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Review Article

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A Comparative Review of Fast-Track Generic Drug approvals: Criteria and Timelines across FDA, Swissmedic, MHRA, and PMDA

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Abstract

Accelerated approval pathways for generic medicines improve patient access and reduce healthcare costs by speeding market entry without compromising quality. The U.S., Switzerland, the U.K., and Japan have developed distinct mechanisms to prioritize generic application reviews amid evolving regulatory frameworks. This review compares fast-track approval criteria, review timelines, documentation requirements, and reliance or harmonization efforts across the FDA, Swissmedic, MHRA, and PMDA. A systematic literature search from January 2000 to June 2025 included peer-reviewed articles and official guidance. Data on review timelines, eligibility criteria, dossier requirements, and reliance agreements were extracted using a standardized template. Comparative tabulation identified similarities and differences. The FDA's Priority Review targets an eight-month approval for eligible ANDAs, supported by GDUFA performance goals. Swissmedic's accelerated assessment shortens review from 330 to 150 days, enabled by pre-application hearings and the Access Consortium. MHRA offers 60- and 110-day tracks through the International Recognition Procedure by accepting reference regulators' decisions. PMDA prioritizes generics within a nine-month timeline, supplemented by pre-submission consultations and "Harmonization by Doing" initiatives. All agencies require bioequivalence via ICH CTD modules but differ in clock-stop policies, administrative demands, and reliance frameworks.

Conclusion: While agencies align on bioequivalence and dossier formats, differences in timelines, review mechanisms, and dossier requirements challenge submission planning. Standardizing performance goals, reducing administrative burdens, and harmonizing reliance agreements are emerging good practices supporting faster global access to generic drugs.

Keywords: Fast-track approval, Generic drug regulation, Abbreviated New Drug Application, Bioequivalence, FDA regulatory pathways, Swissmedic accelerated assessment, MHRA International Recognition Procedure, PMDA Priority Review, Regulatory harmonisation, Expedited generic drug approval

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1. Introduction

Generic medicines ensure affordable, clinically equivalent therapies, enhancing adherence and reallocating healthcare resources. However, divergent regulatory processes can delay market entry and erode cost savings. To address this, major agencies have adopted expedited pathways tailored for generics. Designation and Conditional Early Approval systems to allow submissions without confirmatory trials, achieving review windows as short as nine months-with post-marketing studies required

1.1. Role of generics in healthcare access and cost control

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act, Pub. L. 98-417) streamlined generic drug entry into the U.S. market. Grabowski and Vernon (1) reported that generics rose from 10% of prescriptions in the early 1980s to 40% by the mid-1990s, while Berndt and Aitken (2) found an increase from 49.7% to 74.5% between 1999 and 2004. A generic drug is equivalent to a brand-name product in dosage, strength, route, quality, performance, and intended use.(3) It must contain the same active ingredients and demonstrate bioequivalence, offering the same therapeutic effect at a lower cost.

Generic drugs have saved billions by reducing brand-name drug costs, which rose 62.1% while generics fell 36.9% from 2014-2018. (4) Making up 90% of prescriptions, generics enable savings like the $14.5 billion yearly from Express Scripts' formulary, limiting spending growth and keeping patient costs low ($11.55 per 30 days). Future

savings depend on biosimilars and specialty generics, projected to cut spending by $54 billion and $24 billion respectively, if supported by regulatory policies on

interchangeability. Generics remain vital for optimizing healthcare budgets and access. (4)

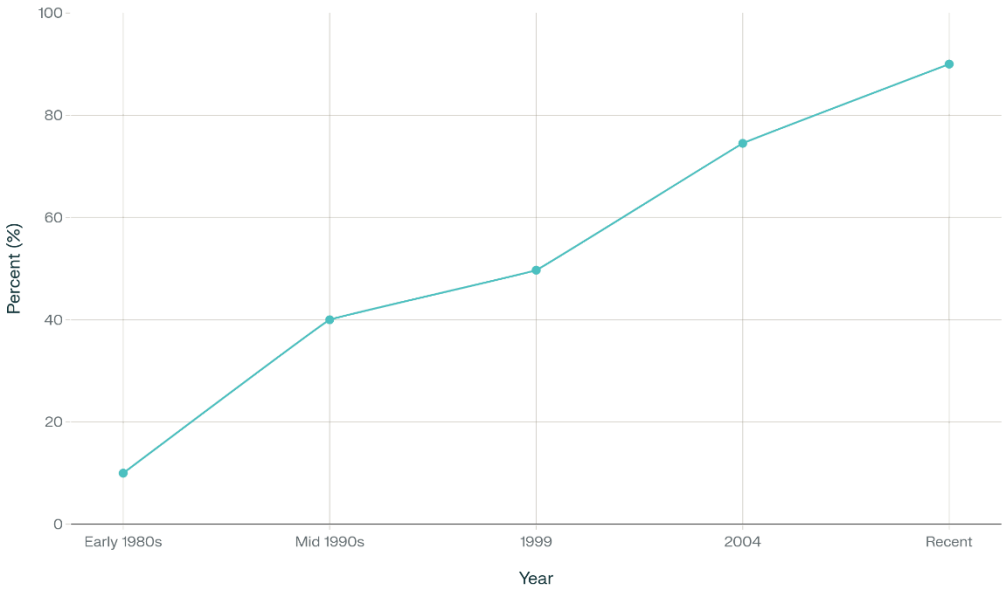


Figure 1. Growth of Generic Drug Prescriptions Over Time

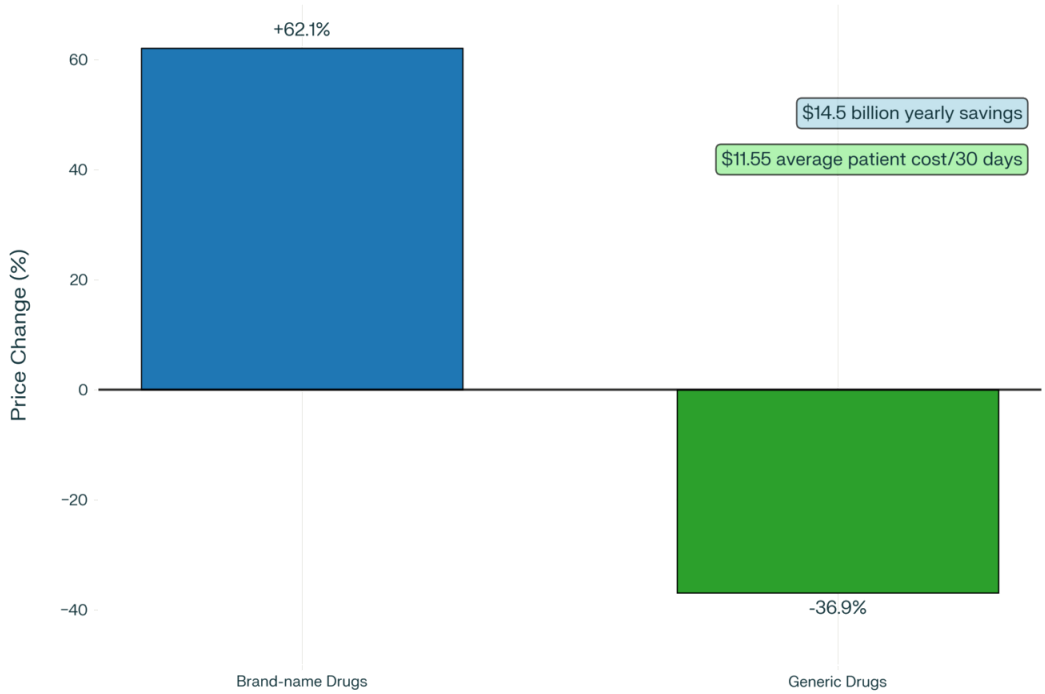


Figure 2. Prescription Drug Price Trends

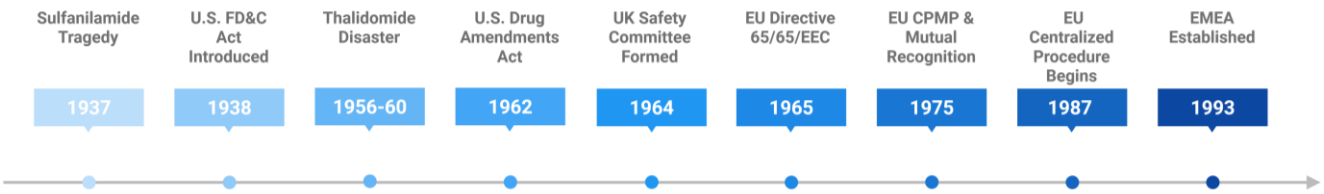


Figure 3. Major Regulatory Milestones

1.2. Need and Development of Regulations for Registration of Medicinal Product

Modern drug regulation arose from 19th-century scientific advances and major safety crises. The 1937 sulfanilamide tragedy led to the 1938 Federal Food, Drug and Cosmetic

Act mandating pre-market safety checks.(5,6) The thalidomide disaster (7) spurred the UK's Committee on the Safety of Drugs (8) and the 1962 U.S. Drug Amendments requiring efficacy proof and GMP compliance.(6) In Europe, Directive 65/65/EEC harmonized laws, (9) followed by standards and mutual recognition under Directives 75/318/EEC and 75/319/EEC, (10) culminating in Regulation EEC/2309/93 establishing the EMEA. (11)

Developing countries now have drug approval systems, but pharmaceutical companies face challenges due to differing national regulations, requiring duplicate documentation and complex data management.

