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Review Paper

Asian Common Technical Document: An Overview of Regulatory Harmonization in ASEAN Countries

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ABSTRACT

The globalization of pharmaceutical markets has emphasized the need of harmaonized regulatory framework to facilitate the efficient registration of medicinal products across different countries. To unify pharmaceutical registration practices among its member states, the Association of Southeast Asian Nations (ASEAN) created the ASEAN Common Technical Dossier (ACTD) and the ASEAN Common Technical Requirements (ACTR). By offering a standard framework for reporting high-quality, non-clinical, and clinical data, the ACTD minimizes regulatory effort duplication and encourages uniformity in product review. The International Council for Harmonization (ICH) Common Technical Document (CTD) and the ACTD share many similarities, but the ACTD has structural and regulatory differences that reflect the particular needs of ASEAN member nations. More recently, the adoption of the Electronic Common Technical Document (eCTD) has revolutionized regulatory submissions worldwide by enhancing efficiency, lifecycle management, and communication between applicants and regulatory authorities. However, due to different national requirements and legal frameworks, eCTD implementation throughout ASEAN is still uneven. This paper gives a thorough history of the development of pharmaceutical regulatory harmonization in ASEAN, explains the components and structure of the ACTD, contrasts it with CTD and eCTD, addresses current regulatory issues, and outlines potential future directions for regional harmonization.The review also examines how standardized dossier preparation can improve regulatory efficiency, shorten approval times, and improve patient access to high-quality, safe, and effective medications. It is anticipated that increased digitization and collaboration among ASEAN regulatory authorities will further enhance pharmaceutical registration procedures and promote global regulatory

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convergence.

INTRODUCTION

The pharmaceutical industry is one of the most highly regulated sectors worldwide because medicines must consistently demonstrate quality, safety, and efficacy before they are approved for marketing. Every country has its own regulatory authority responsible for evaluating pharmaceutical products and ensuring compliance with national legislation. Historically, pharmaceutical manufacturers were required to prepare different registration dossiers for different countries, resulting in duplication of work, increased regulatory burden, delayed approvals, and higher development costs.

To overcome these challenges, international efforts toward regulatory harmonization have been initiated over the past three decades.

The creation of the International Council for Harmonization (ICH), which produced the Common Technical Document (CTD) as a standard format for regulatory submissions, was one of the most important advances (2,17,30).

The US Food and Drug Administration (US FDA), the European Medicines Agency (EMA), the Pharmaceutical and Medical Devices Agency (PMDA) of Japan, Health Canada, and a number of other nations have also embraced the CTD.

Additionally, by replacing paper-based applications with electronic formats that enhance review efficiency, document lifecycle management, and communication between applications and regulatory authorities, the Electronic Common Technical Document (eCTD) has modernized regulatory submission.(3,18)

Recognizing the need for regional harmonization, the Association of Southeast Asian Nations (ASEAN) countries of Brunei, Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam established the ASEAN Consultative Committee for Standards and Quality-Pharmaceutical Product Working Group (ACCSQ-PPWG).The committee started developing the ASEAN Common Technical Requirements (ACTR) for pharmaceutical products to harmonize the registration procedure of medicinal products in ASEAN countries. The purpose of developing the ASEAN Common Technical Dossier (ACTD) is to facilitate dossier preparation, reduce discrepancies, accelerate regional medicine availability, and enable greater exchange and cooperation of information between the authorities.While the ACTD aims to achieve the same objective as the ICH CTD, it uses a slightly different structure because ACTR has four sections for administrative, quality, and nonclinical data, as opposed to five modules in the CTD.The new approach was developed in line with international scientific regulatory guidelines and reflects both the regulators' and the strategic interests of ASEAN.The need for a common technical dossier has increased throughout time because of rising international scientific and regulatory engagement, digitalization, informatization of society, and the growing importance of regulatory oversight.ACTD has been introduced to align with the requirements of several Southeast Asian countries that have adopted electronic submissions and eCTD to improve the quality of regulation. However, the harmonization of requirements in ASEAN countries is complicated by the difference in legislation, capabilities, and specific requirements. The present paper aims to provide an insight into the main aspects of the ASEAN Common Technical Dossier (ACTD). The paper will discuss the structure and history of ACTD, its importance, comparison with CTD and eCTD, challenges, and future prospects.

Aim of the Review

Critically evaluate the ASEAN Common Technical Dossier: regulatory framework, structure, application, comparison with CTD and eCTD, challenges and future prospects in pharmaceutical regulatory harmonization
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Objectives

 To describe the process of pharmaceutical regulatory harmonization in ASEAN
 To explain the structure and components of the dossier
 To compare the ACTD with the CTD and eCTD
 To discuss the benefits and drawbacks of the ACTD
 To highlight the regulatory challenges and future needs.

