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A Comparative Overview of Generic Drug Regulation in US, Europe, Australia and India

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Abstract

This study aims to examine the registration procedures for generic drugs in the United States, India, Australia, and the Europe concerning regulatory submissions. The information and data were gathered from relevant publications and the official websites of the respective drug regulatory agencies: the U.S. Food and Drug Administration (USFDA) for the United States, the Central Drugs Standard Control Organization (CDSCO) and Drug Controller General of India (DCGI) for India, the Therapeutic Goods Administration (TGA) for Australia, and the Medicines and Healthcare products Regulatory Agency (MHRA) for the Europe. Our comparative analysis reveals significant differences in the criteria and processes for generic drug approval among these countries. In the United States, the Abbreviated New Drug Application (ANDA) process through the FDA typically takes about six months. In India, regulatory approval from CDSCO/DCGI is generally faster, with an approval timeline of approximately 90 days. In Australia, the TGA oversees generic drug approvals, which take about 11 months, making it a notably slower process compared to the U.S. and India. In the Europe, the MHRA is responsible for regulating generic drugs, with an approval timeline of approximately 150 days under the national procedure or European procedures when applicable.

This review provides a detailed comparison of the generic drug approval processes in these countries, highlighting key variations in regulatory requirements and approval timelines. Understanding these differences is essential for pharmaceutical companies seeking market entry and regulatory compliance across multiple regions.

Keywords: CDSCO, USFDA, EMA, Generic, Drug, ANDA, TGA

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1. Introduction

A generic drug is a medication designed to be identical to a branded drug in terms of dosage form, strength, route of administration, quality, performance characteristics, and intended use. However, each country has its own regulations and policies governing the registration of generic drugs. (1)

Generic drugs become available once the patent of a brand-name drug expires or its marketing rights are made accessible at an affordable price. Regulatory authorities in each country evaluate and approve generic drugs based on their safety, efficacy, and bioavailability before they enter the market. (2)

Although generic drugs are therapeutically equivalent to their brand-name counterparts, they may differ in form, scoring arrangement, release mechanisms, packaging, excipients (such as colors, flavors, and preservatives), and shelf life. These differences can sometimes cause confusion among patients when substituting medications. The key distinction between generic and brand-name drugs lies in the amount and type of data required for approval. While brand-name drugs must undergo extensive preclinical and clinical trials to establish safety and efficacy, generic drugs rely on bioequivalence studies to demonstrate that they perform similarly to the original drug.(3)

The Hatch-Waxman Act of 1984 (also known as the Drug Price Competition and Patent Term Restoration Act), passed by the 98th U.S. Congress, played a crucial role in facilitating the approval process for generic drugs. This legislation enabled the introduction of the Abbreviated New Drug Application (ANDA) process, allowing pharmaceutical companies to bring generics to the market more efficiently while maintaining high regulatory standards.

Due to the rising strain of escalating healthcare costs, which have reached approximately $400 billion USD,

large innovative pharmaceutical companies and Indian multinational corporations (MNCs) are increasingly expanding their presence in India's generic drug market. To increase market share and sales volume, these companies are focusing on branded generics and over-the-counter (OTC) medications, introducing off-patent drugs from other innovative firms, and implementing localized pricing strategies for patented medications. (4)

In contrast, the generic drug landscape in Australia is largely influenced by the Pharmaceutical Benefits Scheme (PBS), the country's largest pharmaceutical purchaser. Both domestic and international manufacturers compete to supply proprietary and generic medications under the PBS. Generic drug manufacturers can typically enter the market at a lower cost after patents expire, as they incur lower research and development expenses compared to original brand manufacturers. Additionally, many generics are now produced in countries with lower labor costs, further reducing manufacturing expenses.

This study presents a detailed comparison of the generic drug approval processes in these countries, highlighting variations in regulatory requirements and approval timelines set by the respective agencies.

2. Drug Approval Process in US

For products manufactured between 1938 and 1962, the Kefauver-Harris Drug Amendments mandated that all producers of similar drugs submit an Abbreviated New Drug Application (ANDA). The data required for an ANDA was largely comparable to that of a pioneer drug application, with the exception of safety and efficacy requirements.

After 1962, the FDA introduced the "literature-based" New Drug Application (NDA), providing an alternative method for demonstrating drug efficacy and safety. This allowed manufacturers of generic drugs to submit published evidence on the safety and effectiveness of the corresponding branded drug instead of conducting new clinical trials.(5)

Over the past three decades, several disputes have arisen regarding the generic drug approval process. In 1987, the FDA Office of Generic Drugs (OGD) became the subject of an investigation following a complaint from Mylan Laboratories, which alleged that some of its ANDA applications were intentionally delayed. After conducting an internal review, the FDA revised the ANDA approval process, tightened regulatory requirements, and implemented stricter controls over OGD operations.