1.3. Importance of Efficient Regulatory Pathways:

Efficient regulation ensures faster access to safe, effective medicines, lowers costs, avoids duplication, and promotes global market access. Fragmented systems delay treatments and increase development burdens.

To streamline processes, the 1989 ICDRA led to the 1990 creation of the International Conference on Harmonization (ICH) by the EU, US, and Japan, with WHO, EFTA, and Canada as observers. (8) ICH developed the Common Technical Document (CTD) to standardize submissions across regions, supporting faster and harmonized approvals. Regulatory Approvals: Process with Advanced Evasion Tactics Applied, when it comes to getting a new drug onto the market, companies can't just start selling straight away. There are a bunch of rules and checks in place to keep patients safe, and the whole goal is to make sure only medications that are both effective and not dangerous actually reach people. (12)

a. **Starting point:** Companies must obtain approval before making, selling, or distributing medicines. Regulators require proof that the drug is effective and safe.

b. **Application submission:** The process begins when a company compiles detailed data on drug manufacturing, lab results, efficacy, and potential side effects.

c. **Quality, efficacy, and safety checks:** Applications must include evidence that the drug meets quality standards, works as intended, and poses no unacceptable risks, along with an explanation of how it differs from existing products.

d. **Area-specific review:** The application is submitted to the regulator in the intended market. Because laws differ by region, companies may need to adapt their submissions for each jurisdiction.

e. **Purpose:** Every step protects patient safety. Skipping procedures or rushing reviews could lead to harmful consequences.

1.4. Rationale for comparing these four agencies

Regulatory agencies including the FDA, Swissmedic, MHRA, and PMDA control global pharmaceutical markets scientifically. These institutions offer global regulatory standards for generic pharmaceutical approval speeds as founding or core members of the International Council for Harmonisation (ICH).

Each agency's unique and complementary insights aid selection:

a. The FDA (US) characterized by the empty-based evaluation and explicit ANDAs, suitability requests, CGT assignment procedures are embraced by the western world. The foundational comparison technique of it lies in its technique.

b. The other strategic case study of a regulatory dependency is Swissmedic Its partial-regulatory style uses the authority of the EU and others demanding authority ("Recognised/Reference Approvals") within its aesthetics of sovereignty, engaging faster market entry into a smaller and more cost-effective market.

c. UK MHRA is post-Brexit regulator. The development of new accelerated mechanisms of assessment such as the European Commission Decision Reliance Procedure (ECDRP) and the International Reliance Routes indicate how a significant regulator changes its generic approval system after geopolitical upheaval.

d. Japan The PMDA of Japan gives a non-Western perspective of a huge market in Asia. The less bureaucratic decision-making process is cooperative and effective; promotes quality and bioequivalence, and vocalizes local concerns, and balances western paradigms.

The four approaches to generic approvals, including independent assessment by the FDA and PMDA and structured dependency at Swissmedic and the MHRA, invite critical comparison. These agencies address global challenges in patient access and cost through innovative methods for complex generics, easing supply constraints and promoting competition. Comparing major regulators across North America, Europe, and Asia provides valuable guidance for generic manufacturers developing international submission strategies and for national regulators seeking to enhance expedited approval pathways amid increasing harmonization and diverse national goals.

1.5. Scope: Agencies covered (FDA, Swissmedic, MHRA, PMDA)

This review focuses on the fast track systems for authorizing generic drugs in four major regulatory agencies: the U.S. Food and Drug Administration (FDA), Swissmedic (Swiss Agency for Therapeutic Products), the UK Medicines and Healthcare products Regulatory Agency (MHRA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA). Their mandates, jurisdictions, and specific fast track mechanisms for generic applications are summarized below.

a. U.S. Food and Drug Administration (FDA)

The FDA, under the Federal Food, Drug, and Cosmetic Act, regulates pharmaceuticals in the United States and evaluates generic drugs via Abbreviated New Drug Applications (ANDAs, section 505(j)). To expedite approval of generics addressing public health priorities - such as drug shortages or first-to-file paragraph IV

challenges - the FDA grants Priority Review, shortening the goal review time from 10 to 6 months. (13)

Requests for Priority Review must be made explicitly by applicants, except for submissions related to drug shortages or public health emergencies, which the FDA may prioritize automatically. (14) Under the Fast Track process introduced in 1997, sponsors of serious-condition therapies can engage in rolling review, submitting sections of an ANDA as they become available and receiving more frequent interactions with review staff. (15)

b. Swissmedic

Swissmedic oversees medicinal products in Switzerland. In July 2025, it launched a Fast-Track Authorisation Procedure (FTP) pilot for clinical trial applications, reducing review times from 30 to 20 days for known investigational products and from 60 to 40 days for first-in-human studies, with the pilot running through 2026. (16) For marketing authorisations of generics, Swissmedic applies an Accelerated Assessment pathway - targeting a 150-day evaluation - under its guidance document ZL104_00_002e, effective January 2021. (17) Additionally, Swissmedic participates in multilateral reliance initiatives such as the Access Consortium, enabling concurrent reviews with agencies in Australia, Canada, Singapore, and others. (18)

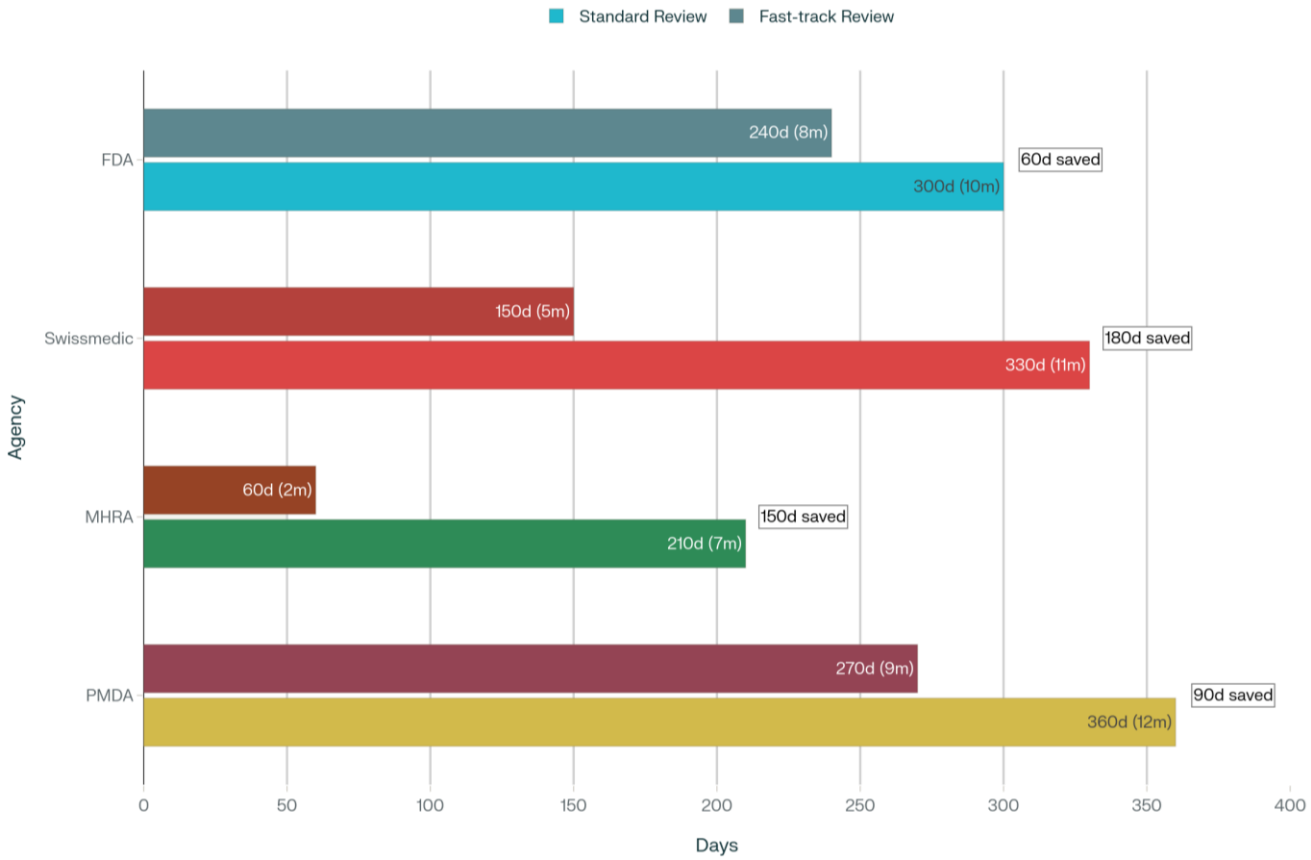


Figure 4. Drug Review Timelines

c. MHRA (UK)