2.Literature Search Strategy

In order to identify published articles, official documents, scientific reports, and regulatory guidelines related to ASEAN Common Technical Dossier (ACTD), Common Technical Document (CTD), Electronic Common Technical Document (eCTD), and pharmaceutical regulatory harmonization, a literature search was performed.Electronic databases searched included:

- PubMed
- Scopus
- Web of Science
- Google Scholar
- ScienceDirect
- SpringerLink
- Wiley Online Library

In addition, official regulatory documents were retrieved from:

- Association of Southeast Asian Nations (ASEAN)
- ASEAN Consultative Committee for Standards and Quality–Pharmaceutical Product Working Group (ACCSQ-PPWG)
- International Council for Harmonisation (ICH)
- World Health Organization (WHO)
- United States Food and Drug Administration (US FDA)
- European Medicines Agency (EMA)

The literature search covered publication from **2003 to 2026**, with greater emphasis on articles published during the last decade.

3. Regulatory Harmonization in ASEAN

3.1 What is Regulatory Harmonization?

Regulatory harmonization is the process of aligning technical requirements, scientific standards, and regulatory procedures among different countries to facilitate the registration and approval of pharmaceutical products.

The primary objectives include:

- Reducing duplication of regulatory work
- Improving efficiency of drug approval
- Promoting public health
- Facilitating international trade
- Ensuring quality, safety and efficacy of medicines
- Reducing registration timelines

Instead of preparing separate dossiers for every country, manufacturers can prepare a standardized dossier accepted by multiple regulatory authorities.

4. ASEAN Common Technical Dossier (ACTD)

Definition

The **ASEAN Common Technical Dossier (ACTD)** is a harmonized regulatory dossier format developed by ASENN member countries for the registration of pharmaceutical products (1).

It provides a common structure for presenting:

- Administrative information
- Quality information

- Non-clinical studies
- Clinical studies

The ACTD was developed to simplify dossier preparation and reduce differences in registration requirements among ASEAN countries.

Objectives of ACTD

The major objectives include:

- Harmonize pharmaceutical registration
- Reduce duplicate documentation
- Facilitate product approval
- Improve regulatory transparency
- Promote efficient regulatory review
- Encourage regional cooperation
- Improve access to medicines

Advantages of ACTD

For Pharmaceutical Companies

- Single dossier format
- Reduced documentation
- Lower submission costs
- Faster registration
- Easier preparation
- Greater consistency

For Regulatory Authorities

- Uniform review process
- Improved evaluation quality
- Better communication
- Efficient assessment
- Reduced workload

For Patients

- Faster access to medicines
- Better quality products
- Improved safety
- Increased availability of innovative medicines

5. ASEAN Common Technical Requirements (ACTR)

The ASEAN Common Technical Requirements (ACTR) provide scientific guidelines for preparing the information included in the ACTD.

ACTR specifies:

- Quality requirements
- Stability requirements
- Validation procedures
- Bioavailability requirements
  - Bioequivalence requirements
  - Non-clinical study expectations
  - Clinical study expectations

ACTR serves as the scientific guideline, whereas ACTD provides the dossier structure.

6. Structure of ACTD

Unlike the ICH CTD, the ACTD consists of four parts **(1,2,9,13).**

ACTD Part	Contents
Part I	Administrative Data and Product Information
Part II	Quality Document
Part III	Non-clinical Document
Part IV	Clinical Document

Part I – Administrative Data and Product Information

This section contains:

- Application form
- Cover letter
- Product information
- Package insert
- Labelling
- Summary of Product Characteristics (SmPC)
- Certificates
- GMP certificate
- Manufacturing license
- Certificate of Pharmaceutical Product (CPP)
- Product samples (if required)

This part is country-specific and may differ among ASEAN member states.

Part II – Quality Document

This part describes the pharmaceutical quality of the drug product.

It includes:

Drug Substance
- General information
- Manufacturer
- Manufacturing process
- Characterization
- Specifications
- Analytical methods
- Validation
- Stability

Drug Product
- Pharmaceutical development
- Manufacturing process
- Batch formula
- Excipients
- Finished product specifications
- Container closure system
- Stability studies

The Quality section ensures consistent manufacturing and product quality.

Part III – Non-clinical Document

This section contains results of laboratory and animal studies.
Major studies include:
Pharmacology
- Primary pharmacology
- Secondary pharmacology
- Safety pharmacology

Pharmacokinetics
- ADME studies
- Absorption
- Distribution
- Metabolism
- Excretion

Toxicology
- Acute toxicity
- Repeated-dose toxicity
- Genotoxicity
- Carcinogenicity
- Reproductive toxicity
- Local tolerance

These studies establish the safety profile before human use.

