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Review Article

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Bridging Regulatory Speed: A US–EU Perspective on Rapid Drug Approvals

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Abstract

However, there is growing pressure on the regulatory community to provide life-saving drugs to patients sooner, and as such, they have come up with flexible approval processes that attempt to strike a balance between speed and sound evidence. This poster will highlight the key options available in the US and Europe. The FDA's Emergency Use Authorization allows promising drugs to be used on a temporary basis during public health crises before full data is available, while Accelerated Approval allows earlier approval for drugs based on surrogate markers that are reasonably likely to predict clinical benefit. The EMA's Conditional Marketing Authorization allows drugs to be marketed while full data is not available (with a commitment to complete studies later), while Accelerated Assessment is simply an expedited review process for drugs that address serious medical needs. These processes highlight the key differences in the degree of risk that each regulatory authority is willing to take, the amount of evidence required, and the post-approval obligations.

Conclusion: EU and US expedited approval pathways enable faster patient access to critical therapies but require strong post-approval evidence, regulatory harmonization, real-world data integration, and sustained scientific transparency to maintain safety and public trust.

Keywords: Conditional marketing Authorisation; Emergency Use Authorisation; Accelerated Approval; Accelerated Assessment; Rapid Drug Approvals

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1. Introduction

Access to essential medicines has remained a challenge in the global health arena. Despite advances in biomedical research, two billion people worldwide do not have access to basic therapeutic care, and this has mainly affected low- and middle-income groups. Chronic conditions such as diabetes, hepatitis, cardiovascular disease, and infectious diseases remain a source of preventable morbidity and mortality. (1)

The COVID-19 pandemic has highlighted vulnerabilities in global supply chains and regulatory response. Global efforts, such as COVAX and vaccine development platforms, have shown that accelerated regulatory decision-making is possible when underpinned by scientific collaboration and resource mobilization. These experiences have refocused attention on the role of regulatory flexibility as a public health instrument. (2,3)

The traditional drug development process is still long and costly. The average time from discovery to approval often takes more than a decade, with substantial economic outlay and high failure rates. The traditional review process can take 10-12 months for regulatory approval alone, further pushing back the availability of new life-saving treatments to patients. (4)

To overcome these limitations, the FDA established Accelerated Approval in 1992, allowing approval of products based on surrogate endpoints that are reasonably likely to predict clinical benefit. Later, other approaches like Fast Track, Breakthrough Therapy Designation, and Priority Review further accelerated procedural processes. Likewise, the EMA created Conditional Marketing Authorization in 2006 and Accelerated Assessment to shorten review times for drugs of high public health significance. (5,6)

2. Regulatory Framework Overview

The EMA harmonizes the evaluation of innovative medicinal products in the EU Member States according to Regulation (EC) No 726/2004. (6) The scientific evaluation is carried out by the Committee for Medicinal Products for Human Use (CHMP), and the Pharmacovigilance Risk Assessment Committee (PRAC) is responsible for post-authorisation safety monitoring.