The MHRA regulates human medicines in Great Britain. As of January 2024, the International Recognition Procedure (IRP) replaced the EU Decision Reliance Procedure, offering two routes:

- Recognition A: Approval within 60 days for products authorised by a reference agency within the previous 2 years.
- Recognition B: Approval within 110 days (with a clock-stop at day 70) for products authorised within the previous 10 years. (19)

For generics, the MHRA also maintains a supply-shortage fast-track for vital medicines and permits rolling review of ANDAs in eCTD format, with no additional fees. (20)

d. PMDA (Japan)

The PMDA, under Japan's Ministry of Health, Labour and Welfare, handles generic approvals via CTD-style ANDAs. The standard target review time for new generics is 12 months - 9 months for dossier evaluation plus up to 3 months for GMP inspections. Under its mid-term plans, the PMDA has steadily reduced the median total review time, aiming for 10 months by FY 2018. (21) Priority Review generics, which are identified as such on the basis of clinical utility and serious-disease considerations, are expected to take 9 months to move between submission and approval. (22) The agency also provides pre-submission consultation in bioequivalence as well as quality, and an iterative discussion helps in the faster acceptance of the dossier. (21)

Generic medicines play a crucial role in enhancing access to health care and in lowering drug prices, with generic products now accounting for nearly 90 percent of prescriptions and huge savings across all world regions. The regulatory bodies have issued expedited pathways to

rapidly introduce products in the market with no compromise on safety or quality.

The FDA shortens generic approvals to about six months through Priority Review and Fast Track. Swissmedic uses Accelerated Assessment and reliance to achieve reviews in around 150 days. The MHRA grants rapid approvals within 60 to 110 days post-Brexit, while Japan's PMDA completes reviews in about nine months via Priority Review and collaboration. Harmonization efforts like the ICH Common Technical Document simplify submissions, helping generics reach markets faster and improving patient access and affordability.

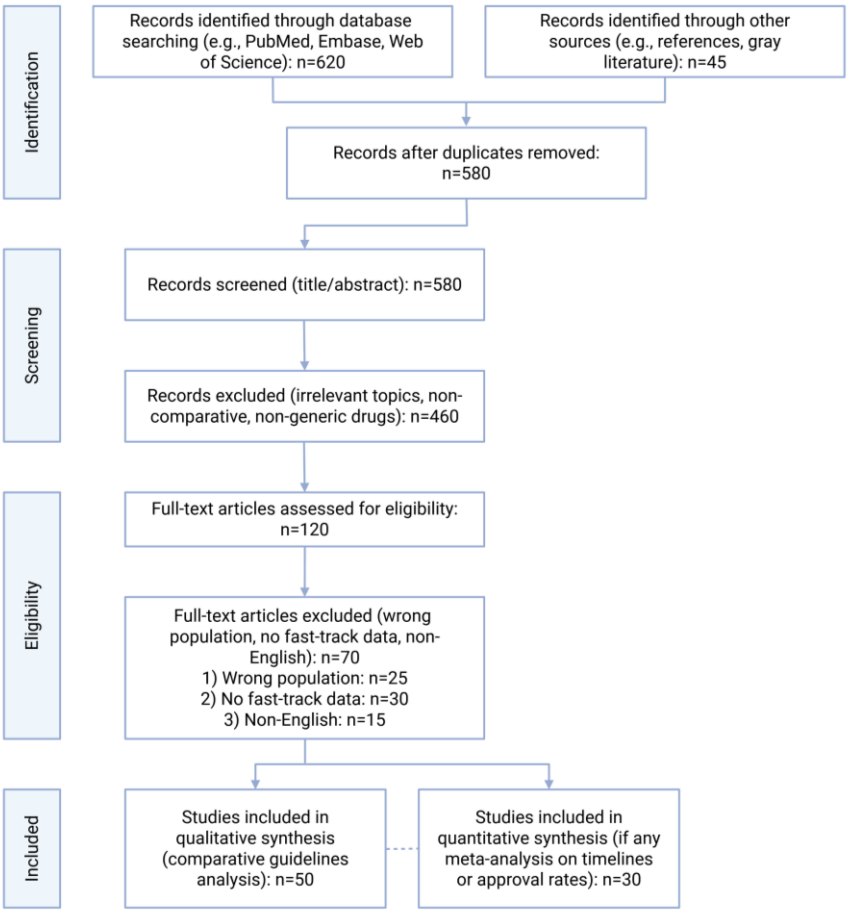


Figure 5. PRISMA statement flow diagram

2. Method/Approach

2.1. Literature-Search Strategy (Databases, Date Range)

A comprehensive literature search was conducted to gather evidence on accelerated approval of generic drugs by the FDA, Swissmedic, MHRA, and PMDA. To ensure transparency and reproducibility, peer reviewed and regulatory grey literature from January 2000 to June 2025 were included across PubMed, Embase, Scopus, and Web of Science (23) Controlled vocabulary such as PubMed MeSH and Embase Emtree, combined with free text terms and Boolean logic, improved precision. Search terms linked generic drug descriptors with expedited approval terms and agency names. Grey literature was expanded through manual searches of regulatory websites, policy archives, and guidance documents, with citation screening adding further sources. (24) This integration of scholarly and institutional evidence provided a robust foundation for analyzing expedited generic drug approval pathways, with inclusion criteria focused on generic fast track mechanisms.

Inclusion Criteria:

- Focus on expedited or fast-track generic drug approval pathways.
- Originates from or pertains to FDA (US), Swissmedic (Switzerland), MHRA (UK), or PMDA (Japan).
- Published in English to ensure consistency in analysis.
- Publication date range: 2000 to 2025, reflecting modern developments.
- Contains methodological detail on pathway design, eligibility, or performance metrics such as timelines and outcomes.

Exclusion Criteria:

- Pathways only addressing new/novel biologics, vaccines, or orphan drugs.
- Document types limited to opinion pieces, commentaries, or editorials without empirical or regulatory detail.
- Duplicate or superseded documents replaced by newer official guidance.
- Non-English sources to maintain clarity and comparability across documents

Eligible documents comprised peer-reviewed articles or official regulatory guidance detailing expedited approval processes for generic drugs issued by the four agencies in English between 2000 and 2025. Studies solely describing novel or biologic drug pathways, opinion pieces without methodological rigor, and superseded guidance were excluded. (25) A two-stage screening process was employed: titles and abstracts were triaged independently by two reviewers, followed by full-text assessment for eligibility, with disagreements resolved by consensus. (26)

2.2. Comparative Framework Dimensions

Data were extracted using a standardized framework covering four key dimensions: review timelines (e.g., six-month FDA priority review, 150-day Swissmedic accelerated assessment), eligibility criteria (e.g., paragraph IV certification, reliance on reference agency decisions), documentation requirements (e.g., CTD modules versus ANDA structure, bioequivalence and stability data), and fee structures including user fees and pre-submission consultations. (27) A piloted extraction form captured agency, pathway name, implementation year, and related attributes. Extraction was performed in duplicate with consensus meetings resolving discrepancies. (28) Narrative synthesis integrated the extracted data, with tabulation enabling pattern recognition across agencies. Conceptual maps and thematic matrices explored links between reliance policies and review timelines. (29) The synthesis was critically appraised for data quality, completeness, and transparency, following PRISMA 2020 reporting standards. (30)

2.3. Limitations of the Review

The review adds scholarly value by providing a cross-jurisdictional comparison of expedited generic drug approval pathways, examining regulatory frameworks, standards, and timelines to highlight global heterogeneity and harmonization opportunities. Its transparent, reproducible methodology using regulatory databases and bias-free source selection ensures rigor, while qualitative synthesis retains contextual nuance where meta-analysis is inappropriate. The findings identify regulatory challenges, good practices, and research gaps on fast-track mechanisms, offering actionable insights for policymakers and industry, and the review is presented with transparency, impartiality, and real-world relevance.

3. Conceptual Overview of Fast-Track Pathways

Expedited regulatory pathways are specialized mechanisms that accelerate the development, review, and approval of medical products addressing serious or life-threatening conditions with needs. While originally designed for novel therapeutics, these pathways fundamentally reshape the regulatory landscape.

