap had the shortest median progression time (FDA1: 1,639 days or 4.5 years), whereas drugs without A. Ap but following a similar expedited pathway took longer (FDA2: 2,744 days or 7.5 years). These timelines were comparable to those of drugs following the standard regulatory pathway (FDA8: 2,612 days or 7.2 years) (Iglesias-Lopez *et al.*, 2021; Gonçalves *et al.*, 2022).

In Europe, similar trends were observed, with products designated under PRIME or breakthrough therapy achieving faster marketing authorisation assessments. Although no noteworthy variance was discovered in the proportions of Advanced Therapy Medicinal Products (ATMPs) receiving expedited review between the EU (33.3%) and the US (55.5%), the FDA consistently completed marketing authorisation assessments more quickly, with a mean

difference of 5.44 months ($p=0.012$). These findings highlight that expedited pathways, particularly in the US, substantially reduce clinical progression and review times, thereby accelerating patient access to innovative therapies, especially in oncology and advanced therapies (Iglesias-Lopez *et al.*, 2021; Gonçalves *et al.*, 2022; Franco *et al.*, 2023). As shown in Figure 3 highlights that clinical progression times are substantially shorter for drugs reviewed under expedited regulatory pathways, particularly in the United States. Drugs in the FDA1 pathway (FTD/BTD/RMATD + PR + A.Ap) had the shortest median progression time (1,639 days or ~4.5 years). In contrast, drugs following standard approval processes (FDA8 and EMA8) had longer progression times (~2,612-2,826 days). The EMA pathways generally showed longer timelines compared with FDA counterparts, even when expedited options like PRIME or A. As were used.

Expedited programs were used far more in the U.S. (89%) than in the EU (43%), with median review times of 192 days for FDA versus 315 days for EMA—a 123-day gap. The FDA frequently used FT and breakthrough designations, while only three drugs received EMA PRIME support. As shown in Figure 4, the FDA's fastest pathway (FDA 1) used expedited support at all stages, achieving a 172-day median review. EMA mostly relied on standard pathways, but combining A. As and conditional approval (EMA 5) shortened reviews to 183 days versus 343 days for standard routes. This highlights that EMA's limited utilisation of expedited pathways contributes to slower approvals (Gonçalves *et al.*, 2022; Hwang *et al.*, 2020).

Comparison of review times (median $\pm$ standard error) for Marketing Authorization Applications (MAAs) of new anticancer

drugs evaluated by the FDA and EMA under different regulatory approval pathways. (a) Review times by the FDA across eight pathways combining FT designation, BT, PR, and A.A. (b) Review times by the EMA across pathways involving PRIME, A. As, and conditional approval. (c) Comparison of review times for drugs undergoing minimum one expedited regulatory program with or without advisory committee meetings.

Table 1 is used in the Timeline section to clearly illustrate how different expedited regulatory pathways function across agencies, showing when they can be granted, the level of regulatory support offered, and their impact on drug progression. It supports the discussion on regulatory productivity by visually comparing how these designations facilitate earlier interactions, guidance, and faster assessments to accelerate access to therapies addressing severe conditions and unmet medical needs.

These findings reinforce that expedited pathways provide significant timeline advantages over traditional approval routes, especially for high-need therapeutic areas like oncology and rare

diseases, ultimately enabling earlier patient access to innovative treatments.

Regulatory Productivity and Administrative Burden Reduction

Innovative regulatory pathways like the FDA's PR and the EMA's A. As streamline approval by reducing evaluation timelines and administrative workload. PR cuts the FDA review period from about 12 months to 6 months, with nearly 60% of U.S. novel drug approvals between 2014-2016 using this pathway (Hanaizi *et al.*, 2023). Similarly, EMA's A. As shortens review from 210 to 150 days but requires early planning since unresolved issues can revert to the standard timeline. The EMA has specific pathways that allow medicines to be approved per limited clinical data when obtaining comprehensive evidence is not feasible or ethical. These mechanisms Conditional Approval and Exceptional Circumstances Approval are designed to balance timely patient access with post-marketing obligations to ensure

