



A COMPARATIVE STUDY OF REGULATORY APPROACHES OF ASEAN COUNTRIES FOR APPROVAL OF GENERIC PHARMACEUTICAL PRODUCTS

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Article History: Received 30th April 2026; Accepted 22nd June 2026; Published 1st July 2026

ABSTRACT

Generic pharmaceutical products play a crucial role in improving access to affordable medicines, particularly in developing and emerging economies. The Association of Southeast Asian Nations (ASEAN) represents a rapidly expanding pharmaceutical market with diverse regulatory systems governing the approval of generic drugs. Although ASEAN has undertaken several harmonization initiatives, including the ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirements (ACTR), significant regulatory differences persist among member states. This study aims to compare the regulatory approaches adopted by selected ASEAN countries for the approval of generic pharmaceutical products. A descriptive and comparative analysis was conducted using regulatory guidelines, official publications, and secondary literature from national regulatory authorities, ASEAN bodies, and the World Health Organization (WHO). The findings indicate partial harmonization in dossier format and quality requirements; however, variations remain in bioequivalence requirements, approval timelines, and post-approval regulatory controls. Strengthening regulatory reliance mechanisms and further harmonization could enhance access to generic medicines across the ASEAN region.

Keywords: Generic drugs, ASEAN, Regulatory harmonization, ACTD, Bioequivalence, Drug approval.

INTRODUCTION

Pharmaceutical regulatory systems are fundamental to ensuring that medicinal products available in the market meet acceptable standards of quality, safety, and efficacy. Regulatory authorities act as gatekeepers to protect public health while facilitating access to essential medicines. In recent decades, the increasing globalization of pharmaceutical development and manufacturing has highlighted the need for regulatory convergence and harmonization across countries to reduce duplication, regulatory delays, and unnecessary costs (ICH, 2021; WHO, 2017). Generic pharmaceutical products play a critical role in healthcare systems by providing affordable alternatives to innovator medicines once patent protection expires. Generic drugs are defined as products that are pharmaceutically equivalent and bioequivalent to a reference listed drug and are intended to be interchangeable in clinical practice (WHO, 2017). The widespread use of

generics has been shown to significantly reduce healthcare expenditure and improve patient access to essential medicines, particularly in low- and middle-income countries (Kaplan & Laing, 2019).

In spite of their public health importance, the regulatory approval of generic medicines remains complex. Regulatory authorities typically require comprehensive documentation demonstrating pharmaceutical equivalence, manufacturing quality, and bioequivalence with the innovator product. Variations in national regulatory requirements for bioequivalence studies, stability testing, and dossier formats can create substantial barriers to market entry, even when products meet internationally accepted scientific standards (Shah *et al.*, 2018). To address these challenges, several regional and international harmonization initiatives have been established. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

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has successfully harmonized regulatory standards among major regulatory authorities such as the United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), and Pharmaceuticals and Medical Devices Agency (PMDA) of Japan (ICH, 2021). Similarly, the European Union has implemented centralized and decentralized approval procedures that allow generic medicines to gain access to multiple markets through a single regulatory pathway (EMA, 2020).

In Southeast Asia, the Association of Southeast Asian Nations (ASEAN) represents a diverse group of ten countries with varying levels of economic development, healthcare infrastructure, and regulatory maturity. ASEAN is one of the fastest-growing pharmaceutical markets globally, driven by population growth, epidemiological transition toward chronic diseases, and expanding healthcare coverage (ASEAN Secretariat, 2019). However, the presence of multiple national regulatory authorities with differing requirements has historically posed challenges to pharmaceutical manufacturers seeking regional market access. Recognizing the need for regulatory convergence, ASEAN established the ASEAN Pharmaceutical Product Working Group (PPWG) with the objective of harmonizing technical requirements for pharmaceutical product registration. One of the most significant outcomes of this initiative is the development of the ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirements (ACTR). The ACTD provides a standardized dossier structure for submission of quality, non-clinical, and clinical data, including data for generic drug applications (ASEAN Secretariat, 2019).