3.1. US Food and Drug Administration (FDA)

The FDA's Fast Track program (1988) facilitates development of drugs treating serious conditions by increasing sponsor - FDA communication and allowing "rolling" submission of application modules (e.g., clinical, manufacturing) before complete dossier filing. (31) In 1992, the Accelerated Approval pathway was created to permit approval based on surrogate or intermediate clinical endpoints reasonably likely to predict clinical benefit, subject to post-marketing confirmatory trials; failure to verify benefit can trigger withdrawal. (32) Priority Review reduces the standard ten-month review clock to six months for New Drug Applications (NDAs) and Biologics License Applications (BLAs) meeting criteria of significant safety or efficacy improvements in serious diseases. (33) In 2012, Breakthrough Therapy designation was introduced to grant intensive FDA guidance, rolling review, and senior management commitment for products showing preliminary evidence of substantial improvement over existing therapies. (34, 35) Most recently, the Regenerative Medicine Advanced Therapy (RMAT) designation (2017) extends Breakthrough advantages to cell and gene therapies, with added support for accelerated approval and post-approval requirements. (36)

3.2. European Medicines Agency (EMA)

The EMA's Accelerated Assessment (2005) shortens the CHMP opinion timeline from 210 to 150 days (excluding applicant response time) for products of major public-health interest and innovation with strong evidence addressing unmet needs. (31, 37) For very rare or life-threatening conditions where comprehensive data are impractical, the Marketing Authorization under Exceptional Circumstances allows conditional approval without full data, with obligations for ongoing safety and efficacy monitoring. (38) The Conditional Marketing Authorization pathway (2006) grants one-year renewable approvals based on initial positive data in serious conditions or orphan products, requiring comprehensive follow-up data. (39) In 2016, the PRIME scheme (PRIority MEdicines) was launched to support early dialogue and guidance for pioneering therapies - especially advanced-therapy medicinal products - by appointing rapporteurs, organizing kick-off meetings, and offering scientific advice, with potential for accelerated assessment. (40, 41)

3.3. Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Japan's Priority Review (2000s) allocates nine months instead of 12 for products addressing serious diseases with superior clinical usefulness or orphan status. (42) The Conditional and Term-Limited Approval system (2014) grants up to seven years for regenerative medical products based on early-phase promising data, mandating post-approval studies and resubmission within the term. (43, 44) A similar Conditional Approval pathway for drugs (2017) applies when confirmatory trials are deemed infeasible, requiring post-marketing surveillance and studies but without a fixed validity term. (44) Unique to Japan is the *Sakigake* (さきがけ) designation (2015), requiring first-in-Japan development with early-phase efficacy signals; it offers expedited six-month review, prioritized consultation, concierge PMDA support, and extended re-examination periods. (45, 46)

3.4. Historical Evolution of Fast-Track Mechanisms

Expedited pathways gained traction with the FDA Modernization Act of 1997, which addressed review delays and established orphan drug incentives. (35) The Accelerated Approval pathway arose during the HIV crisis to balance rapid access and evidence needs. (32) Europe

later introduced conditional and exceptional routes (2005-2006), and Japan followed with Sakigake and conditional systems (2014-2017), advancing global alignment of urgent-need frameworks. (39, 43, 47)

3.5. Relevance to Generics versus Novel Drugs

Fast-track pathways exclusively serve novel therapeutics; generics, requiring demonstration of bioequivalence to reference products rather than novel clinical benefit, are ineligible. Generics follow established abbreviated regulatory routes (e.g., ANDA in the US or EMA's generic procedures) without expedited designations. For biosimilars - complex biologics that mimic original biologics - some accelerated pathways (e.g., FDA's Biosimilar User Fee Act timelines) may apply, but they remain distinct from innovative drug designations. Thus, fast-track designations incentivize R&D of first-in-class or innovative products, not market entry of generics.

4. Agency Profiles

4.1. U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) employs expedited programs within the Office of Generic Drugs (OGD) in the Centre for Drug Evaluation and Research (CDER) to accelerate generic drug availability, reducing costs and improving patient access.

Under the Federal Food, Drug, and Cosmetic Act, generic products are approved via Abbreviated New Drug Applications (ANDAs) under section 505(j). ANDAs rely on the safety and efficacy findings of a Reference Listed Drug rather than de novo clinical trials. The OGD oversees ANDA reviews, publishes generic-competition metrics, and implements user-fee programs under the Generic Drug User Fee Amendments (GDUFA) to ensure affordable generics reach the market promptly. (48)

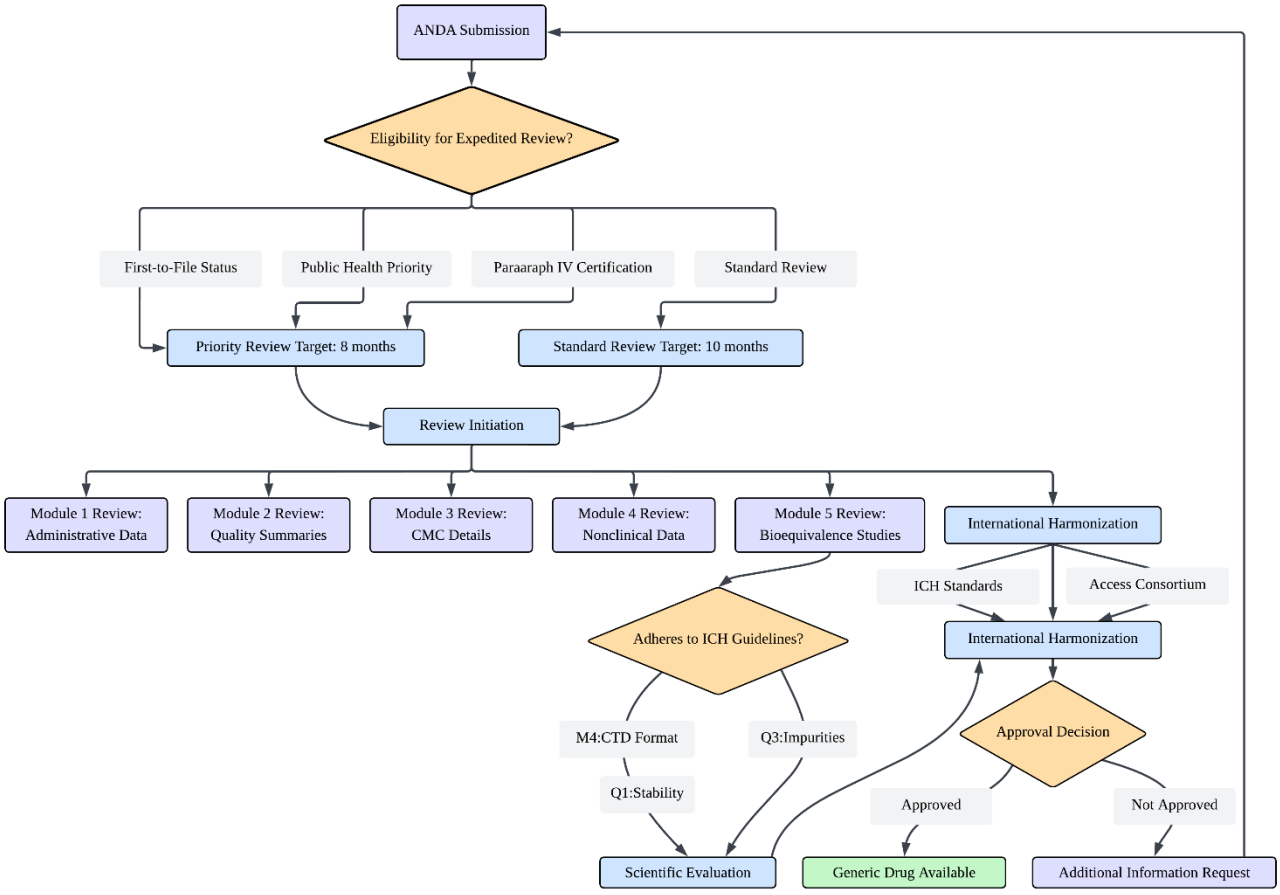
b. Fast-Track Procedures

Although "Fast Track" designation formally applies to novel therapies, ANDAs benefit from Priority Review under CDER's Management of Policy and Procedures (MAPP) 5240.3. First-to-file ANDAs eligible for 180-day exclusivity or those addressing drug shortages can request Priority Review to accelerate evaluation. (49)

c. Eligibility Criteria

Generic applications qualify for expedited review if they meet one or more criteria:

- First-to-File Status: Earliest submitted ANDA eligible for 180-day exclusivity.
- Public Health Priorities: Generics addressing current or potential drug shortages receive automatic prioritization. (50)



a. Regulatory Context

- Paragraph IV Certifications: ANDAs containing patent-challenge certifications often receive prioritization,

Figure 6. USFDA's Approval Process Flow chart

d. Target Review Timelines

Standard ANDA reviews target completion within 10 months. Priority Review shortens this to 8 months, aligning with the six-month goal for Priority NDAs plus generic-specific allowances. The FDA publishes quarterly performance metrics demonstrating ongoing reductions under successive GDUFA reauthorizations. (51)

e. Documentation Requirements

ANDA dossiers follow the ICH Common Technical Document (CTD) format - Modules 1-5 - comprising administrative data, quality, nonclinical, and clinical (bioequivalence) information. (52) Key modules include:

- Module 2: Summaries of bioequivalence studies and quality assessments
- Module 3: Chemistry, Manufacturing, and Controls (CMC) details, including stability protocols
- Module 4: Nonclinical data (typically waived for generics)
- Module 5: Bioequivalence study reports demonstrating therapeutic equivalence. (53)

f. Reliance and Harmonization Efforts

The FDA adheres to ICH guidelines (M4 for CTD; Q1 for stability; Q3 for impurities) to harmonize dossier structure globally. (54) While generics do not directly rely on foreign approvals, the FDA participates in international forums - such as ICH and the Access Consortium - to align scientific standards and share best practices, indirectly expediting generics by fostering common technical expectations. (55)

By integrating ANDA-specific Priority Review under established user-fee programs and leveraging ICH harmonization, the FDA's expedited pathways ensure timely access to safe, effective generics without compromising quality.