Currently, manufacturers of pharmaceutically equivalent generic drugs must demonstrate bioequivalence and pharmaceutical equivalence, as the original active ingredient has already been proven safe and effective. Pharmaceutical equivalence means that the generic and branded drugs contain the same active ingredient(s), dosage form, route of administration, and strength. Bioequivalence, on the other hand, is established when two drugs exhibit comparable bioavailability under similar testing conditions.

While pharmaceutical equivalence is a relatively straightforward concept, bioequivalence is more complex. Bioequivalence is assessed through pharmacokinetic parameters, particularly the area under the concentration-time curve (AUC) and the maximum drug concentration (Cmax). These measures determine whether the generic drug's absorption and availability in the body are similar to those of the brand-name counterpart.(6)

2.1 Types of Reviews in Generic Drug Approval Process (7):

a) ANDA Regulatory Review Process:

When an applicant submits an Abbreviated New Drug Application (ANDA) to the Center for Drug Evaluation and Research (CDER) or the Office of Generic Drugs (OGD), the ANDA review process begins. The submission is typically made by documentation personnel, who also provide a cover letter detailing the ANDA number and the date of receipt.

Upon receipt, the ANDA is assigned to a consumer safety officer, who begins by reviewing the preliminary ANDA verification form. The review of the submitted ANDA includes assessing bioequivalence, as well as evaluating chemical, pharmacological, and microbiological aspects. The data review is typically completed within the first 60 days following the filing of the ANDA.

b) Bioequivalence Review Process:

Two key characteristics of generic medications that ensure their therapeutic equivalence to brand-name drugs are medication equivalency and bioequivalence. Pharmaceutical equivalency ensures that both the novel (brand-name) and generic medications have the same potency, dosage form, and mode of administration.

Bioequivalence is established when two products, tested under similar conditions, show comparable bioavailability. This is typically assessed by analyzing the area under the curve (AUC) and the maximum concentration (Cmax) of the drug. For a generic drug to be considered bioequivalent to the branded product, the mean Cmax must fall between 80% and 125%, and the AUC must also fall within a 90% confidence interval (CI).

c) Label Review Process:

The label review process ensures that the labeling of generic drugs is consistent with that of the reference listed drug (RLD). After the final review, applicants will either receive an approval letter or be informed of any deficiencies that require resolution.

Once the applicant has addressed any deficiencies and met all approval criteria, they will receive final approval and be permitted to commercialize the pharmaceutical product. If the RLD is still under patent protection or if there are any exclusivities in place, the license will only be granted under the appropriate conditions.

