

**REGULATORY REQUIREMENTS FOR THE SUBMISSION OF CTD AND ECTD AS PER
CDSCO IN COMPARISON WITH CAMBODIA****Dr. P. Ashok Kumar*, Reshma B. Y., Usha K. J., Sandhya Y. R., Lekhashree J.**

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ABSTRACT

Stringent regulatory standards apply to the creation of Common Technical Documents (CTD) and Electronic Common Technical Documents (eCTD) for regulatory submissions in India, which are overseen by the Central Drugs Standard Control Organization (CDSCO). The essential regulatory considerations affecting the creation of CTD and eCTD submissions in accordance with CDSCO criteria are summarized in this abstract. It emphasizes how crucial adherence to these rules is to ensure the prompt and effective registration of pharmaceutical goods in India. The advantages of eCTD in simplifying the regulatory process are also briefly covered in the abstract, along with the changing environment of electronic submissions. For pharmaceutical businesses seeking market authorization in India and for regulators striving to maintain the highest standards, understanding and adherence to CDSCO's regulatory requirements are essential.

KEYWORDS: CTD is for Common Technical Documents; ECTD stands for Electronic Common Technical Documents; Central Drugs Standard Control Organization stands for central Drugs Standard Control Organization.

1. INTRODUCTION**1.1. CDSCO (Central drug standard control organization)**

CENTRAL DRUG STANDARD CONTROL ORGANISATION (CDSCO) regulates the nation's registered medical devices, cosmetics, and pharmaceuticals for quality.

It is the National Drug Regulatory Authority of the Government of India and is in charge of establishing drug standards, approving clinical trials, monitoring the quality of imported drugs, coordinating the work of state drug control organizations, and giving professional advice in order to ensure consistency in the application of the drugs and cosmetics laws. Cosmetics Act in addition to the granting and renewal of licenses for certain key categories of drugs such blood and blood products, intravenous fluids, vaccines, sera, r-DNA products, and medical devices. The Indian government is currently working to improve the standards of the

nation's regulatory practices and introduce a high level of uniformity in these activities. throughout the States. A strong regulatory framework should be built with the assistance of science to support and advance national research and development. Throughout the States. A strong regulatory framework should be built with the assistance of science to support and advance national research and development.

1.2. CTD (Common technical documents)

"Internationally agreed upon format for the preparation of applications regarding new drugs intended to be submitted to regulatory authorities in participating countries" is known as CTD. To ensure effective data review, the CTD is a "set off specifications for a dossiers for the registration of medicines" and is intended to be the standard format for submitting regulatory information (such as applications, supplements, and reports) to the relevant health authorities (HAS).

A Common Technical Document (CTD) is a list of leaflets that must be submitted with a pharmaceutical registration application to the regulatory agency in order to get market authorization. The data format is primarily described by CTD. It is common for RA specialists to be familiar with the paperwork required for the approval of a drug product. Contrarily, the orderly organization of information is the main focus of CTD. CTD documentation must to be clear, uncomplicated, and transparent. Regulators in Europe, Japan, and the US have endorsed and recognized the CTD format, which is one that the ICH has established. The CTD is described by the FDA as an information package combining clinical, non-clinical, manufacturing, and technical data that would be submitted for registration of innovative pharmaceuticals in all three ICH territories, namely the US, the EU, and Japan. In semi-regulated markets like the ASEAN countries, paper submission of ACTD and CTD format dossiers as well as computer submission of CD format dossiers are employed.

1.3 (eCTD) Electronic Common Technical Document

ECTD (Electronic common technical documents) For regulatory bodies, it is quite challenging to sort through and evaluate this vast amount of data. For the evaluation process, a lot of time will be needed. Additionally, it might be quite time-consuming to identify a specific file in order to learn about a specific CTD issue during its review. The applicant finds it challenging to create numerous copies of this extensive CTD application. Hard copies, their color coding, and their organization into modules require the applicant to invest a significant amount of money, technical expertise, and time. These CTD's shortcomings prompted ICH to create an electronic version of CTD. The HL7 RPS Project's specifications were prepared by the ICH M2 EWG. In 2010, ICH assembled the Expert Working Group for eCTD, gave them the go ahead for eCTD development, and awarded the topic code M8. The task of further developing eCTD recommendations is under ICH M8. Under Step 2b of the ICH process, the Draft eCTD Implementation Guide (v.2.0) and associated papers were made available for regulatory consultation until May 22, 2015. In 2010, eCTD became necessary for centralized processes. While eCTD is not required in Europe, it is in the USA. For MAA, eCTD is submitted in addition to the paper submission.

AIM

To safeguard and advance India's public health. Mission: To protect and improve public health by ensuring the efficacy, quality, and safety of medications, cosmetics, and medical equipment.