4.2. Swissmedic

Swissmedic, based in Bern, is Switzerland's regulatory authority for medicines and medical devices. Established on 1 January 2002, it succeeded IKS and SANZ, and operates under the Federal Department of Home Affairs.

a. Regulatory context

In Switzerland, the Swiss Agency for Therapeutic Products (Swissmedic) serves as the national regulatory authority responsible for the evaluation, authorization, and surveillance of medicinal products, including generics, under the Therapeutic Products Act (TPA). Swissmedic's mandate encompasses scientific assessment of quality, safety, and efficacy based on submitted documentation, coupled with post-marketing vigilance and inspection functions. (56)

b. Fast-track procedures

Swissmedic offers a Fast-Track Authorisation Procedure (FTP) for generic and established products whose applications meet predefined criteria. As of 15 October 2024, the FTP and Temporary Authorisation processes were consolidated into an Accelerated Application Hearing (AAA) mechanism, replacing separate FTP applications. Applicants may request a AAA between two and twelve months before dossier submission to determine, in consultation with Swissmedic, whether accelerated or temporary approval is feasible. The AAA culminates in a binding decision documented in official minutes and communicated within the hearing. (57)

c. Eligibility criteria

Eligibility for the FTP/AAA requires demonstration that the product conforms to conditions set out in Swiss TPA Art. 18, including: the product having a known active pharmaceutical ingredient approved in Switzerland or a reference country; identical indication, dosage form, and strength to the reference product; and no safety or efficacy concerns from previous assessments. Products addressing imminent public-health needs or shortages may also qualify. (58) To forego the AAA, applicants can submit supplemental documentation with their request illustrating full compliance with FTP criteria; Swissmedic then issues an official order approving the accelerated route and confirming the dossier submission date. (59)

d. Target review timelines

Under FTP, Swissmedic targets a 150-day scientific assessment for marketing authorisation applications for generics, compared with 330 days under standard review, excluding applicant response periods. (60) The AAA itself is scheduled to occur six to eight weeks following the request, lasting up to 1.5 hours, and concludes with a written decision within 30 days of formal control completion. (57) Temporary authorisations follow a similar timeline, with Swissmedic issuing final decisions no later than 30 days after documentation assessment. (59)

e. Documentation requirements

Documentation for FTP and standard MAA submissions must adhere to the ICH Common Technical Document (CTD) format. Modules 2-5 covering quality, nonclinical, and clinical (bioequivalence) data are required alongside Module 1 regional information specified by Swissmedic's eCTD guidance. Module 1 must include a cover letter, application form, administrative data, and regional particulars (e.g., Swiss regional XML instance), structured according to OS000_00_007e guidance. (61)

f. Reliance or harmonization efforts

Though generics do not benefit from direct reliance on foreign approvals, Swissmedic actively participates in multilateral harmonisation initiatives. Notably, Swissmedic is a member of the Access Consortium - a collaboration with Australia's TGA, Health Canada, Singapore's HSA, and the UK's MHRA - to share assessment reports, technical guidelines, and inspection findings to enhance. (62)

4.3. Medicines and Healthcare products Regulatory Agency (MHRA)

The Medicines and Healthcare products Regulatory Agency (MHRA) is the United Kingdom's regulatory authority for medicines, operating under the Human Medicines Regulations 2012. It ensures that medicinal products, including generics, meet high standards of

quality, safety, and efficacy before granting marketing authorisations (MAs). (63)

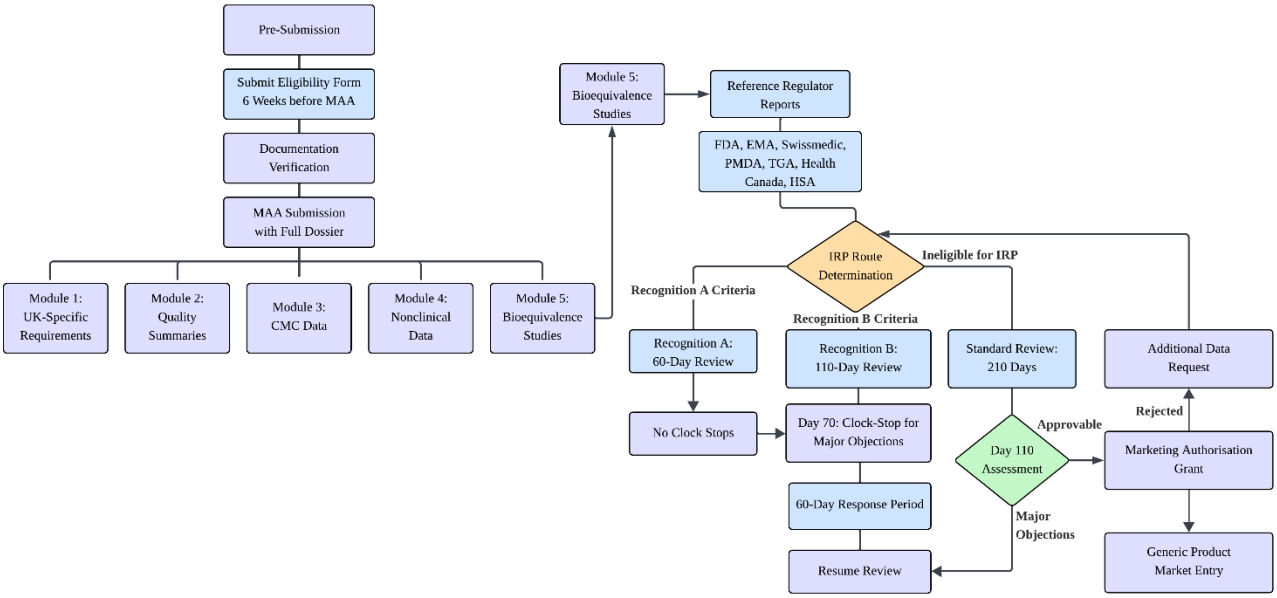


Figure 7. Swissmedic's Approval Process Flow chart

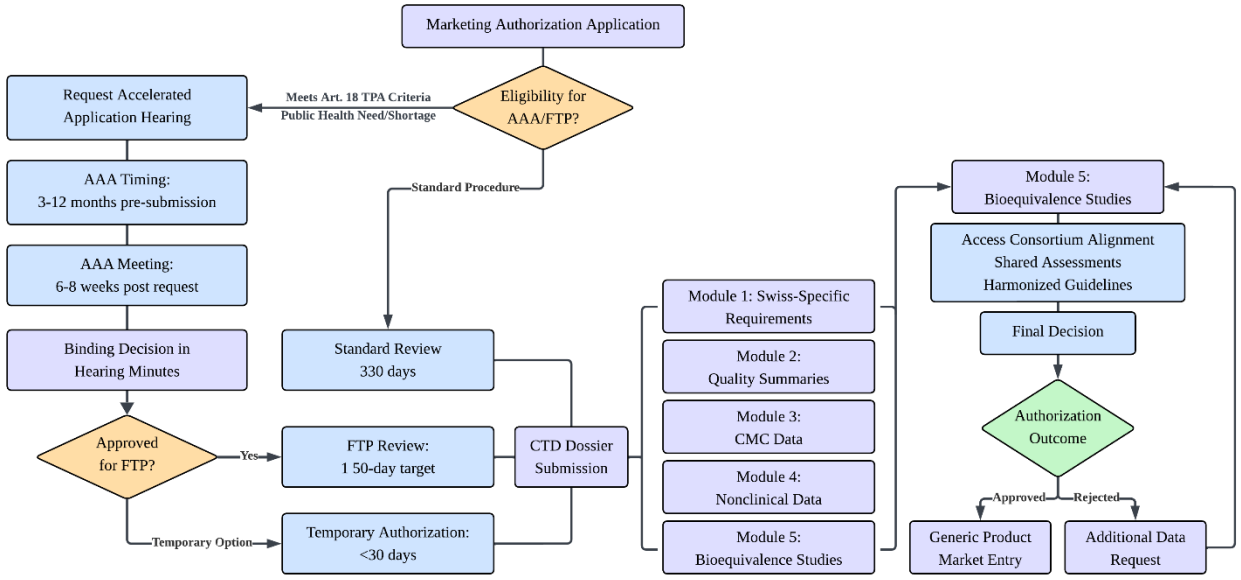


Figure 8. MHRA's Approval Process Flow chart

a. Regulatory context

Regulatory context encompasses national legislation and post-Brexit frameworks. Since 1 January 2024, MHRA replaced the European Commission Decision Reliance Procedure (ECDRP) and Mutual Recognition/Decentralised Reliance Procedure (MRDCRP) with the International Recognition Procedure (IRP), reflecting its independent status and ability to leverage assessments from seven "reference regulators" (RRs): FDA, EMA, Swissmedic, PMDA, TGA, Health Canada, and HSA Singapore. (64)

b. *Fast-track procedures*

Under IRP, two expedited routes accelerate marketing authorisation applications. Recognition A offers a 60-day calendar-day timetable from validation without clock-stops, provided the RR granted full approval within the past two years, the manufacturing process and GMP compliance mirror the RR's, and none of the Recognition B criteria apply. (65)