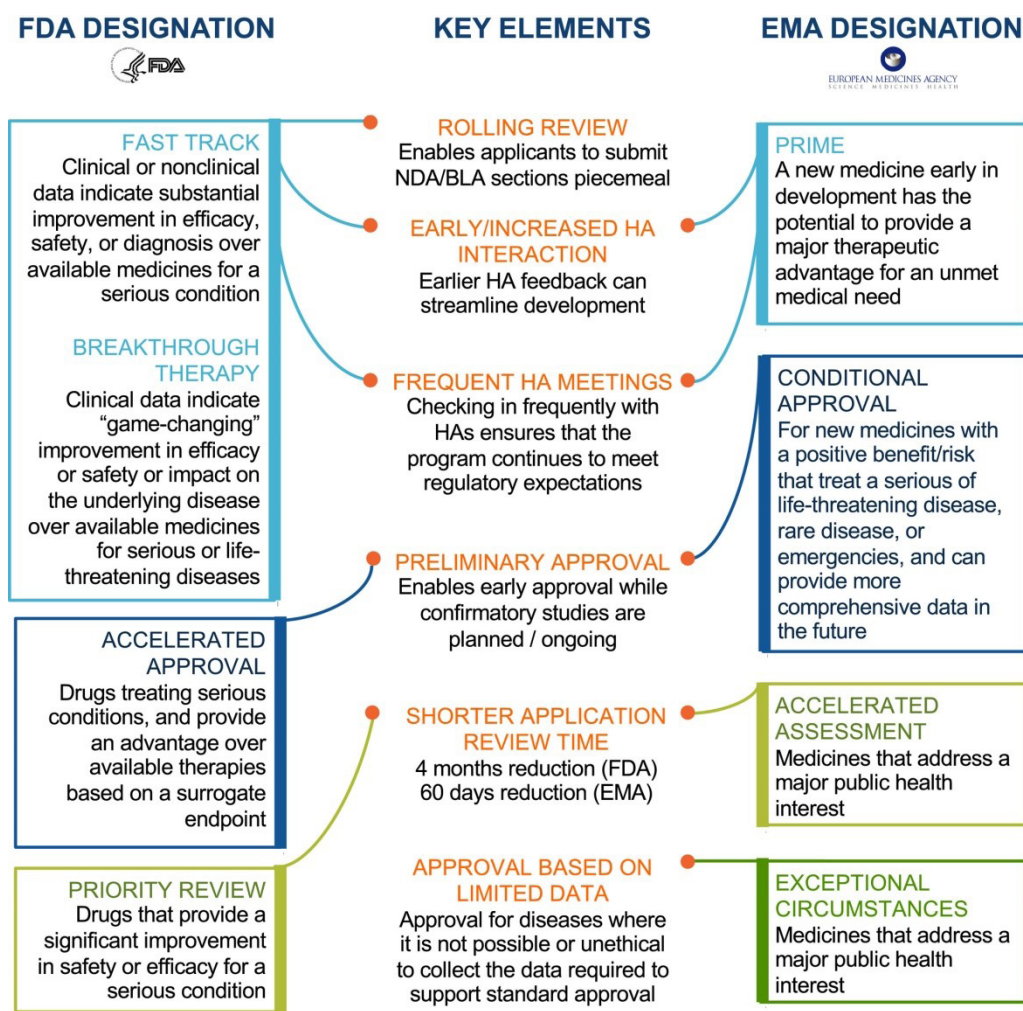


Figure 3: Side-by-side comparison of expedited programs offered by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), including key eligibility criteria, regulatory incentives, procedural advantages, and intended objectives (Cox *et al.*, 2020).