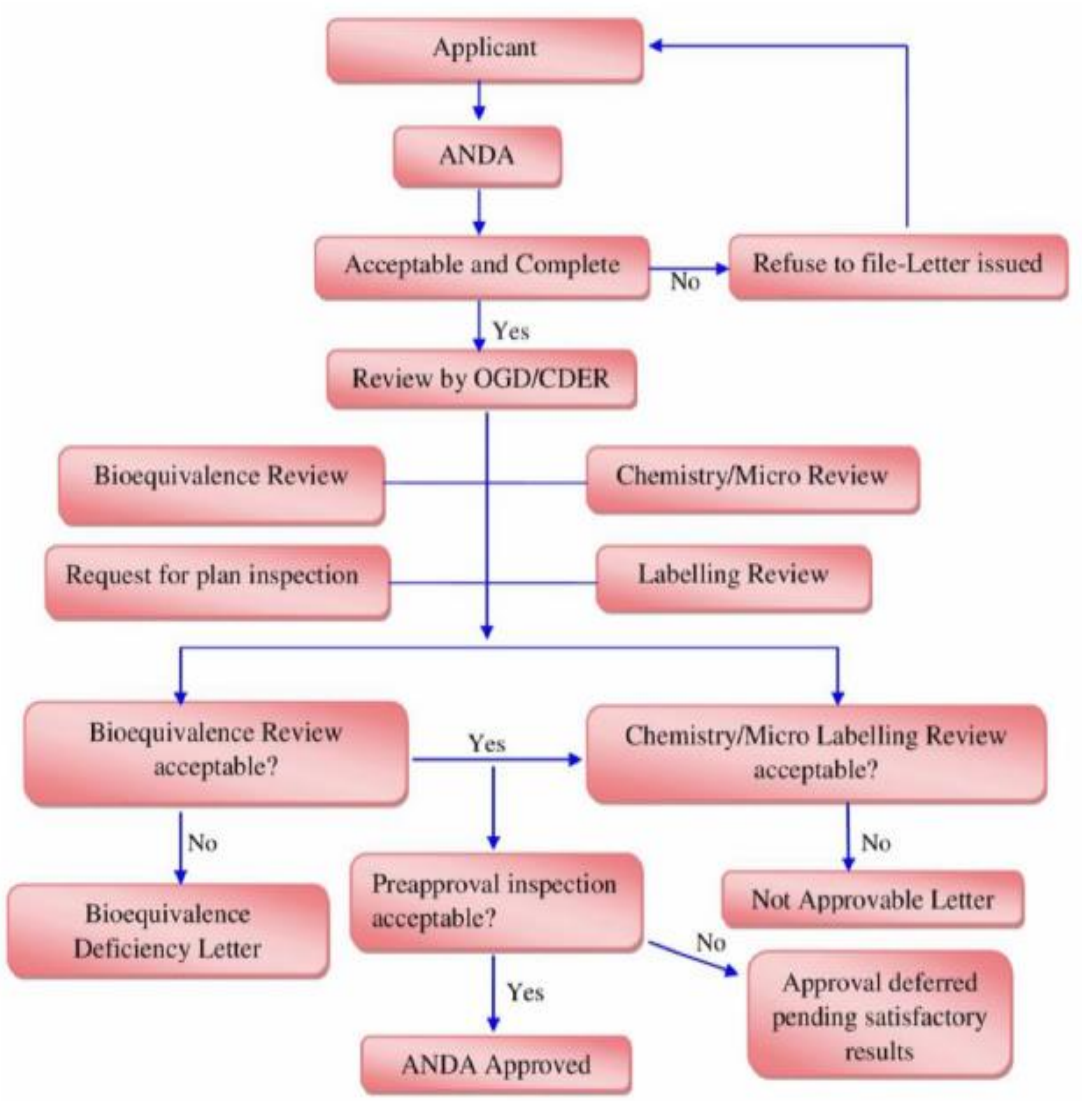

Figure 1. Drug Approval Process in US (8)

3. Drug Approval Process in India (9)**:**

The New Medication Application process differs significantly from the Abbreviated New Drug Application (ANDA) process. While the applicant and regulatory bodies may rely on existing safety and efficacy data from previously approved medicines, additional non-clinical and/or clinical evidence is typically required to support new claims for an already licensed medication.

The specific new claim made by the applicant will determine the additional information needed to assess the safety and efficacy of the new generic drug. If the drug is already available in major markets and has been approved by multiple regulatory agencies for the proposed new claim, this may help in streamlining the approval process.

In cases where the generic medication demonstrates both pharmacological equivalence and bioequivalence to the licensed reference product, and there are no metabolic alterations due to ethnic differences, the approval process may proceed more efficiently. Additionally, if the new claim involves a serious, life-threatening condition or a disease of significant concern, the regulatory requirements for animal toxicological and clinical data may be reduced or even waived.

To approve the production or import of such novel medications, the Central Drugs Standard Control Organization (CDSCO) will evaluate the application's scientific rationale. If necessary, the matter may be referred to specialists or expert committees for further review.

3.1 Documents Required in order to submit an abbreviated new medication application:

Ingredients:

- Bio-equivalency and bioavailability
- Examiner/canter's name
- Source and stability of raw materials

Raw material:

- Method of production
- QC characteristics, stability, and requirements
- Animal toxicity

Fixed Dose Combination (FDC) Authorization /License:

- Rationale
- Data related to pharmacokinetics and pharmacodynamics

- any additional data

New dosage forms or further approval, or approval of a new indication:

- The number and date of the prior approval
- The rationale
- Quality, safety, and efficacy data