Recognition B allows 110 calendar days with one 60-day clock-stop at day 70 for major objections; it covers products authorised by RRs up to ten years prior or those with conditional approvals, new sites, UK-specific pharmacovigilance requirements, or substantive CMC changes. (65)

c. Eligibility criteria

Eligibility for IRP requires identical qualitative/quantitative composition and pharmaceutical

form to the RR product, shared applicant identity, completed eligibility form submitted six weeks before MAA, and English translations of all RR documents. (64, 65) Generics must also respect UK data and market exclusivity periods, and comparator products used in bioequivalence studies must be sourced from UK/EU/EEA markets until Windsor implementation. (66)

d. Target review timelines

Target review timelines under IRP significantly undercut the standard 210-day national route. Recognition A aims for MA grant within 60 days; Recognition B within 110 days, reverting to 210 days if major objections persist beyond day 110. (65)

e. Documentation requirements

Documentation requirements follow ICH CTD Modules 1-5 with UK-specific Module 1.2 containing eligibility form and cover letter stating IRP route, RR, and any conditional approvals or UK-specific risk minimisation measures. (64) Applicants must include full RR assessment reports (initial and major post-authorisation), final product information, and a table of dossier differences versus the RR submission. (64)

f. Reliance or harmonization efforts

Reliance and harmonization efforts are embodied in IRP and MHRA's membership in the Access Consortium and Project Orbis, which facilitate work-sharing, common technical standards, and inspection outcomes. MHRA adheres to ICH guidelines (M4/Q1/Q3) to align dossier structure globally, ensuring consistency in quality, stability, and impurity evaluations. (67)

4.4. The Pharmaceuticals and Medical Devices Agency (PMDA)

The Pharmaceuticals and Medical Devices Agency (PMDA) is Japan's regulatory body for pharmaceuticals and medical devices. As an Independent Administrative Institution, it ensures their safety, efficacy, and quality, functioning similarly to the FDA in the U.S. and other national regulators.

a. Regulatory context

The Pharmaceuticals and Medical Devices Agency (PMDA) operates under Japan's Ministry of Health, Labour and Welfare to evaluate and regulate pharmaceuticals via the Pharmaceutical and Medical Device Act. Generic drugs are approved through Abbreviated New Drug Applications (ANDAs) in Common Technical Document (CTD) format, with scientific assessment conducted by expert review teams complemented by external specialists to ensure rigorous evaluation of quality, efficacy, and safety. (68)

b. Fast-track procedures

Fast-track procedures for generics centre on the Priority Review designation, introduced under PMDA's Mid-Term Plan (2009-2013) to shorten review timelines for applications addressing critical public-health needs or patent-challenge scenarios. Standard generics undergo a 12-month total review (nine months for dossier assessment plus up to three months for GMP inspection), whereas priority generics target a nine-month total review, comprising eight months of dossier evaluation and one month for inspection and administrative processes. By FY 2018, PMDA aimed to routinely achieve this nine-month target through intensive pre-submission consultations and streamlined inquiry cycles. (69)

c. Eligibility criteria & Target review timelines

Eligibility for Priority Review requires demonstration of therapeutic equivalence to a reference product and evidence of market-need factors such as impending or actual drug shortages. Sponsors may request designation during pre-submission consultations with PMDA's Office of Bioequivalence, which clarify bioequivalence study designs, analytical methods, and quality expectations. Products meeting these criteria and those containing Paragraph IV patent-challenge certifications qualify for accelerated timelines. (69)

d. Documentation requirements

Documentation requirements adhere to ICH's M4 CTD guidelines, with Modules 2-5 covering quality, nonclinical, and clinical (bioequivalence) data, and Module 1 containing PMDA-specific administrative information per the "Overview of Generic Drug Policy and Introduction of its Review Process" (70). Applicants may submit Drug Master Files (DMFs) for proprietary API details, referencing the MF registration certificate to protect proprietary manufacturing processes while ensuring regulatory transparency. (70)

e. Reliance or harmonization efforts

PMDA actively engages in international harmonization and reliance efforts. As a founding ICH member, it incorporates ICH guidelines for CTD structure, stability testing (Q1), and impurity control (Q3). Through the Harmonization by Doing (HBD) initiative with the U.S. FDA, PMDA conducts joint scientific sessions to align evaluation standards and regulatory science approaches. Participation in APEC's Regulatory Harmonization Steering Committee further promotes work-sharing and capacity building, with PMDA designated as a Centre of Excellence for Good Registration Management and pharmacovigilance. Mutual Recognition Agreements (MRAs) for GMP inspection results reduce duplication and reinforce global convergence of regulatory practices. (71)

By coupling defined target timelines, structured pre-submission support, and robust international collaboration, PMDA's fast-track pathways enhance timely patient access to high-quality generic medicines in Japan without compromising regulatory rigor.

5. Comparative Analysis

The generic drugs are now playing an important and fast-growing role in enhancing patient access to essential drugs at affordable prices across the world. With healthcare prices escalating to hitherto unseen levels and the need of affordable treatment solutions to be more widely accessible, generic drugs represent an important tool that help achieve this goal through fostering greater access to therapeutic substitutes, which ultimately benefits the

directions of both the national and the global health, as well as the financial capability of patients and healthcare facilities to address them. In appreciation of how crucial this is, regulatory authorities in various countries worldwide have come up and established so called expedited review pathways especially crafted to promote the acceleration of the generic drug evaluation and approval process. The objectives of the pathways are to help the products be easily captured in the market without lowering the level of requirements to make sure that safety, efficacy, and quality would not be at stake.

When there is large-scale harmonization in the global regulatory bodies as the common objective of approving new drugs with fewer administrative hassles and reducing review periods to a considerable extent is involved, the actual execution of the same shows there is a prominent variance. Differences in such areas are mostly due to different eligibility rules, workflows, and areas of focus, which are revealed by the specific healthcare environment, population health, and legislative frameworks of each control body. The non-uniformity of best practice approaches emphasizes the complexity of attaining a uniform global regulatory practice but also presents a chance of learning and adoption of best practice.