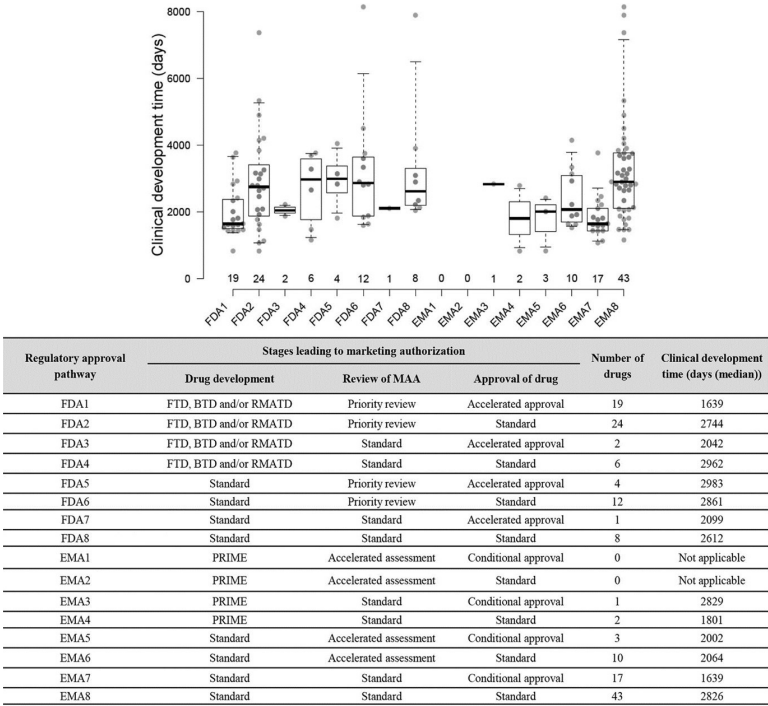


Figure 4: Comparison of median clinical development and regulatory review times for new anticancer drugs approved via standard and expedited pathways in the United States (FDA) and the European Union (EMA). The Figure illustrates the impact of accelerated regulatory mechanisms on time to approval across regions (Iglesias-Lopez *et al.*, 2021).

safety along with efficacy are eventually verified (Office of the Assistant Secretary for Planning and Evaluation, n.d.).

CMA is an EMA pathway that permits earlier approval of medicines for severe, rare, or emergency conditions based on limited early data showing a favourable risk-benefit profile. Unlike the FDA’s A.Ap, CMA does not rely solely on surrogate endpoints but requires sponsors to meet “Specific Obligations,” like confirmatory trials and submission of long-term safety along with efficacy data. The approval is valid for one year, with annual renewal until sufficient evidence is provided to convert it into a standard marketing authorization (Hwang *et al.*, 2020; U.S. Food and Drug Administration, n.d.). Exceptional Circumstances Approval, on the other hand, applies when it is impossible or unethical to collect the comprehensive data usually required for approval—for example, in ultra-rare diseases or conditions where clinical trials are not feasible. Unlike Conditional Approval, approvals under Exceptional Circumstances are not normally converted into standard marketing authorizations. However, annual reassessment and post-marketing obligations remain mandatory to ensure ongoing evaluation of the medicine’s safety and benefit-risk profile. These EMA-specific pathways illustrate the agency’s unique approach to providing early access to medicines while maintaining high regulatory standards. They enable approval based on limited data sets but place significant administrative responsibilities on sponsors, including annual reassessments and clearly defined post-approval studies or safety measures (Mooghali *et al.*, 2024). In the context of regulatory productivity, the EMA provides expedited pathways

like Conditional Approval to enable earlier access to high-need therapies. However, these mechanisms are more administratively complex than FDA programs, requiring extensive pre-submission planning and strict post-marketing obligations. While FDA A.Ap often relies on surrogate endpoints and converts to full approval after confirmatory data, the EMA approach involves annual renewals and ongoing evidence generation (Cox *et al.*, 2020). This cautious framework can delay full authorisation and patient access in Europe likened to the U.S., even though it ensures stronger post-approval oversight and data collection. As shown in Table 2 comparison between different regulatory approval pathways influence review timelines and administrative processes between the FDA and EMA. It highlights how combinations of expedited programs like FT, BTD, PR, A.Ap (FDA), and PRIME, A. As, conditional approval (EMA) impacts the overall time to approval (Detela and Lodge, 2019).

By presenting median review times, the table shows that FDA pathways generally lead to faster approvals compared to EMA pathways, demonstrating where administrative delays occur. It supports the argument that EMA uses expedited programs less frequently, contributing to longer review durations and potentially greater administrative burden. Overall, both PR and A. As demonstrate substantial gains in regulatory productivity by shortening review timelines while maintaining the same evidence standards as standard procedures. However, the EMA process involves greater administrative planning, which can sometimes counteract these gains if procedural delays occur. These pathways collectively underscore how regulatory agencies

are evolving to meet the increasing demand for faster access to innovative therapies for severe and life-threatening conditions while minimizing administrative complexities for sponsors.

Influence on Pharmaceutical Innovation and Unmet Medical Needs

Presents results on how expedited pathways foster early progression and approval of breakthrough therapies, especially in areas of high unmet medical need like oncology, rare diseases, and advanced therapies.

Innovative regulatory pathways, particularly the FDA's BTM, have significantly influenced pharmaceutical innovation and the progression of treatments for unmet medical needs. BTM provides intensive FDA guidance, PR, and rolling submissions for drugs showing substantial improvement over existing therapies for severe or life-threatening conditions. Studies show that BTM shortens late-stage drug progression time by about 30% and enables market entry 2-3 years faster likened to conventional pathways. Drugs granted BTM are often more innovative, with higher clinical benefit and trial success rates, especially in oncology and rare diseases (Kashoki *et al.*, 2020; Teixeira *et al.*, 2020; European Medicines Agency, n.d.).