Part IV – Clinical Document

This section includes human clinical study data.
Contents include:
- Clinical overview
- Clinical summary
- Bioavailability studies
- Bioequivalence studies
- Phase I studies
- Phase II studies
- Phase III studies
- Phase IV studies (if available)
- Clinical safety
- Clinical efficacy

Table 1. Comparison between ACTD, CTD, and eCTD

Parameter	ACTD	CTD	eCTD
Full form	ASEAN Common Technical Dossier	Common Technical Document	Electronic Common Technical Document
Developed by	ASEAN PPWG	International Council for Harmonisation (ICH)	ICH
Primary purpose	Harmonized registration in ASEAN	Harmonized global dossier	Electronic submission and lifecycle management
Submission format	Paper/PDF	Paper or electronic	Fully electronic (XML-based)
Number of sections	Four Parts	Five Modules	Five electronic modules
Administrative information	Part I	Module 1	Module 1

Quality information	Part II	Module 3	Module 3
Non-clinical studies	Part III	Module 4	Module 4
Clinical studies	Part IV	Module 5	Module 5
Summaries	Included within Parts II–IV	Module 2	Module 2
Regional adaptation	ASEAN-specific	ICH regions	Global electronic standard
Lifecycle management	Limited	Limited	Comprehensive
Navigation	Manual	Manual	Hyperlinked and searchable
Review efficiency	Moderate	High	Very high
Submission updates	Resubmission often required	Paper/electronic updates	Incremental electronic updates
Validation	Manual	Manual	Automatic validation
Regulatory review	Conventional	Harmonized	Digital and efficient
Global acceptance	ASEAN countries	Worldwide (ICH and many non-ICH regions)	Increasingly adopted worldwide
Review time	Moderate	Faster	Fastest
Cost	Low	Moderate	Higher initial implementation cost
Environmental impact	Higher (paper usage)	Moderate	Lowest (paperless)

7. Challenges in ACTD Implementation

country-specific public health Several factors continue to influence the effective implementation of ACTD:

- Variability in national regulatory requirements.
- Differences in review procedures among ASEAN authorities.
- Limited adoption of eCTD infrastructure.
- Need for continuous training of regulatory professionals.
- Rapid evolution of international regulatory standards.
- Balancing regional harmonization with priorities.

Addressing these challenges reguires enhanced collaboration, capacity building and investment in digital regulatory systems.

8. Future Perspectives

The future of ACTD is closely linked to the ongoing modernization of pharmaceutical regulatory systems.

Key future directions include:

- Wider implementation of eCTD across ASEAN.
- Increased reliance on digital submission platforms.
- Greater regulatory convergence with ICH guidelines.
- Expansion of regulatory reliance and work-sharing initiatives.
- Integration of artificial intelligence and automation into dossier review.
- Continuous updating of ACTD to reflect advances in pharmaceutical science and technology.

A harmonized electronic submission system across ASEAN would further reduce regulatory burden and improve access to medicines throughout the region.

RESULTS AND DISCUSSION

The implementation of the ASEAN Common Technical Dossier (ACTD) has been a major milestone in harmonizing pharmaceutical

regulatory requirements across ASEAN member countries.

ACTD requires the use of a standard dossier layout that improves application uniformity and accelerates the evaluation process. Unlike the ICH CTD, ACTD consists of only 4 sections to describe the same aspects of a product's quality, safety, and efficacy. Its simplicity is achieved through the inclusion of quality, non-clinical, and clinical summaries in each section. Thus, the dossier is easier to be read and understood by the ASEAN regulatory authorities, which shortens the approval time. However, since ACTD dossier differs from the 5-part format of the ICH CTD, the companies will have to adapt the same document for different regions in order to submit it successfully. The electronic common technical document (eCTD) has profoundly impacted regulatory submissions by enabling electronic lifecycle management, improving document navigation, automating validation, and facilitating communication (3,18,19).

While several ASEAN countries have started implementing the eCTD partially, the process is not uniform due to different national requirements, levels of technical expertise, and policies. The harmonization will take place at a higher level and require massive investment in building and maintaining the required infrastructure. In general, the eCTD will have a significant regulatory impact on the region, including more excellent collaboration among the member states' regulatory agencies and an increased production of high-quality medicinal products. Moreover, the worldwide adoption of standards and the eCTD specification in particular will facilitate international drug development and regulation.

CONCLUSION

The ASEAN Common Technical Dossier (ACTD) is an example of a successful harmonization process, which allows member states to make the process less time consuming and less bureaucratic since it reduces redundant procedures and paperwork. Additionally, it promotes consistency between countries in terms of the evaluation process, which results in improved approval rates for pharmaceutical products in member states, and it allows for a greater level of flexibility.

Although having a similar purpose to the ICH CTD, the ACTD was developed in order to meet the specific regulatory requirements applicable in the ASEAN region through the special four-part structure. The transition to the electronic common technical document (eCTD) will allow optimizing regulatory interactions, enhancing transparency, and improving management of product life cycles and submissions. Nevertheless, the harmonization process faces challenges related to legal, technical, and operational issues.

The future initiatives should focus on promoting synergies among ASEAN regulatory authorities, the use of the eCTD, building regulatory reliance, and aligning ACTD with global trends. These programs will drive the industry to create innovative pharmaceutical products and promote the region's long-term growth as a reliable supplier of quality generic drugs and active pharmaceutical ingredients, while shortening the time to clinical trials of innovative medicines and bringing safe and effective drugs to patients.

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