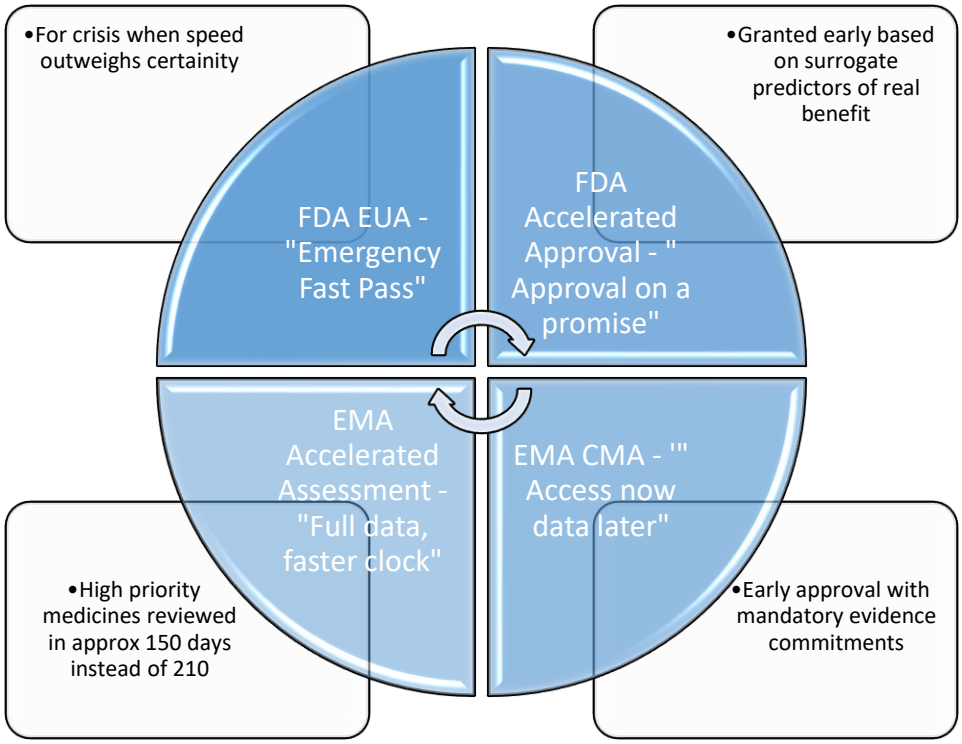

Figure 1. Expedited Approval Pathways

The centralised procedure confers a single marketing authorisation that is valid in all EU and EEA Member States. In this context, there are two main acceleration mechanisms:

- Conditional Marketing Authorisation (CMA) – enables approval based on less comprehensive information if the benefit-risk profile is positive and the applicant undertakes to fulfil certain obligations. (7)
- Accelerated Assessment (AAss) – shortens the standard 210 active days of review to 150 days for products of major public health interest. (6)

The EMA model focuses on annual reassessment and renewal procedures to address evidentiary uncertainty.
United States Regulatory Landscape

The FDA operates under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Expedited programs include:

- **Accelerated Approval (AA)** – approval based on surrogate endpoints reasonably likely to predict clinical benefit. (5)
- **Emergency Use Authorization (EUA)** – temporary authorisation during declared public health emergencies under Section 564 of the FD&C Act. (8)
- Priority Review, Fast Track, and Breakthrough Therapy Designation.

Recent legislative updates under the FDA Omnibus Reform Act (FDORA) 2022 strengthened enforcement mechanisms for confirmatory trials and clarified withdrawal procedures. (9) The U.S. approach permits earlier market entry but relies heavily on enforceable post-marketing commitments and regulatory oversight.

3. Expedited Approval Pathways

CMA is a very useful tool of the EMA that allows promising drugs to reach patients earlier if the full data is not available yet. This applies to drugs used for serious, life-threatening, rare, or emergency-related diseases with well-defined unmet medical needs. The available evidence must demonstrate a positive benefit-risk ratio, the sponsor must agree to complete the confirmatory studies, and the early access must provide greater benefits than the limitations of the data. CMA is granted for one year and can be renewed depending on the progress made, and it is expected to have robust post-approval surveillance by CHMP and PRAC, to be finally replaced by full authorization once the benefits are established.

Accelerated Assessment is a procedural acceleration mechanism and not a separate form of authorisation, lowering the standard assessment procedure evaluation time from 210 active days (not including clock stops) to 150 days. It is regulated by Article 14(9) of Regulation (EC) No 726/2004 and is applicable to products of major public health significance, especially those that relate to therapeutic innovation or substantial progressions beyond existing choices. The application for justification must be made at least two to three months prior to the marketing authorisation application, and the eligibility decision is made on a case-by-case basis by CHMP. The accelerated procedure, often divided into stages (such as 120 + 30 days for advanced therapies), requires a full dossier at the time of submission and restricts clock stops, ensuring efficiency while maintaining high scientific standards. This procedure is often used in conjunction with CMA for products that qualify for both procedures, improving patient access without undermining quality standards. (7)

EUA is the FDA's "first resort" in rapidly authorizing medical products in response to a public health emergency. Created through the 2004 Project Bio Shield