Comparative studies show that PRIME shares many objectives with the FDA's BTM, particularly in promoting early alignment

of regulatory expectations and global progression strategies. However, PRIME has been used less frequently than BTM, which has limited its overall impact on reducing review times and expediting approvals in Europe (Kashoki *et al.*, 2020).

As seen in Figure 5, FDA-approved drugs benefitting from BTM consistently reached the market faster, often 2-3 years earlier than drugs following conventional pathways. In contrast, EMA's PRIME scheme contributed to fewer expedited approvals, with a smaller proportion of medicines utilizing A. As and conditional approval routes. This difference reflects the more stringent evidence requirements and multi-country coordination challenges in the EU regulatory system, which can extend review timelines.

The data on the count and growth rate of out-licensing agreements involving Chinese innovative drugs (2020-2023) were obtained from the Annual Reports on the Progress of Clinical Trials for New Drug Registration in China, published by the CDE under the NMPA. Overall, while PRIME offers an important tool for facilitating innovation and early access to high-impact therapies, its lower uptake and relatively modest time savings compared to FDA's BTM suggest the need for further optimization of EMA's expedited pathways to enhance regulatory productivity and better address unmet medical needs as per Figure 6.

Table 1: Comparison of breakthrough, PRIME, and RMAT designations (Hanaizi *et al.*, 2023).

Designation	Breakthrough Therapy (U.S. Food and Drug Administration, n.d.)	Priority Medicines (PRIME) (European Medicines Agency, 2015)	Regenerative Medicine Advanced Therapy (RMAT) (U.S. Food and Drug Administration, n.d.)
Regulatory Body	U.S. FDA	European Medicines Agency (EMA)	U.S. FDA
Year Introduced	2012	2016	2018
Eligibility Criteria	For severe conditions, with early clinical data suggesting significant improvement on meaningful clinical endpoints over existing options	For therapies showing promise of major clinical benefit or addressing unmet needs, with initial clinical evidence supporting potential	For regenerative treatments aimed at curing or improving severe conditions, supported by early evidence of potential to meet medical needs
Key Benefits	- Includes FT advantages - Enhanced progression guidance from FDA - Involvement of senior officials	- Early scientific and regulatory support - Dedicated rapporteur assigned early - Kick-off meeting with expert committees - Possibility of accelerated review - Continuous EMA contact person	- Offers same benefits as Breakthrough Therapy - Early interaction regarding utilisation of surrogate or intermediate endpoints
Stage of Development Considered	Available at any stage of drug progression	Typically evaluated in Phase 1 or 2	Applicable at any progression phase
Approved Drugs Eligible	Yes, if indicated	No	Yes, if indicated
Requires Evidence of Major Advantage	Yes	Yes	No

Table 2: Regulatory approval pathways for new anticancer drugs evaluated by the FDA and EMA, including phases of drug progression, review of Marketing Authorization Application (MAA), type of approval, count of drugs, median review time, and count of drugs undergoing advisory committee meetings (Hwang *et al.*, 2020; Hanaizi *et al.*, 2023).

Number of drugs referred to advisory committee meeting (regulatory agency)		Pharmacology	Clinical data package	Target population and indication	Risk-benefit assessment	Clinical safety	Clinical efficacy
7 (both the FDA and the EMA)	US	1	1	1	4	1	1
	EU	1	4	3	1	2	7
4 (only the FDA)	US	1	1	0	4	2	1
8 (only the EMA)	EU	0	4	5	0	2	8
Total 11 (the FDA)	US	2	2	1	8	3	2
Total 15 (the EMA)	EU	1	8	8	1	4	15