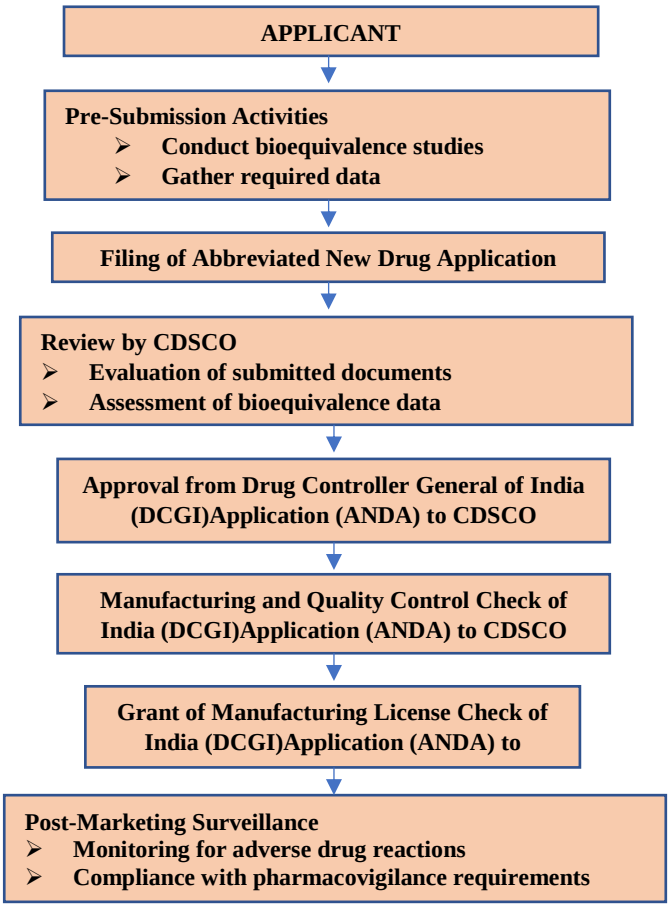

Figure 2. Generic Drug Approval Process in India (10)

4. Drug Approval Process in Australia (11)**:**

The Therapeutic Goods Administration (TGA) is the regulatory authority responsible for overseeing the approval and regulation of generic medications in Australia. For a generic drug to be registered in Australia, it must first be included in the Pharmaceutical Benefits Scheme (PBS). The PBS portal currently lists a substantial number of generic medications, many of which are marketed under brand names in Australia.

The TGA adheres to international standards that align with U.S. and EU drug laws, ensuring that Australian regulations are in line with major global drug approval frameworks. However, due to the relatively small market size and the high registration costs, Australia presents a challenging investment opportunity for multinational generic companies that typically operate in high-volume markets.

The approval process for a generic medication in Australia typically takes around 11 months, which is longer compared to the approval timelines of other major markets.

4.1 List of required documents (12)**:**

a) Pre-PPF: - (To TGA)

- Notification for each new ingredient
- Application form for new chemical (AAN), biological (ABN), herbal (AHN) name
- Application for orphan drug designation
- Justification of new fixed combination
- Acceptance as submission based on literature

b) PPF: -

(i) Applicant details:

- Applicant name
- eBS client ID
- Postal address
- Address for Correspondence
- Contact numbers
- Position (RA officer/ Agent)
- Email Address
- Facsimile number

(ii) Product details

4.2 Phases of Generic Drug Approval Process (13)**:**

Phase 1: Pre-submission

The process of registering generic drugs begins with the pre-submission phase, which applies to both Category 1 and Category 2 generic medications. This phase requires

the submission of the Pre-Planning Form (PPF) along with the payment of application fees.

Phase 2: Electronic Submission of New Generic Medication Application

In this phase, the applicant submits the new generic drug application electronically through the electronic Business Service (eBS) platform. Upon receipt of the application, the TGA will inform the applicant of its status—whether it is on hold, under review, or accepted. If the application is placed on hold, the notice letter will provide the reasons for the delay.