Act under section 564 of the FD&C Act, EUA allows for the use of unapproved products or approved products for a new indication to diagnose, treat, or prevent a life-threatening disease caused by biological agents, chemicals, radiation, or nukes. The HHS Secretary must first declare the emergency, and then the FDA reviews four criteria: the agent presents a serious or life-threatening risk, there is some evidence the product works, the benefits outweigh the known and potential risks, and there isn't a suitable approved alternative. EUAs are rapid (as in the case of COVID-19), have specific terms and conditions, fact sheets for healthcare providers and patients, and reporting requirements. They automatically expire when the emergency ends or may be withdrawn if the situation changes, providing speed without sacrificing fundamental safety standards. (8)

Accelerated Approval, established in 1992 and enacted under section 506 (improved by FDASIA 2012 and FDORA 2022), allows drugs for serious or life-threatening diseases with unmet needs to enter the market earlier based on the use of surrogate endpoints (such as shrinkage) or intermediate endpoints that are reasonably likely to predict a clinical benefit. This avoids waiting for the final outcome, such as overall survival benefit. Post-approval confirmatory studies are required to confirm the benefits; new 2022 provisions require studies to begin early, with regular progress reports, and provide FDA with more power to enforce deadlines or withdraw approval if necessary. It promotes innovation while demanding strong follow-through to ensure that the benefit-risk remains valid. (7)

Table 1. Rapid Drug Approval Pathways

Factor	FDA EUA	FDA Accelerated Approval	EMA Conditional Marketing Authorisation	EMA Accelerated Assessment (AAss)
Regulatory Basis	FD&C Act §564 (Emergency authority)	FD&C Act + 21 CFR 314/601 (Surrogate endpoint rule)	EU Regulation (EC) 507/2006	Regulation (EC) 726/2004
Core Purpose	Rapid access during emergencies	Earlier approval using surrogate markers	Early access with incomplete data	Faster evaluation of full dossier
When Used	Public health emergencies (pandemics, bio threats)	Serious or life-threatening diseases with unmet need	Serious/unmet-need diseases; emerging threats	Major public health interest / high innovation
Evidence Requirement	"May be effective" based on totality of limited evidence	Surrogate/ intermediate endpoints reasonably predicting benefit	Incomplete clinical data acceptable with commitments	Full, mature data package required
Type of Approval Granted	Temporary authorization	Accelerated marketing approval	Conditional marketing authorization	Standard MA (but faster review)
Validity	Only during emergency; revocable anytime	Becomes full approval once confirmatory trials succeed	Valid 1 year; renewable until obligations complete	Standard validity once approved
Post-Authorization Obligations	Safety monitoring; fact sheets	Mandatory confirmatory studies	Mandatory specific obligations (clinical data, safety updates)	No special obligations beyond regular MA
Level of Uncertainty Accepted	High — emergency-driven flexibility	Moderate — surrogate-based prediction	Moderate–high — data not yet complete	Low — no compromise on evidence quality
Example Product Types	Vaccines, antivirals, diagnostics in emergencies	Oncology drugs, rare disease therapies	Pandemic vaccines, orphan drugs	Breakthrough therapies, advanced biologics
Risk–Benefit Approach	Benefits outweigh potential risks in emergency context	Acceptable risk with expected future confirmation	Acceptable risk with strong monitoring	Standard benefit–risk, but prioritized review

4. Eligibility Criteria and Data Requirements

The criteria for expedited approval routes in the US and EU are primarily based on two considerations: the severity of the disease and the presence of a well-defined unmet medical need. The FDA and EMA restrict expedited approval routes to serious or life-threatening diseases like cancer, rare genetic disorders, neurodegenerative diseases, or high-mortality rates of infections, where waiting for traditional development could result in irreversible harm or death. Mild and self-limiting diseases are not considered, as these routes are designed for high-priority diseases where rapid access could make a real difference in outcomes. (6,7)

The other criterion that filters expedited approval routes is the presence of an unmet medical need. For FDA's Accelerated Approval, this indicates that there is no adequate approved therapy available, or the new drug provides a substantial advantage in efficacy, safety, or patient subgroups. EMA's Conditional Marketing Authorisation (CMA) requires that there is no satisfactory authorized method available in the EU, or a significant therapeutic advantage, assessed holistically by the

CHMP, which is often associated with orphan, emergency, or severely debilitating diseases. (6,7)