Comparative Overview of Country-Specific Regulatory Pathways

Across ICH and comparator agencies, multiple expedited pathways exist spanning development, review, conditional approval, and reliance mechanisms, each with distinct eligibility criteria and time benefits. In Japan, the PMDA offers Sakigake, a Japan-first scheme emphasizing early engagement and a 6-month review, alongside Conditional Early Approval (CEA) and Priority Review (≈ 9 months). China's NMPA provides Breakthrough Therapy (BT) and Conditional Approval (CA) at the development stage, embedding intensive regulator-sponsor interactions and reliance on early endpoints, with Priority Review available at NDA; since reforms, CA and PR have become widely used. Australia's TGA applies Provisional Approval (time-limited, renewable), Priority Review (150 days), and Comparable Overseas Regulator (COR) reliance (120-175 days), though expedited uptake remains sparse (≈ 5 -9% of NASs in recent years). Switzerland's Swissmedic employs Fast-Track, Temporary Authorisation (TA), and Article 13 reliance, with updated 2024 guidance reinforcing the role of foreign assessment reports. Canada maintains two major routes: Priority Review (180 days) and Notice of Compliance with conditions (NOC/c) (≈ 200 days, with enforceable commitments).

Patterns of use diverge. Japan applies Sakigake narrowly and continues to rely on CEA in settings where confirmatory trials are impractical. China has strongly adopted BT and CA, with the latter accounting for a major share of expedited approvals and demonstrating reduced median review times (304-351 vs ≈ 502 days for standard). Australia uses Priority Review sparingly, while Provisional and COR serve as more practical entry routes; in 2024 only 3 of 33 NASs were expedited. Switzerland increasingly uses Article 13 reliance and time-limited approvals, while Canada's

expedited share has remained steady at ≈ 18 -19%, with NOC/c extensively studied post-approval.

Ten-year approval trends show expedited uptake varying considerably: ≈ 43 -48% in Japan, 27-31% in Switzerland, 18-19% in Canada, and $<10\%$ in Australia, while China has markedly expanded expedited approvals post-reform. Timeline comparisons highlight clear advantages: PMDA Sakigake (6 months) vs ~ 9 months Priority; NMPA expedited (304-351 days) vs ~ 502 non-expedited; TGA Priority (150 days) and COR (120/175) vs standard ≈ 255 -370 days; Health Canada PR (180 days) vs standard 300; and Swissmedic Art. 13 permitting major time compression through reliance (Tian *et al.*, 2024; Kuribayashi *et al.*, 2024; Lexchin, 2025; Gu *et al.*, 2025; Xu *et al.*, 2025).

Overall, expedited pathways are heterogeneous in scope and utilization: Japan and Canada apply them selectively, Australia sparingly, Switzerland and China increasingly, with China's CA and BT representing the most rapid and widely deployed expansions.

Barriers and Challenges to Effective Implementation

Results show that FDA's Breakthrough Therapy Designation (BTD) strongly impacts oncology, with about 48% of designations for cancer drugs. Combined with A.Ap, BTD has driven more innovative drug approvals in oncology and rare diseases, shortening progression by 2-3 years, providing early regulatory support, improving trial success, and boosting commercial prospects for smaller developers (Hwang *et al.*, 2020; Del Grosso *et al.*, 2025). Similarly, the EMA's PRIME scheme aims to support medicines addressing unmet medical needs through early dialogue and A.As. However, PRIME designations and resulting approvals remain lower compared to BTD, reflecting differences in uptake and regulatory requirements. Both programs have

encouraged the utilisation of novel endpoints, adaptive trial designs, and cross-agency alignment, which collectively reshape how innovation is pursued (Wang *et al.*, 2022). Despite these successes, concerns remain about the robustness of evidence supporting expedited approvals. Many pivotal trials rely on surrogate endpoints, small sample sizes, or non-randomized designs, increasing uncertainty around long-run safety along with efficacy. Delays or failures in confirmatory post-approval studies further raise regulatory oversight challenges (Mulder *et al.*, 2020). These findings underscore that while BTD and PRIME are powerful tools for accelerating innovation, their ultimate value depends on strong evidence generation, rigorous post-marketing follow-up, and continued collaboration between agencies to ensure patient safety and therapeutic benefit.

Recommendations for Optimizing Innovative Approval Pathways Globally

To boost the productivity and bearing of expedited approval programs like the FDA's BTD and the EMA's PRIME scheme, several evidence-based measures can be implemented. Strengthening early engagement between regulators and developers through structured pre-submission meetings and continuous scientific advice can help align expectations for trial designs, endpoints, and evidence requirements, reducing delays in later stages (Franco *et al.*, 2023; Nagai, 2019).