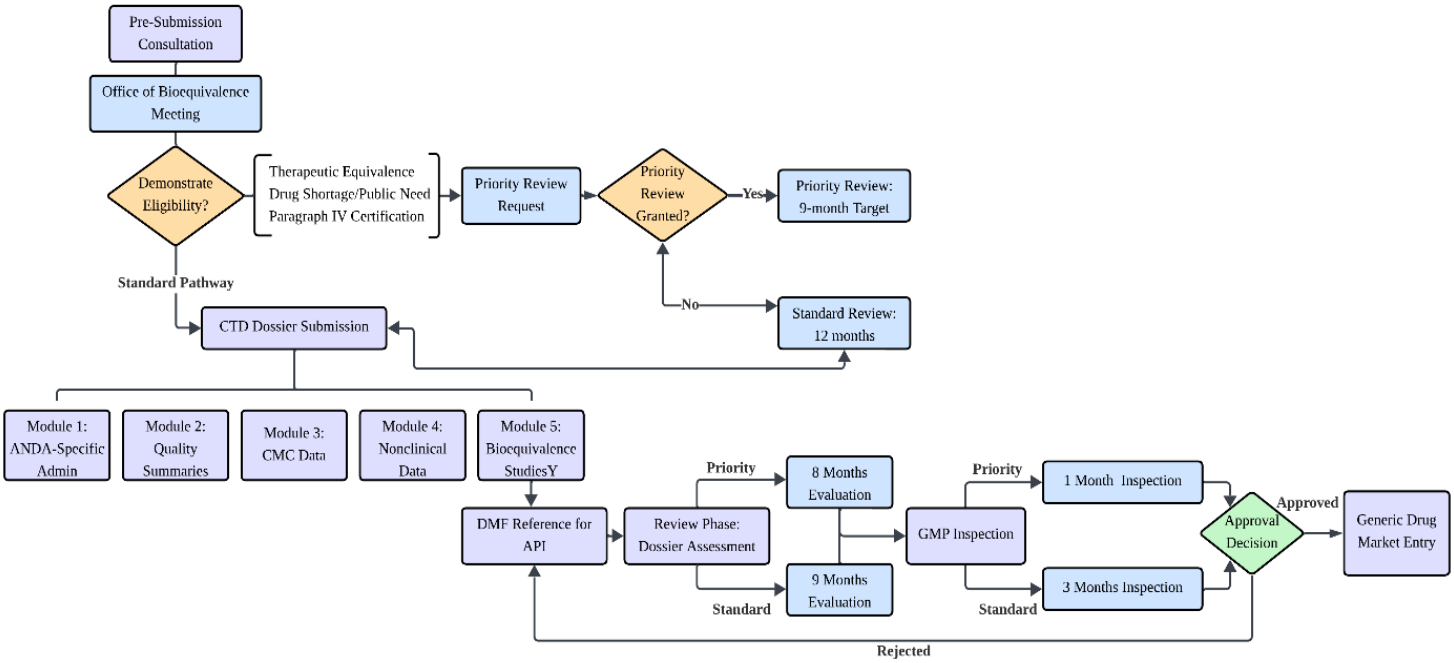


Figure 9. PMDA's Approval Process Flow char

Table 1. Synthesis of Key Parameters

Agency	Target Timeline	Bioequivalence Focus	Reliance/Harmonization Options
FDA (US)	Standard ANDA: 10 months; Priority Review: 8 months for qualifying ANDAs (e.g., first-to-file, shortages) (72)	Sole reliance on bioequivalence studies demonstrating therapeutic equivalence; quality assessments and facility inspections under GDUFA metrics (73)	Participation in ICH and bilateral work-sharing dialogues (e.g., HBD with PMDA); no formal reliance on foreign approvals (74)
Swissmedic	Accelerated Assessment: 150 days vs. 330 days standard (for generics under Accelerated Assessment pathway (75)	CTD Modules 3-5 bioequivalence and stability data; targeted "labelling loops" reductions to accelerate authorization (76)	Access Consortium work-sharing with TGA, Health Canada, HSA Singapore, and MHRA; bilateral GMP inspection MRAs (77)
MHRA (UK)	Recognition A: 60 days; Recognition B: 110 days; Standard: 210 days (IRP introduced 2024) (78, 79)	eCTD Module 5 bioequivalence reports; enhanced Module 1 UK-specific data (80)	International Recognition Procedure (IRP) leveraging reference regulator assessments; participation in Project Orbis and Access Consortium (78, 81)
PMDA (JP)	Standard: 12 months (9 + 3 months GMP); Mid-Term Plan objective for Priority Review: 9 months (82)	Bioequivalence studies in CTD Modules 3-5, optional API DMFs for confidential manufacturing data (83)	APEC-RHSC collaboration; Harmonization by Doing (HBD) program with FDA; founding ICH member; GMP inspection MRAs (84)

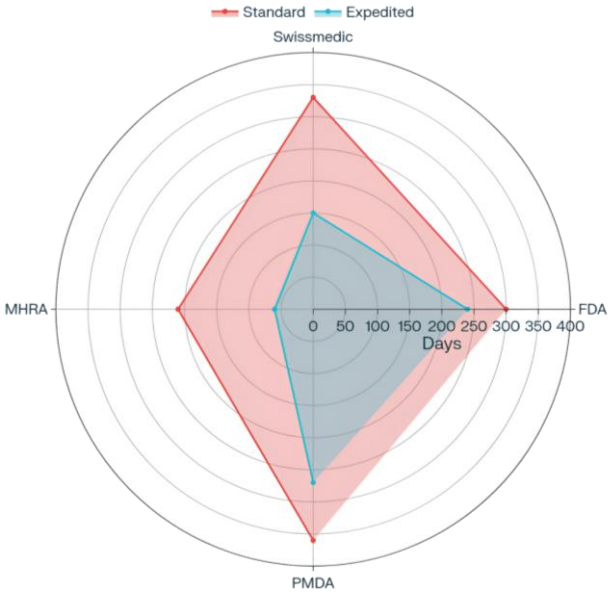


Figure 10. Drug Review Timelines Represent as Spider Radar Chart

5.1. Narrative Discussion of Convergences and Divergences

All the four regulatory bodies (i.e., FDA US, Swissmedic Switzerland, MHRA UK and PMDA Japan) emphasize the scientific high standards of bioequivalence as the basis of general drug approval. This requirement ensures that proposed generics meet the same therapeutic expectations as their innovator counterparts, providing prescribers and patients with confidence in efficacy and safety. Each agency requires generic applicants to submit detailed studies substantiating that the rate and extent of absorption of the generic drug matches that of the reference product within predefined parameters. (72)

This emphasis on bioequivalence is structurally embedded in the global adoption of the International Council for Harmonisation (ICH) Common Technical Document (CTD) format. Agencies expect submission of comprehensive data spanning Modules 2 through 5 (76):

a. Module 2: Summaries and overviews synthesizing the full body of quality, nonclinical, and clinical findings.

b. Module 3: Quality data, including manufacturing processes, controls, and characterization of drug substance and product.

c. Module 4: Nonclinical study report in case they are required with the particular cases.

d. Module 5: Clinical evidence concentrated on bio similarity studies, pharmacokinetic comparison as well as where this was required, supplemental clinical evidence.

These agencies encourage science-based and internationally consistent by requiring the CTD conformance, and the centrality of bioequivalence data, in this international harmonization framework. This not only simplifies regulatory submission on multinational generic manufacturers but further strengthens common belief in safety, quality, and interchangeability of therapeutically approved generic medicines. It indicates a move towards the best approaches on generic drug assessment on a global scale, involving not just scientific rigour but also regulatory harmonization. (82) The move provides that generics are approved on a global scale to maintain consistent safety and efficacy standards, and this makes it easy to build confidence with patients in addition to making cracking international markets.

The review and approval of generic drug application have significant variations in implementation among all the regulatory bodies around the globe, both located in time, which are determined not simply by legislative environments and agency-specific requirements but also by overall institutional capabilities, strategic health policy approaches, and the level of regulatory modernisation. The Food and Drug Administration (FDA) of the United States works under legislation initiative of the Generic Drug User Fee Amendments (GDUFA III) that helps streamline and improve predictability of the review mechanism. Within this framework, FDA is under a series of ambitious performance goals, such as reviewing and taking action on 90 percent of the priority Abbreviated New Drug Applications (ANDAs) within an eight-month interval and the discharge of all other ANDAs within a ten-month cycle, a well-scaled-up balance between pace and quality of regulatory scrutiny. (72)

In Switzerland, Swissmedic has instituted an Accelerated Assessment pathway that dramatically compresses the traditional 330-day generic drug evaluation timeline to a streamlined 150 days for qualifying applications. (75) This expedited process is facilitated by forward-looking regulatory interventions, most notably the implementation of pre-application Accelerated Application Hearings and the refinement of internal review protocols, which have collectively curtailed the occurrence of **x**iterative "labelling loops" and improved procedural throughput. (75, 76)

In the United Kingdom, the Medicines and Healthcare products Regulatory Agency (MHRA) has responded to the regulatory autonomy afforded by Brexit by introducing the International Recognition Procedure (IRP), an

innovative two-tiered mechanism that permits remarkably truncated review timelines - 60 calendar days for Recognition A and 110 days for Recognition B. This marks a significant departure from the prior EU-aligned 210-day standard and reflects a strategic pivot toward international harmonization and regulatory agility. (78)

Meanwhile, Japan's Pharmaceuticals and Medical Devices Agency (PMDA), guided by its Mid-Term Plan, is actively pursuing a reduction in the standard review duration for priority generic applications from twelve months to nine months. This objective is being advanced through the structural integration of dossier evaluation with Good Manufacturing Practice (GMP) inspections, thereby consolidating parallel review activities into a unified and tightly managed nine-month procedural framework. (82)

Reliance and Harmonization frameworks diverge significantly in both their structural design and regulatory scope. The U.S. Food and Drug Administration (FDA), for instance, does not operate under a formal reliance model; rather, it prioritizes independent regulatory decision-making rooted in domestic legal authority. While it participates in collaborative scientific dialogues - such as the Harmonization by Doing (HBD) initiative with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) - these engagements do not extend to accepting or relying on foreign regulatory approvals. Instead, the FDA emphasizes internal alignment through harmonized inspection protocols and review mechanisms, guided by the Generic Drug User Fee Amendments (GDUFA) performance metrics. (73, 74)

In contrast, Swissmedic demonstrates a more explicit reliance approach through its active participation in the Access Consortium, a strategic alliance with the Therapeutic Goods Administration (TGA) of Australia, Health Canada, Singapore's Health Sciences Authority (HSA), and the UK's Medicines and Healthcare products Regulatory Agency (MHRA). This collaboration facilitates the exchange of assessment reports and inspection outcomes among participating agencies, significantly reducing duplicative regulatory efforts and streamlining market entry processes. (77)

Another development of the reliance concept is the International Recognition Procedure (IRP) maintained by the MHRA. Using the IRP, the MHRA has been able to take advantage of full marketing-authorisation reviews undertaken by specially nominated reference regulators with the MHRA retaining its independence to undertake targeted scientific reviews and make final decisions. (79)

In the meantime, PMDA strengthens their international regulatory involvement with two capacities, that is, as a founding member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and as an important contributor to regional activities. Remarkably, it participates in the Asia-Pacific Economic Cooperation Regulatory Harmonization Steering Committee (APEC-RHSC) that facilitates arrangements involving work-sharing, mutual recognition of Good Manufacturing Practice (GMP) inspections, (84) and a wider regional regulatory convergence and efficiency.