Requirements for evidence remain high but with flexibility. FDA accepts surrogate endpoints (e.g., shrinkage) or intermediate endpoints reasonably likely to predict real benefit, with good studies, and mandatory confirmatory post-approval trials (improved by 2022 regulations for rapid initiation and reporting, and potential withdrawal). EMA's CMA requires a favourable benefit-risk balance from existing (usually Phase II/early Phase III) information, with plans to finish full studies subsequently, and annual renewals reflecting progress. Both require robust safety information and risk management strategies, and valid non-clinical/CMC packages, to ensure that provisional approvals are based on sound grounds, but with subsequent validation for long-term value. (5)

Table 2. Eligibility criteria

Parameter	FDA Accelerated Approval	EMA Conditional MA
Surrogate endpoints	Accepted if reasonably predictive	May be accepted
Completeness of data	Partial clinical maturity permitted	Incomplete data allowed
Post-approval studies	Mandatory confirmatory trials	Legally binding obligations
Renewal process	Not annual	Annual renewal required

5. Review Timelines and Procedural Flexibilities

The EU and US apply smart procedural adjustments in their expedited procedures to bring essential drugs to market faster, especially in cases of high unmet needs or emergencies, without compromising on safety evaluation procedures.

In the EU, the normal centralized marketing authorization procedure takes a maximum of 210 active days (not including clock stops for applicant response times), with additional time for the European Commission to finalize matters after the CHMP has issued its opinion. For suitable candidates, Accelerated Assessment reduces the active evaluation period to about 150 days if the drug has high public health significance and the applicant can justify this early on, preferably through pre-submission meetings six to seven months prior to submission to optimize planning. In times of emergencies such as the COVID-19 pandemic, EMA's rolling review process allows evaluators to review bite-sized chunks of information as they receive them, instead of waiting for the complete set, thus shortening the overall evaluation time by conducting parallel evaluation with ongoing studies. (6)

In the US, Emergency Use Authorization (EUA) is not time-sensitive but is intended to be relatively fast: after the HHS has declared an emergency and certain conditions are met (serious threat of disease or injury, likely benefit, benefits outweigh risks, no adequate alternatives), the FDA can authorize an EUA in days or weeks, depending on the strength of the data. In non-emergency situations, Priority Review under PDUFA shortens the target from ten months (standard review) to six months for new drugs that treat serious conditions with substantial advantages through the use of focused teams, resources, and milestones that keep the science rigorous but move at a faster pace. (7)

Both agencies devote more resources to these high-priority applications, using methods such as early communication, rolling submissions, and inter-team coordination to deal with incremental data and risk-benefit analyses in real-time. Although this flexibility helps speed up timelines and responsiveness, it also poses challenges to reviewer workloads and requires a delicate balance to ensure high-quality and sustainable reviews that are truly patient-centred.

6. Benefit–Risk Assessment Under Uncertainty

One of the key components of the decision-making process in the regulation of medicinal products is the benefit-risk balance assessment, particularly in situations where the information available is not comprehensive or is uncertain. The European Medicines Agency (EMA) and the Food and Drug Administration (FDA) in the United States use a systematic approach to ensure that the therapeutic benefit is not outweighed by the risk, but with a different procedural emphasis.

6.1 EMA Benefit–Risk Framework

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6.2 FDA Risk-Based and Public Health-Driven Assessment

The FDA employs its Benefit-Risk Framework (BRF) to make educated decisions regarding new medications and biologics by bringing together experts from different disciplines to evaluate the strength of evidence for benefits compared to risks. Evaluators also consider the bigger picture of the severity of the disease, the magnitude of the unmet need, and what is already present in the market, while zooming in on efficacy and safety data to decide if the benefit-risk profile is promising enough for the intended use. They also consider patient feedback and real-world experience when it can shed light on what benefits or risks are most important to patients. Uncertainties, such as a lack of knowledge about the disease, variability in patient response, or problems with the design of the study (such as endpoints and diversity of study enrolment), are openly acknowledged and considered in the final evaluation. (7)

The BRF is more of a qualitative tool that presents the evidence, unknowns, and reasoning behind the decision, which makes it more transparent in the documents used in the review. In the faster tracks, such as Accelerated Approval or in cases of Emergency Use Authorization