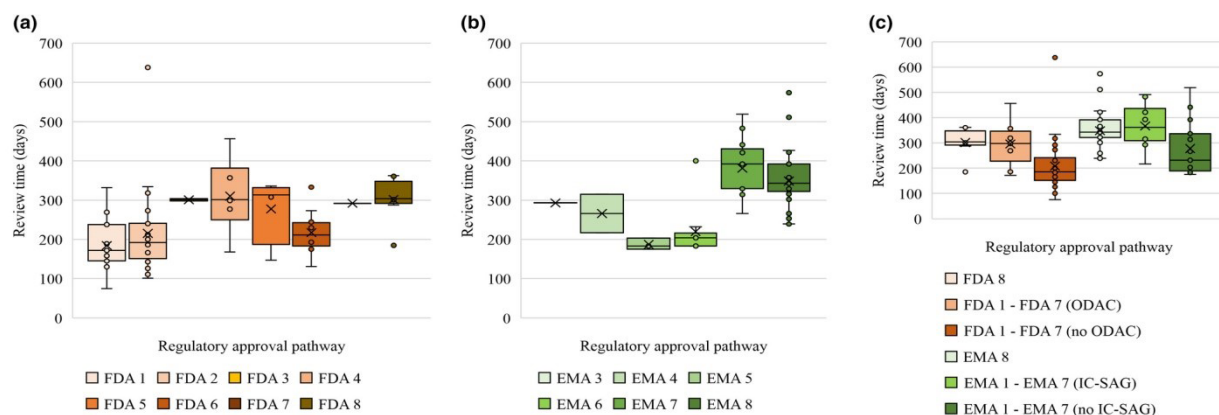
Harmonization across major regulatory agencies is also essential. Greater alignment of eligibility criteria, review timelines, and

evidence standards along with initiatives like parallel scientific advice can support global drug progression, especially for rare diseases where patient recruitment is challenging. Equally important is the need for stronger post-marketing evidence generation. Expedited approvals often rely on surrogate endpoints or limited data, so agencies must enforce timely completion of confirmatory trials and encourage the utilisation of real-world evidence to monitor long-run safety along with efficacy (Hwang *et al.*, 2020; Tan *et al.*, 2025).

Finally, ensuring faster patient access requires collaboration with Health Technology Assessment (HTA) bodies and payers to integrate approval decisions with reimbursement strategies. Together, these measures can make expedited pathways more effective in accelerating access to transformative therapies while safeguarding patient safety and maintaining robust evidence standards.

DISCUSSION

Our findings emphasize that while expedited regulatory pathways shorten progression and review timelines, their impact in Europe remains limited due to lower uptake and higher administrative complexity within the EMA framework. For oncology drugs, median clinical progression time decreased from 6.7 years to 4.5 years under expedited programs; however, EMA review times (≈ 337 days) remained longer than FDA (≈ 201 days), resulting in a clear 136-day lag. Expedited pathways were used in 43% of



Regulatory Approval Pathway	Stages Leading to Marketing Authorization			Number of Drugs	Median Review Time (days)	Number of Drugs in Advisory Meetings
	Drug Development	Review of MAA	Approval of Drug			
FDA 1	Fast track and/or breakthrough therapy designation	Priority review	Accelerated approval	19	172	2
FDA 2	Fast track and/or breakthrough therapy designation	Priority review	Standard	24	192	0
FDA 3	Fast track and/or breakthrough therapy designation	Standard	Accelerated approval	2	301	1
FDA 4	Fast track and/or breakthrough therapy designation	Standard	Standard	6	301	2
FDA 5	Standard	Priority review	Accelerated approval	4	314	2
FDA 6	Standard	Priority review	Standard	12	212	1
FDA 7	Standard	Standard	Accelerated approval	1	291	0
FDA 8	Standard	Standard	Standard	8	304	3
EMA 1	PRIME	Accelerated assessment	Conditional approval	0	NA	0
EMA 2	PRIME	Accelerated assessment	Standard	0	NA	0
EMA 3	PRIME	Standard	Conditional approval	1	293	1
EMA 4	PRIME	Standard	Standard	2	266	1
EMA 5	Standard	Accelerated assessment	Conditional approval	3	183	0
EMA 6	Standard	Accelerated assessment	Standard	10	204	1
EMA 7	Standard	Standard	Conditional approval	17	392	7
EMA 8	Standard	Standard	Standard	43	343	5

Figure 5: Overview of key expedited regulatory pathways, outlining the stages leading to marketing authorization, the number of drugs approved under each pathway, and the associated median regulatory review times. This Figure provides a consolidated comparison of pathway efficiency and regulatory throughput (Gonçalves *et al.*, 2022).