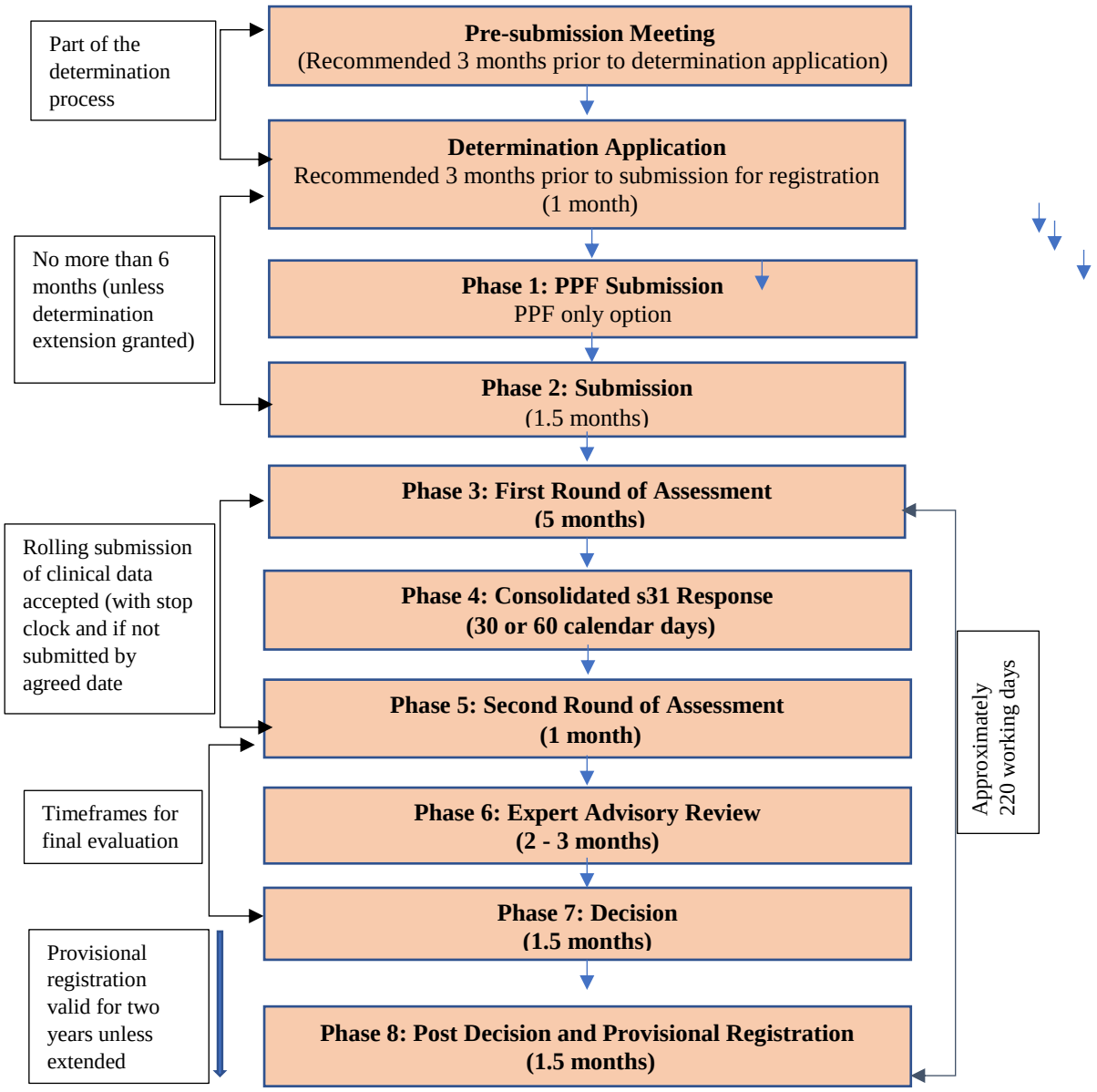

Figure 3. Drug Approval Process in Australia (14)

Phase 3: First Round Assessment

During this phase, the TGA reviewers carefully assess all the data and information contained in the application dossier.

Phase 4: Response to Consolidated Section 31 Request

If any questions arise during the review of the dossier, the TGA will issue a Consolidated Section 31 Request to the applicant. This request seeks additional information or clarification. The applicant is required to respond using the Consolidated Section 31 Request form. This form is used when there are queries about the application or when the provided data is deemed insufficient.

Phase 5: Second Round Assessment

Once the applicant submits the Section 31 Request form, the TGA evaluation team will verify the new information and proceed with the second round of assessment. The final report is then compiled by the TGA after completing this second review.

Phase 6: Expert Advisory Review

If necessary, the TGA may seek independent advice from the Advisory Committee on Medicines (ACM). This committee will provide expert input on the final report to aid the decision-making process.

Phase 7: Decision

Following a thorough review of the dossier, the TGA expert team will decide whether to approve or deny the application.

Phase 8: Post-decision

The post-decision phase begins once the applicant is notified of the TGA's decision. During this phase, any remaining administrative and regulatory tasks are completed.

5. DRUG APPROVAL PROCESS IN EUROPE:

5.1 Regulatory Bodies Involved

In Europe, the European Medicines Agency (EMA) plays a pivotal role in the approval process for generic drugs. The EMA evaluates and approves medicines intended for the European Union market. The approval process can follow two distinct pathways:

Centralized Procedure: This procedure is managed by EMA and is applicable for medicines that are intended to be marketed throughout the EU. It allows a drug to be authorized for use in all EU member states once approved.

National Procedure: If the company seeks approval for a drug only in a specific EU member state, it can apply through the national regulatory bodies. This is most often used for generics that are limited to a specific market, not for a widespread EU authorization. (15)

5.2 Steps in the Drug Approval Process for Generic Drugs

Step 1: Submission of Marketing Authorization Application (MAA)

The first step in the process is for the generic drug manufacturer to submit a Marketing Authorization Application (MAA) to EMA. This application must include evidence that the generic product is bioequivalent to the reference (brand-name) drug. Bioequivalence means that the generic drug performs in the same way in terms of rate and extent of absorption into the bloodstream as the original branded drug.

Additionally, the MAA includes detailed information about the pharmaceutical formulation, including the active ingredient, dosage form, strength, and route of administration. The aim is to demonstrate that the generic medicine can be used interchangeably with the brand-name product.(16)

Step 2: Evaluation by the European Medicines Agency (EMA)

Once the MAA is submitted, it is reviewed by the Committee for Medicinal Products for Human Use (CHMP) at EMA. The CHMP's responsibility is to assess whether the generic drug meets the required safety, quality, and efficacy standards. For generics, the key criteria involve proving bioequivalence with the reference product.