(EUA), the FDA is more willing to accept the unknowns at the front end if the situation warrants quicker access to potentially life-saving treatments as long as there are good plans for follow-up studies. (7)

7. Post-Approval Obligations and Lifecycle Management

Expedited approval routes in the EU and US are accompanied by more stringent post-approval obligations to manage the risk of uncertainty inherent in early approvals, employing lifecycle frameworks to maintain the risk-reward balance on the positive side as more information becomes available. (6)

Regarding confirmatory trials, the EU's Conditional Marketing Authorization (CMA) obligates firms to fulfil certain trials (usually validating benefits based on surrogates) within specified timeframes, with annual renewals until sufficient data is available to convert to conventional approval—failure to comply may result in non-renewal or revocation. The US's Accelerated Approval process demands post-marketing confirmatory trials to validate clinical benefit, with recent changes encouraging firms to initiate trials prior to or shortly after approval, with regular progress updates, and withdrawal from the market at a faster rate if delays or failures occur. EUA products may include active trials and real-world data gathering to facilitate future full approval. (6)

Pharmacovigilance systems are very important: Sponsors in the EU must have "enhanced" systems in accordance with an approved Risk Management Plan (RMP), which involves reporting, updates, and further studies to detect "rare or late-emerging" safety issues. In the US, reporting systems like FAERS, studies, and close monitoring (especially for EUAs) are used, often observational studies or registries. (9)

Risk management is done differently: RMPs in the EU are mandatory for all new drugs—a complete, constantly evolving document that details risks, knowledge gaps, and risk minimization plans—while REMS in the US are only used when needed, with special programs like restricted distribution or educational programs. Both organizations strictly enforce compliance: The EMA can withdraw or revoke CMAs that do not comply with requirements, while the FDA can withdraw Accelerated Approvals (with new streamlined processes).

8. Transition to Full Approval or Withdrawal

The fast-track approvals are intended to be a short-term measure, with a clear path to full approval once the data warrants this or withdrawal if it doesn't hold up to scrutiny. In the EU, a Conditional Marketing Authorisation (CMA) can be converted to a standard full marketing authorisation once the company has met all the required obligations, such as confirmatory clinical trials, and submitted sound data that proves a consistent positive benefit-risk profile. The EMA will review this through their standard procedures, and if everything is in order, the conditional status will be lifted, confirming the drug's long-term safety, efficacy, and quality. Failure to meet the obligations on time can lead to rejection of renewal applications, potentially causing suspension or revocation of the marketing authorisation. (6)

With respect to US Emergency Use Authorizations (EUAs), the authorization is only effective for as long as the public health emergency is in place—or until the criteria no longer apply, such as when better options emerge or new safety/efficacy concerns arise. To remain on the market, sponsors are required to submit a Biologics License Application (BLA) or New Drug Application (NDA) for full approval, with data that meets standard requirements. Withdrawals of Accelerated Approvals: Challenges persist, as there have been instances of delays or outright failure in the completion of post-marketing confirmatory studies, particularly within the realm of oncology, which have led to an increase in FDA withdrawals. These cases highlight the fine balance that must be struck between providing timely access to patients and providing adequate, sound evidence of efficacy and safety. (7)

9. Conclusion

This review of expedited approval procedures in the EU and US clearly indicates that these procedures are essential tools for addressing urgent public health needs and providing timely access to new therapies. While the EMA and FDA have flexible procedures for expedited development and approval, there are important differences in their legal frameworks, risk tolerance, and post-approval structures. Conditional approvals, emergency approvals, and accelerated approvals all share a common requirement for enhanced post-market data development and pharmacovigilance to address remaining risks.

Enhancements in confirmatory trial timelines, harmonization of criteria for surrogate endpoints, and the validated role of real-world evidence may enhance the efficiency of expedited approval procedures. International cooperation and reliance may also enhance efficiency and global access while preserving regulatory autonomy. As these regulatory frameworks continue to develop, it will be important to preserve scientific integrity, transparency, and public trust to ensure that expedited approval procedures fulfil the promise of providing timely, safe, and effective access to patients.

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Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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