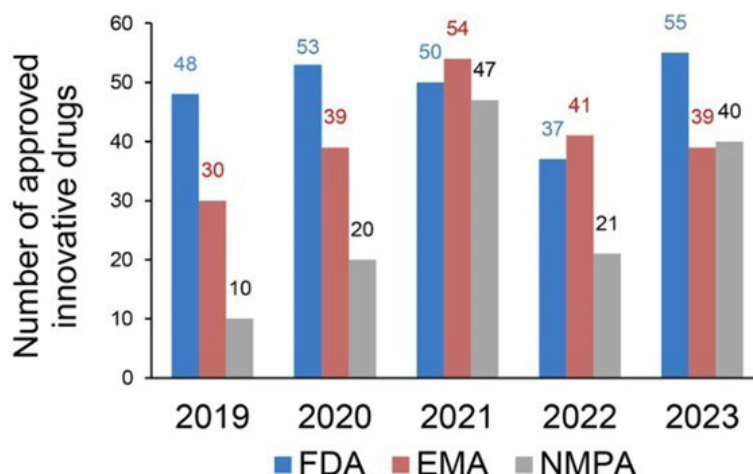


Figure 6: Interpretative summary highlighting the relative uptake, regulatory impact, and time savings associated with EMA's PRIME scheme compared with the FDA's Breakthrough Therapy Designation (BTD) (Tan *et al.*, 2025; Papapetropoulos *et al.*, 2024).

EU cases compared with 89% in the U.S., reflecting EMA's more cautious application of PRIME and A.As. In many cases, EMA's A. As reverted to standard timelines because of unresolved issues, adding procedural delays (Hwang *et al.*, 2020; Hanaizi *et al.*, 2023).

Although PRIME offers early guidance similar to FDA's Breakthrough Therapy Designation, its lower adoption reduces its overall impact on accelerating market entry for high-need therapies. For orphan-designated oncology drugs, EMA's median review time (≈ 353 days) was 109 days longer than the FDA. These delays are consistent with broader trends showing the FDA leading approvals for 84 anticancer drugs between 2004 and 2023, compared with only 5 first approvals by the EMA (Tan *et al.*, 2025).

EMA's framework, while ensuring stronger post-marketing oversight through annual reassessments and structured obligations, tends to delay conversion to full approval. This cautious approach safeguards evidence quality but can slow patient access to innovative therapies. Increasing the uptake of EMA expedited pathways, simplifying administrative procedures, and strengthening global regulatory alignment could enhance timely access without compromising safety along with efficacy standards. Expedited regulatory programs show clear differences in their implementation and effectiveness between the FDA and EMA. At the FDA, 70% of FT applications and 39% of Breakthrough Therapy Designation (BTD) requests were granted, with BTD demonstrating a greater impact reducing progression time to 4.8 years versus 8 years for non-expedited drugs. FT showed a smaller reduction of about one year. BTD requires preliminary clinical evidence, whereas FT may be grounded in

nonclinical or early clinical data (Hanaizi *et al.*, 2023; European Medicines Agency, 2016; European Medicines Agency, 2018).

PR at the FDA shortens review time by four months but does not significantly affect overall progression duration. The EMA's A. As reduces review time from 210 to 150 days, though around 50% revert to standard timelines due to unresolved issues. The FDA's A.Ap pathway had 198 approvals by 2019, with 57.5% converting to full approval and 35% still awaiting confirmatory data. In oncology, most conversions occurred within 3.4 years (European Medicines Agency, 2016; European Medicines Agency, 2018).

The EMA's CMA allows earlier access for high-need therapies, but with stricter post-marketing obligations. From 2006 to 2016, 30 CMAs were granted, with 47% converted to full approval and 37% remaining conditional. PRIME, introduced in 2016, saw limited uptake, with only 36 approvals from 177 applications in two years and just three drugs approved by 2019. The Exceptional Circumstances pathway has been rarely used, with seven approvals between 2016 and 2018 (European Medicines Agency, 2018; Beaver *et al.*, 2018).