In addition to bioequivalence data, the CHMP also reviews any supporting data submitted by the manufacturer. This includes information on manufacturing processes, stability, quality control, and other relevant scientific data.

Typically, the evaluation by EMA takes approximately 210 days but could extend if the CHMP requires additional information or if the submitted dossier has any deficiencies. (17)

Step 3: Opinion and Recommendation

Once the evaluation is complete, the CHMP issues an opinion. If the evaluation is favorable, the CHMP will recommend that the European Commission grants marketing authorization for the generic drug. This is a critical stage because the opinion of the CHMP can lead to the approval of the generic drug, allowing it to be marketed in the entire EU. If the opinion is negative, the company may need to make amendments to the application or supply additional data. (18)

Step 4: Marketing Authorization and Post-Market Surveillance

Once the European Commission grants marketing authorization, the generic drug can be sold and distributed throughout the European Union. The approval granted is typically valid for 5 years. After this period, the approval can be renewed, usually indefinitely, as long as the product continues to meet regulatory standards.

Post-market surveillance is a critical aspect of the process. Even after approval, the generic drug is subject to pharmacovigilance, which is the ongoing monitoring of its safety and efficacy in the general population. This is done to identify any rare adverse effects or issues that might arise once the drug is in widespread use. (19)

5.3 Key Considerations for Generic Drug Approval in Europe

Bioequivalence Studies

Bioequivalence is a cornerstone of the approval process for generic drugs in Europe. To be considered bioequivalent, the generic drug must demonstrate that it releases the active ingredient in the same way, and at the same rate and extent, as the reference product. This is determined through pharmacokinetic studies, typically measuring parameters such as Cmax (maximum concentration) and AUC (area under the curve) for both the generic and reference product.

Bioequivalence studies ensure that patients using generics will receive the same therapeutic benefit as those using the brand-name drugs. (20)

Pharmaceutical Equivalence

Pharmaceutical equivalence refers to the fact that the generic and the branded drug must contain the same active substance(s) in the same concentration and dosage form. They must also be administered through the same route (e.g., oral, intravenous). This is important because any deviation in the formulation may lead to differences in how the drug behaves in the body, potentially affecting its safety and efficacy. (21)

Branded vs. Generic Drug Considerations

The key distinction between a branded and a generic drug is that a branded drug requires substantial clinical evidence to prove its safety and efficacy. In contrast, a generic drug does not need to repeat the clinical trials of the original drug. Instead, the generic drug manufacturer can reference the data from the branded product as long as the generic is bioequivalent and pharmaceutically equivalent.

The process for generic drug approval is therefore more streamlined and cost-effective compared to new drug development. However, generics must meet the same high standards of safety, efficacy, and quality (22)

5.4 Alternatives to the Centralized Procedure

In addition to the Centralized Procedure, there are two other pathways available for generic drug approval:

- Mutual Recognition Procedure (MRP)
- Decentralized Procedure (DCP)

5.5 Approval Timeline for Generic Drugs in Europe

The approval timeline for generic drugs in Europe typically takes around 1-2 years. The Centralized Procedure managed by EMA typically takes around 210 days, but this can extend if additional data or clarifications are needed from the applicant. In some cases, the national procedures (MRP or DCP) may take longer due to the involvement of multiple countries. (23)

6. Comprehensive Overview

Table 1. Comparison between regulation of US, India, EU, Australia

Aspects	US	India	EU	Australia
Regulatory body	Food & Drug Administration (FDA)	Central Drug Standard Control Organization (CDSCO)	European medicine agency	Therapeutic Goods Administration (TGA)
Application type	Abbreviated New Drug Application (ANDA)	Abbreviated New Drug Application (ANDA)	Marketing Authorization Application	New Generic Product
Pre-submission Phase	Pre-IND meeting to discuss requirements	Pre-application consultation available	Pre-submission review is available	Pre-submission planning form (PPF)
Assessment duration	10 Months for standard & 6 months for priority application (avg.)	6 months for NDA approval (avg.)	210 days for the approval through centralized procedure	3 months for new generic drug
Review round	Typically, one round; additional information may be requested	Single round review; further queries may extend the process	Two rounds review; first round is initial review and follow-up review meetings	Two rounds of assessment with potential requests for additional information
Expert Review	Advisory committees may be consulted	Review by Subject Expert Committees (SEC)	Committee for Medicinal Products for Human Use (CHMP)	Involves expert advisory committees
Decision Notification	Approval letter issued; if rejected, reasons provided	Approval or rejection communicated via official letter	Positive or Negative feedback; if negative timeline for re-evaluation	Written notification post-evaluation
Post-approval monitoring	Post-marketing studies may be required	Post-marketing surveillance mandated	Post marketing surveillance is required	Risk Management Plans (RMPs) required
Market Exclusivity	180 days market exclusivity for first filer with ANDA	No specific exclusivity	No specific exclusivity for generics, but protection for reference product exists	No specific exclusivity
Fees	Fees vary; approx. $2.8 million for standard NDA	50,000 INR	National fee (including hybrid applications): £103,059 Decentralised procedure where UK is CMS: £99,507	Fees vary; approx. $20,939 for new generics