Although the introduction of ACTD has improved consistency in dossier format and facilitated regulatory submissions across ASEAN member states, full harmonization has not yet been achieved. National regulatory authorities continue to apply country-specific requirements related to administrative procedures, bioequivalence study acceptance, local clinical data, and review timelines (WHO, 2020). In particular, differences in bioequivalence requirements—such as mandatory local studies versus acceptance of foreign data—remain a major regulatory challenge for generic drug manufacturers operating in the ASEAN region (Shah *et al.*, 2018). Furthermore, approval timelines for generic medicines vary considerably across ASEAN countries, ranging from less than one year in more mature regulatory systems to more than two years in developing regulatory environments. Such variability can delay patient access to affordable medicines and reduce the economic benefits associated with generic competition (Kaplan & Laing, 2019). These regulatory differences underscore the need for a systematic comparison of ASEAN regulatory approaches to identify gaps, challenges, and opportunities for further harmonization. Therefore, this study aims to conduct a comparative analysis of regulatory approaches adopted by selected ASEAN countries for the approval of generic pharmaceutical products. By examining regulatory frameworks, dossier requirements, bioequivalence criteria, approval timelines, and post-approval obligations, the study

seeks to provide insights that may support regulatory convergence, improve market access, and ultimately enhance public health outcomes across the ASEAN region

MATERIALS AND METHODS

Study Design

This study employed a descriptive and comparative research design based on qualitative analysis of regulatory frameworks governing generic drug approval in ASEAN countries.

Data Sources

Secondary data were collected from: Official guidelines and publications of ASEAN national regulatory authorities. ASEAN PPWG, ACTD, and ACTR documents. WHO regulatory assessment reports. Peer-reviewed journal articles and regulatory policy reviews

Selection of Countries

Five ASEAN countries were selected to represent varying levels of regulatory maturity: Singapore, Malaysia, Thailand, Indonesia, Philippines.

Parameters for Comparison

The regulatory approaches were compared based on: Regulatory authority structure, Generic drug definition, Dossier submission requirements, Bioequivalence study requirements, Approval timelines, Post-approval regulatory obligations

RESULTS AND DISCUSSION

Each ASEAN country operates through an independent national regulatory authority (NRA). Singapore's Health Sciences Authority (HSA) and Malaysia's National Pharmaceutical Regulatory Agency (NPRA) demonstrate advanced regulatory systems with reliance-based review pathways, while other countries employ more traditional full-review approaches (WHO, 2020). Generic drugs are pharmaceutical products intended to be interchangeable with innovator products. They contain the same active pharmaceutical ingredient (API), dosage form, strength, route of administration, and intended use. Key advantages: Reduced healthcare expenditure, Increased patient access, Encouragement of market competition. Challenges: Regulatory complexity. Bioequivalence study requirements, Market authorization delays. ASEAN introduced: ASEAN Pharmaceutical Product Working Group (PPWG), ASEAN Common Technical Dossier (ACTD), ASEAN Common Technical Requirements (ACTR). All selected countries accept the ASEAN Common Technical Dossier (ACTD) format for generic drug submission. ACTD has improved consistency in dossier structure; however, country-specific administrative and technical requirements remain (ASEAN Secretariat, 2019). Bioequivalence (BE) requirements show significant

variation. Singapore and Malaysia generally accept foreign BE studies conducted in compliance with international standards, whereas Indonesia and Thailand often require local BE studies or impose additional conditions (Shah *et al.*, 2018). Approval timelines for generic drugs vary

widely among ASEAN countries, ranging from approximately 6-9 months in Singapore to over 24 months in Indonesia and the Philippines. These differences are largely attributed to regulatory capacity, review models, and local data requirements (Kaplan & Laing, 2019).

Table 1. Regulatory Authorities and Responsibilities.

Country	Authority	Key Functions
Singapore	HSA	Marketing authorization
Malaysia	NPRA	Product registration
Thailand	Thai FDA	Drug approval
Indonesia	BPOM	Regulatory control
Philippines	FDA Philippines	Market authorization

Table 2. Bioequivalence Requirements Comparison.

Country	Local BE Required	Foreign BE Accepted
Singapore	No	Yes
Malaysia	No	Yes
Thailand	Sometimes	Conditional
Indonesia	Often	Limited
Philippines	Case-based	Conditional

Table 3. Average Generic Drug Approval Timelines.