Across Japan, China, Australia, Switzerland, and Canada, expedited pathways share a common aim of earlier patient access in serious conditions, yet their design and utilisation differ (Tian *et al.*, 2024; Kuribayashi *et al.*, 2024; Lexchin, 2025). Japan's toolkit is unusually development-centric: Sakigake ties shorter review (to six months) to Japan-first development and offers concierge-style PMDA support, whereas CEA is calibrated for feasibility-limited settings where confirmatory trials are impracticable (Kuribayashi *et al.*, 2024). China's BT/CA/PR suite has become a central engine for access, with 2024 median review times 304-351 days under BT/CA, materially faster than non-expedited reviews (502 days) (Tian *et al.*, 2024; Gu *et al.*,

2025). Australia relies more on Provisional (time-limited) and COR reliance for predictability, while maintaining a relatively conservative use of Priority Review (only 3/33 NASs expedited in 2024). Switzerland blends fast-track and temporary authorisation with an assertive Article 13 reliance model that can forego LoQs when a trusted reference assessment is accepted. Canada's PR (180 days) and NOC/c (200 days) remain the core accelerators, with NOC/c shifting evidentiary burden post-approval and an active literature tracking condition fulfilment (Lexchin, 2025). When we benchmark the last decade using CIRS' harmonised methods for the six agencies (PMDA, TGA, Swissmedic, Health Canada; plus FDA/EMA for context), total NAS throughput remains stable while the share of expedited reviews diverges: TGA stays low but rising (~5%→9%), PMDA/Swissmedic are moderate with slight declines (~48%→43% and 31%→27%), and Health Canada is steady at ~19%→18% (2015-2019 vs 2020-2024, common approvals). This aligns with each agency's policy posture: Japan front-loads development support, Australia emphasises reliance, Switzerland operationalises formal reliance/fast-track, and Canada balances speed with conditionality (Kuribayashi *et al.*, 2024; Lexchin, 2025). China, while outside the CIRS panel, shows surging innovative approvals and heavy use of CA/BT/PR, with measured but meaningful time-to-approval gains (Kuribayashi *et al.*, 2024; Xu *et al.*, 2025).

Overall, FDA programs, particularly BT and A.A, are more frequently used and lead to faster progression and review. In contrast, EMA pathways are more cautious and administratively demanding, leading to slower uptake and longer timelines.

CONCLUSION

Expedited regulatory processes have proven critical to expedite medication development and review, hence enhancing patient access to medicines in oncology and rare disorders. The FDA uses Breakthrough Therapy and Priority Review a lot, whereas EMA's PRIME and Accelerated Assessment are used less often since they have tougher rules. Japan's Sakigake delivers the fastest acceleration in the world. China's Breakthrough Therapy, Conditional Approval, and Priority Review all have high hopes for quick results. Australia's Comparable Overseas Review and provisional registration focus on trust. Switzerland uses Article 13 and fast-track options, while Canada uses Priority Review and NOC/c with set review windows. Over the last ten years, these programs have continuously sped up durations compared to normal reviews. However, how often they are used depends more on regulatory frameworks than on industry demand. Choosing a path has become distinctive to the market: Japan for early launches, China for significant unmet needs, Australia and Switzerland for efficiency based on reliance, and Canada for flexibility based on data. In the end, choosing the right channels strategically is just as important as designing the clinic to get patients in quickly.

ABBREVIATIONS

EMA: European Medicines Agency; **CMA:** Conditional Marketing Authorisation; **A.As:** Accelerated Assessment; **EU:** European Union; **MA:** Marketing Authorization; **HIV/AIDS:** Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome; **MAH:** Marketing Authorization Holder; **MRP:** Mutual Recognition Process; **DCP:** Decentralized Procedure; **PR:** Priority Review; **PRISMA:** Preferred Reporting Items for Systematic Reviews and Meta-Analyses; **CHMP:** Committee for Medicinal Products for Human Use; **EEA:** European Economic Area; **FT:** Fast Track; **ATMPs:** Advanced Therapy Medicinal Products; **US:** United States (of America); **RMATD:** Regenerative Medicine Advanced Therapy Designation; **CDE:** Center for Drug Evaluation; **NMPA:** National Medical Products Administration; **CEA:** Conditional Early Approval; **CA:** Conditional Approval; **BT:** Breakthrough Therapy (Designation); **NAS:** New Active Substances; **CIRS:** Centre for Innovation in Regulatory Science; **LoQs:** List of Questions; **PRIME:** PRiority Medicines; **HTA:** Health Technology Assessment; **PMDA:** Pharmaceuticals and Medical Devices Agency; **NOC:** Notice of Compliance; **TA:** Temporary Authorisation; **COR:** Comparable Overseas Regulator; **ICH:** International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; **NDA:** New Drug Application; **TGA:** Therapeutic Goods Administration.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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