Primary Labelling Document	Prescribing Information (PI)	Package Insert	Summary of Product Characteristics (SmPC)	Product Information (PI)
Patient Leaflet	Medication Guide / Patient Package Insert	Prescribing information labelling format as per NDCT rule	Standardized format per SmPC guideline	Mandatory format per PI guideline
Braille Requirements	Not mandatory	Not mandatory	Mandatory for name and strength of the drug	Not mandatory
Risk Management Plan (RMP)	Required for certain products	Required for specific categories	Required for all products	Required for high-risk products
Generic Drug Approval Pathway	ANDA (505(j))	Abbreviated NDA	Hybrid/Generic MAA	AAN
Market Exclusivity for First Generic	180 days	No specific exclusivity	No specific exclusivity	No specific exclusivity
Patent Term Restoration	Up to 5 years	No provision	Up to 5 years	Up to 5 years
Approval Timeline for Generics	10-36 months	12-30 months	12-24 months	12-24 months
Special Provisions for Pediatric Drugs	PREA & BPCA	Encouraged	PIP Required	Encouraged
Use of Foreign Clinical Data	Allowed with bridging studies	Allowed with justification	Allowed with justification	Allowed with justification

7. Conclusion

Drug regulatory bodies play a crucial role in controlling and authorizing generic medications, which serve as cost-effective alternatives to branded pharmaceuticals, benefiting the general population. By enabling the sale of generics in international markets, these regulatory bodies help boost the global market income. However, ensuring the quality and safety of generics remains a significant challenge, prompting regulatory agencies to implement stringent approval guidelines. Typically, generic drugs are authorized only after the patent on the branded counterpart expires, generally after 20 years. In this context, regulatory bodies across different countries, including the United States, India, Australia, and Europe, each follow distinct protocols for generic drug approval. In the U.S., the process is referred to as the Abbreviated New Drug Application (ANDA), while India and Australia use the Marketing Authorization Application (MAA) and the Product Registration Form (PPF), respectively. The approval timelines vary, with India taking an average of 12 months, while the U.S. and Australia require 16 and 18 months, respectively. This suggests that India's Central Drugs Standard Control Organization (CDSCO) is particularly efficient in evaluating generic drug applications. Price setting also varies across regions, with the U.S. offering the lowest prices for generics, while Australia tends to set higher prices. Although regulatory agencies ensure compliance with laws and standards, stricter enforcement and more comprehensive regulations are essential to guarantee the quality and safety of generic drugs, aligning them with the standards of branded medications. Moreover, the European regulatory framework also places considerable emphasis on the safety, efficacy, and quality of generics, further highlighting the global necessity for uniform standards in this sector.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Reference

1. Marketing authorisation | European Medicines Agency [Internet]. EMEA: EU; 2025 [cited 2025 Feb 7]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation
2. Shukla N, Sangal T. Generic Drug Industry in India: The Counterfeit Spin. Journal of Intellectual Property Rights [Internet]. 2009 Apr 21 [cited 2025 Jan 13];14:236–40. Available from: https://nopr.niscpr.res.in/bitstream/123456789/4192/1/JIPR%2014%283%29%20236-240.pdf