5.2. Identification of Best Practices and Common Challenges

Best practices within leading regulatory bodies show a continuum of approaches toward achieving efficiency in review, transparency, and high-quality submissions aligned with each agency's mandate. The MHRA has pioneered a tiered International Recognition Procedure (IRP), a structured reliance model that accounts for prior regulatory decisions from trusted agencies. This model specifies different routes based on the depth and type of review already undertaken, offering applicants procedural clarity and predictable timelines while enabling MHRA to focus resources on targeted scientific reassessment when necessary. Importantly, the framework preserves domestic regulatory independence by ensuring that final judgment remains with the MHRA, thereby protecting review integrity. (79) Swissmedic in Switzerland has demonstrated that efficiency can be realized through internal process optimization.

By streamlining procedures and reducing cycles in labeling negotiations, a historically time-intensive part of marketing authorization, Swissmedic has removed redundancies in internal communication and clarified labeling requirements. These improvements reduce total review times without lowering evidentiary requirements or shifting burdens to sponsors, showing how operational transparency and workflow refinements can yield measurable performance gains. (76) Japan's PMDA employs a proactive model of regulatory science through its pre-submission consultation system, particularly in generic drug reviews where bioequivalence studies are involved. By enabling early interaction on study design, regulatory expectations, and dossier preparation, PMDA prevents deficiencies and shortens review timelines, increasing the likelihood of first-cycle approvals. However, industry uptake of this planning process varies, meaning efficiency gains are not uniform. (82) The U.S. FDA emphasizes transparency and accountability through performance monitoring under the GDUFA III framework. The plan defines clear milestones for generic drug reviews and publishes performance metrics that track timeliness of reviews, communication, and approvals. These publicly available benchmarks hold the FDA accountable, give industry stakeholders insight into review processes, and support continuous improvement by informing real-time adjustments in policy and resource allocation. (72)

Together, these practices, whether reliance-based models, internal operational improvements, early engagement strategies, or transparent performance monitoring, demonstrate a toolkit adaptable across regulatory frameworks. Each contributes to more efficient reviews and higher quality outcomes without undermining regulatory sovereignty or scientific standards.

6. Discussion

A global trend toward convergence of regulatory frameworks in fast-track mechanisms for approving generics is emerging, driven by shared goals of public health improvement, technological advancement, and the growing role of both industry and patient groups advocating for timely access to affordable medicines. Four interrelated themes define this shift: global harmonization

tendencies, central roles of multilateral organizations (ICH, WHO, IPRP), its multi-stakeholder nature, and persisting knowledge gaps that guide future research priorities.

6.1. Global Trends in Fast-Track Harmonization

Over the past two decades, agencies have increasingly aligned fast-track frameworks, moving from isolated systems to interconnected structures emphasizing mutual recognition and reliance. Reliance and work-sharing initiatives, such as the Access Consortium (Australia, Canada, Singapore, Switzerland, UK MHRA) and FDA-led Project Orbis, demonstrate pooled technical assessments that cut duplication and accelerate reviews. (85) APEC reported a 14.3% increase in mutual acceptance of Good Manufacturing Practice certificates between 2008-2020 and a 28% rise in multisite licensing, reflecting deeper convergence. (86) Early reliance models based on bilateral MRAs are giving way to multilateral platforms like IPRP and ICMRA, which provide inclusive global frameworks. (87) Harmonization now incorporates digital standards such as eCTD and structured data schemas; ICH M4Q(R2) revisions support standardized quality models, while collaborative projects like the Pharmaceutical Quality Knowledge Management prototype aim to create interoperable infrastructures by 2027. (88) The COVID-19 pandemic highlighted the importance of agile fast-track mechanisms, with APEC economies leveraging models such as WHO's Collaborative Registration Procedure to maintain supply continuity using reliance on assessments from stringent authorities. (86)

6.2. Role of ICH, WHO, and IPRP in Regulatory Convergence

The International Council for Harmonisation (ICH) has broadened its focus from novel medicines to generics, exemplified by the 2018 Reflection Paper recommending harmonized bioequivalence study designs, convergence on biowaivers, and avoidance of duplicative guidelines through coordination with WHO. (89) Its Generic Drug Discussion Group further advances these efforts. (89) WHO's Good Reliance Practices (GRelP) framework enables regulators with limited resources to leverage external assessments, focusing their expertise on surveillance and local oversight, while its Collaborative Registration Procedure expedites access in low- and middle-income countries by providing abridged pathways based on stringent authority approvals and shared assessment data. (90) IPRP, formed in 2018 through the merger of IGDRP and IPRF, promotes cooperation via working groups on quality, bioequivalence, and information sharing, aligning its activities with ICH guidelines and WHO reliance frameworks to reduce fragmentation and foster consistency in generics regulation. (91)

6.3. Implications for Industry, Regulators, and Patients

For industry, harmonization streamlines submissions, reduces redundant studies, and accelerates global launches, with platforms like Access Consortium and Project Orbis facilitating concurrent approvals. Regulators benefit from better resource allocation by depending on reference assessments and focusing locally on pharmacovigilance, with multilateral work-sharing enhancing inspection quality and capacity building. Patients gain quicker access to affordable generics, ensuring consistent quality, safety, and efficacy standards worldwide, thereby improving therapeutic options and public trust.

6.4. Knowledge Gaps and Avenues for Future Research

Despite progress, knowledge gaps remain. Quantitative studies are needed to measure patient-level outcomes such as faster therapy access, savings, and adherence improvements. Definitions of review timelines vary, impeding direct comparisons, and research should standardize metrics for benchmarking. Global consensus is limited for bioequivalence frameworks addressing complex generics such as liposomes or oligonucleotides; empirical validation is still required. Resource-constrained settings face uncertainties regarding the scalability of reliance models, necessitating operational research to address infrastructure and legal barriers. As regulators explore real-world evidence (RWE) for surveillance and label updates, frameworks for harmonized, cross-border RWE collection and sharing must be developed. Additionally, research is needed on governance, standards, cybersecurity, and interoperability of regulatory digital platforms envisioned to support systems like Pharmaceutical Quality Knowledge Management. Progress will depend on collaborative efforts among regulators, industry, academia, and patient groups using implementation science, mixed methods, and digital innovation.

7. Conclusion

The expedited approval of generics by the FDA, MHRA, Swissmedic, and PMDA is grounded in the ICH Common Technical Document and robust bioequivalence requirements ensuring therapeutic equivalence. However, timelines and reliance models differ: the FDA's eight-month Priority Review (GDUFA), MHRA's 60-day International Recognition Procedure, Swissmedic's Access Consortium collaborations, and PMDA's nine-month Priority Review under "Harmonization by Doing" reflect diverse legal systems, resources, and regulatory strategies. Reliance approaches vary; the MHRA formally recognizes trusted foreign decisions, Swissmedic focuses on harmonized evaluations, PMDA emphasizes experiential cooperation, and the FDA engages selectively through initiatives like the FDA EMA Generic Medicines Cluster and Project Orbis.

Deeper reliance agreements, broader work sharing, and clear review timelines could enhance efficiency and transparency. Greater harmonization in Module 1 and pharmacovigilance reporting would simplify compliance, while expanded pre-submission scientific advice, as practiced by the FDA and PMDA, could improve dossier quality and reduce delays.

The review is limited by public data dependence, which may omit agency updates or pilot programs, complicating efficiency comparisons. Nonetheless, the findings underscore the value of best practice sharing, stronger cooperation, and deeper convergence to accelerate and

standardize global generic approvals without compromising safety or efficacy.

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Conflict of Interest

The authors declare that they have no competing interests related to this work.

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Ethical Considerations

Only published data were used (no ethics approval needed); sources were cited, no conflicts declared, and authors are accountable.

Availability of Data and Materials

Data used to support the review was identified through the publicly available regulatory guidance documents, peer-reviewed research articles, and the official agency reports in the time period between 2000 and June 2025. The manuscript refers to these sources. No original data was collected and analysed in the study. Figures and illustrations were selected with the help of Adobe Illustrator. To clarify additional questions about the data extraction, one should address them to the corresponding author.

Authors' Contributions

SND led the project by conceptualizing the review, conducting the literature search and data extraction for FDA and Swissmedic pathways, drafting the introduction, methods, results, discussion, and conclusion, supervising manuscript development, approving the final version, and ensuring accountability for all aspects of the work.

SSA performed data analysis and synthesis for the MHRA and PMDA mechanisms, helped design the methodology and comparative framework, assisted with writing and critical revision, approved the final version, and ensured accuracy of the assigned sections.

SAS integrated the findings, contributed to writing the introduction, discussion, and conclusion, provided editorial input and critical revisions, approved the final version, and ensured accuracy of the assigned sections.

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