Country	Timeline (Months)
Singapore	6-9
Malaysia	12-18
Thailand	18-24
Indonesia	24-36
Philippines	18-24

Post-approval regulatory controls, including variations, pharmacovigilance reporting, and GMP inspections, differ across ASEAN countries. While pharmacovigilance systems are well-established in Singapore and Malaysia, developing systems continue to evolve in other member states (WHO, 2020). The present study provides a comparative evaluation of regulatory approaches adopted by selected ASEAN countries for the approval of generic pharmaceutical products. The findings demonstrate that although ASEAN has made measurable progress toward regulatory harmonization, particularly through the adoption of the ASEAN Common Technical Dossier (ACTD), substantial regulatory divergence persists across member states. These differences have important implications for pharmaceutical manufacturers, regulatory authorities, and patient access to affordable medicines. One of the most significant achievements observed in this study is the region-wide acceptance of the ACTD z contributed to harmonization by standardizing the structure of quality, non-clinical, and clinical data, thereby reducing

administrative complexity and duplication of documentation (ASEAN Secretariat, 2019). Similar benefits have been reported in other harmonized regulatory regions, such as the European Union, where the Common Technical Document (CTD) has facilitated multi-country submissions (EMA, 2020). However, despite structural harmonization, the content requirements and interpretation of data remain country-specific in ASEAN, limiting the full benefits of ACTD implementation. Bioequivalence (BE) requirements emerged as the most critical area of regulatory divergence among ASEAN countries. While regulatory authorities in Singapore and Malaysia generally accept foreign BE studies conducted in accordance with internationally recognized guidelines, other countries such as Indonesia and Thailand frequently require locally conducted BE studies or impose additional conditions. These findings are consistent with earlier reports highlighting that national confidence in foreign clinical data strongly influences regulatory decision-making in developing regulatory systems (Shah *et al.*, 2018; WHO,

2020). Mandatory local BE studies significantly increase development costs and prolong approval timelines for generic products. This regulatory approach may discourage market entry, particularly for small and medium-sized pharmaceutical companies, and ultimately reduce the availability of affordable generic medicines (Kaplan & Laing, 2019). In contrast, regulatory reliance mechanisms—whereby one authority relies on the assessment or approval of a trusted reference authority—have been shown to improve regulatory efficiency without compromising product quality or patient safety (WHO, 2017). Approval timelines for generic drugs varied considerably across the selected ASEAN countries, ranging from less than one year in Singapore to more than two years in Indonesia and the Philippines. These differences can be attributed to variations in regulatory capacity, review models, availability of trained assessors, and extent of reliance on external assessments. Similar variability in approval timelines has been observed in other non-harmonized regions, emphasizing the importance of regulatory capacity building and procedural optimization (ICH, 2021).

Post-approval regulatory requirements, including variations management, pharmacovigilance reporting, and Good Manufacturing Practice (GMP) compliance, also showed notable differences among ASEAN countries. Mature regulatory authorities demonstrated robust pharmacovigilance systems and risk-based inspection models, while developing systems are still strengthening post-marketing surveillance mechanisms. Effective post-approval regulation is essential for maintaining public confidence in generic medicines and ensuring continued product quality throughout the lifecycle (WHO, 2020). Overall, the findings suggest that ASEAN's regulatory harmonization efforts have achieved partial success but remain limited by national sovereignty, differing levels of regulatory maturity, and varying public health priorities. While complete harmonization may not be immediately achievable, incremental approaches such as enhanced reliance pathways, mutual recognition of BE studies, and joint review procedures could significantly improve regulatory efficiency. Similar strategies have proven successful in other regional initiatives, including the African Medicines Regulatory Harmonization (AMRH) program (WHO, 2017). The study underscores the importance of continued collaboration among ASEAN member states to address regulatory disparities and strengthen convergence. Improved harmonization would not only benefit pharmaceutical manufacturers by reducing regulatory burden but also enhance patient access to high-quality, affordable generic medicines across the ASEAN region.

CONCLUSION

This comparative study demonstrates that while ASEAN has made considerable progress toward harmonizing regulatory requirements for generic drug approval, significant differences persist among member states. Variability in bioequivalence requirements, approval

timelines, and post-approval controls continues to affect timely access to affordable generic medicines. Further harmonization, increased acceptance of foreign bioequivalence data, and enhanced regulatory reliance frameworks are recommended to improve regulatory efficiency and support public health objectives across the ASEAN region.

ACKNOWLEDGMENT

The authors express sincere thanks to the Head of the Sri Sivani College of Pharmacy, Chilakapalem, Srikakulam, (Affiliated to Jawaharlal Nehru Technological University Gurajada Vizianagaram), Andhra Pradesh for the facilities provided to carry out this research work.

CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL

Not applicable

FUNDING

This study received no specific funding from public, commercial, or not-for-profit funding agencies.

AI TOOL DECLARATION

The authors declares that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

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