3. Bera A, Mukherjee A. The importance of generic drugs in India. Int J Pharm Chem Biol Sci [Internet]. 2012;4:575–87 [cited 2025 Jan 13]. Available from: https://www.ijpcbs.com/articles/the-importance-of-generic-drugs-in-india.pdf
4. Dadhich A, Upadhyaya M. A review: Exploring branded generic drugs by Indian pharmaceutical multinational companies as a new prospect. An Int Res J [Internet]. 2011;2(6):235–9 [cited 2025 Jan 11]. Available from: https://pharmacophorejournal.com/storage/models/article/oRXFDczIoRP5ys4QH29d1BlEdzdX3TvkWGziwxUdoZ2GVYkUV8EYNif86EcQ/a-review-exploring-branded-generic-drugs-by-indian-pharmaceutical-multinational-companies-as-a-new.pdf
5. FDA. Milestones in U.S. food and drug law. FDA [Internet]. 2023 Jan 30 [cited 2025 Jan 16]. Available from: https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law
6. Wyoming JRH, PharmD, BCPS. Generic drugs: History, approval process, and current challenges [Internet]. U.S. Pharmacist. 2009 [cited 2025 Jan 11]. Available from: https://www.uspharmacist.com/article/generic-drugs-history-approval-process-and-current-challenges
7. Rafi N, DS S, Narayanan VA. Regulatory requirements and registration procedure for generic drugs in the US. Indian J Pharm Educ Res [Internet]. 2018 Jun 15 [cited 2025 Jan 12];52(4):544–9. Available from: https://ijper.org/sites/default/files/IndJPhaEdRes_52_4_544_0.pdf
8. Am S, Dp M, Da B. Regulatory requirements and drug approval process in India, Europe, and US. Pharmaceut Reg Affairs [Internet]. 2018;7(2):2167–7689 [cited 2025 Jan 12]. Available from: https://www.hilarispublisher.com/open-access/regulatory-requirements-and-drug-approval-process-in-india-europe-and-us-2167-7689-1000210.pdf
9. Kumar B, Chandra A. A comparative study of the drug approval process in US, India, Japan, and Europe. World J Pharm Res [Internet]. 2016 Dec 1;6(1):311–22 [cited 2025 Jan 12]. Available from: https://www.researchgate.net/publication/347354859_A_COMPARITIVE_STUDY_OF_THE_DRUG_APPROVAL_PROCESS_IN_US_INDIA_JAPAN_AND_EUROPE
10. Central Drugs Standard Control Organization (CDSCO). New drug approval process - Organogram [Internet]. [cited 2025 Feb 26]. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/New-Drugs/Process/NDD_APPL_Organogram.pdf
11. Priya S, Yallabandi D, Prakash J, Deepika RP, Reddy RK. A comparative study of regulatory requirements for filing generic drug product between US, India, and China. World J Pharm Pharm Sci [Internet]. 2020 Oct 20;2701–17 [cited 2025 Feb 1]. Available from: https://www.researchgate.net/publication/344758667_A_COMPARATIVE_STUDY_OF_REGULATORY_REQUIREMENTS_FOR_FILING_GENERIC_DRUG_PRODUCT_BETWEEN_US_INDIA_AND_CHINA
12. Therapeutic Goods Administration (TGA). CTD Module 1: Administrative information and prescribing information for Australia [Internet]. 2024 [cited 2025 Jan 22]. Available from: https://www.tga.gov.au/resources/guidance/ctd-module-1-administrative-information-and-prescribing-information-australia
13. Therapeutic Goods Administration (TGA). Prescription medicines registration process [Internet]. 2024 [cited 2025 Jan 27]. Available from: https://www.tga.gov.au/resources/guidance/prescription-medicines-registration-process
14. Therapeutic Goods Administration (TGA). Applying for provisional registration for a prescription medicine [Internet]. 2024 [cited 2025 Feb 7]. Available from: https://www.tga.gov.au/resources/guidance/applying-provisional-registration-prescription-medicine
15. European Medicines Agency (EMA). Marketing authorisation [Internet]. 2025 [cited 2025 Feb 7]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation
16. European Medicines Agency (EMA). Generic and hybrid applications [Internet]. 2025 [cited 2025 Feb 7]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/generic-hybrid-medicines/generic-hybrid-applications
17. European Medicines Agency (EMA). Authorisation of medicines [Internet]. 2018 [cited 2025 Feb 5]. Available from: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines
18. Jang E. Accountability of the European Medicines Agency in marketing authorisation of new medicines: Qualitative and literature analysis [Internet]. 2020 Aug 10 [cited 2025 Jan 30]. Available from: https://www.wemos.org/wp-content/uploads/2023/04/Accountability-of-the-EMA-in-Marketing-Authorisation-of-New-Medicines.pdf
19. European Medicines Agency (EMA). Pharmacovigilance: Post-authorisation [Internet]. 2025 [cited 2025 Feb 11]. Available from: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation
20. European Medicines Agency (EMA). Guideline on the investigation of bioequivalence [Internet]. 2010 Jan 20 [cited 2025 Feb 10]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-bioequivalence-rev1_en.pdf
21. European Medicines Agency (EMA). Investigation of bioequivalence - Scientific guideline [Internet]. 2010 Mar 10 [cited 2025 Feb 8]. Available from: https://www.ema.europa.eu/en/investigation-bioequivalence-scientific-guideline
22. European Medicines Agency (EMA). Generic medicine [Internet]. 2018 Jun 27 [cited 2025 Feb 10]. Available from: https://www.ema.europa.eu/en/glossary-terms/generic-medicine
23. European Medicines Agency (EMA). Authorisation of medicines [Internet]. 2024 Jul 31 [cited 2025 Feb 13]. Available from: https://www.ema.europa.eu/en/about-us/what-we-do/authorisation-medicines