The CTD is a globally accepted framework for the creation of new drug application submissions intended for regional regulatory authorities in participating nations. The CTD is intended to encourage regulatory requirements for the creation and registration of pharmaceuticals across various countries and regions.

among other things, improving or adjusting the effectiveness of each RNA processing reaction necessary for the full completion of the synthesis of the mature RNA. The CTD's activity is greatly influenced by the state of phosphorylation in which it is. The introduction of eCTD was done to lighten the workload of the HAs' reviewers. Due to the fact that all Regulatory authorities use it as a standard format, it also streamlines the filing procedure. An interface and worldwide specification for the pharmaceutical sector to agency transfer of regulatory information is the electronic common technical document (eCTD). It is crucial to submit applications, modifications, supplements, and reports on pharmaceutical products to regulatory agencies during the progress of clinical trials. Electronic Common Technical Document (eCTD) is the standard format to enable worldwide regulatory submission.

OBJECTIVE

The main objectives of CTD and ECTD

- The CTD is an internationally agreed format for the preparation of applications regarding new drugs intended to be submitted to regional regulatory authorities in participating countries.
- Enhancing or modulating the efficiency of all of the RNA processing reactions required for completion of synthesis of the mature RNA The CTD format influences the content of the review by imposing a consistent order of information and data.
- Harmonization CTD has driven fundamental changes in regulatory practice.
- The phosphorylation state of the CTD is critical in determining its activity.
- CTD presents the agreed common format for preparation of a well-structured dossier that will be submitted to regulatory authorities.
- A common format for the technical documentation will significantly reduce the time and resources needed to compile applications for registration and will ease the preparation of electronic submissions.
- The purpose of introducing eCTD was to reduce the burden on the reviewers of the Has
- It also simplifies the process of submission as all the Regulatory authorities use it as a standard format
- Local affiliates can review updates in real-time.
- Handling, managing, and archiving trial and document-essential information is less time-consuming
- Documents are easily accessible via search and tracking.
- CTD presents the agreed common format for preparation of a well-structured dossier that will be submitted to regulatory authorities.
- A common format for the technical documentation will significantly reduce the time and resources needed to compile applications for registration and will ease the preparation of electronic submissions.

2. Review on comparison CTD and ECTD

2.1. History

- Firstly introduced in 1995-1996
- CTD was agreed in harmonized structure and format for new product application

- CTD was developed by the European medicine's agency (EMA), food and drug administration (FDA), the ministry of health, labour and welfare (Japan).

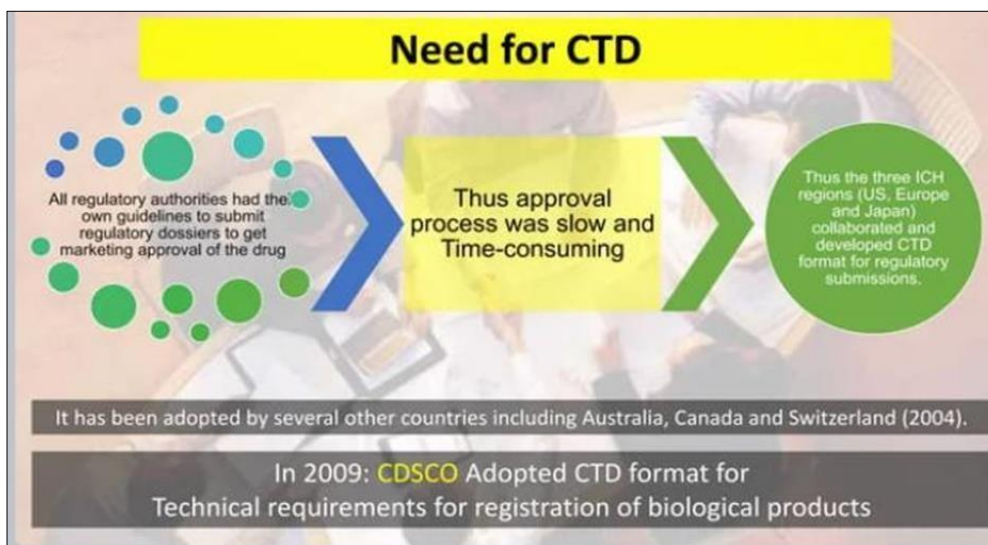


Figure no. 1: Need for CTD.

2.2. Why CTD?

- Hurdles put down by the three major regulatory authorities
- Objective of ICH to prepare the CTD
- Reduce the time and resources used to compile application
- It will ease the preparation of electronic submission
- To facilitate easier exchange of regulatory information and thereby faster availability of new medicines.



Fig. no. 2: eCTD.

2.3. ECTD benefits

- Easy to distribute and review
- More efficient use of resources, less cost and stress to the organization
- Highly organized electronic table of contents
- Searchable, Self-Validating
- Integrated document and life-cycle management
- Cross submission integration

2.4. CDSCO (Central drugs standard control organization)



Figure no. 3: CDSCO.

Central Drugs Standard Control Organization (CDSCO) exercises regulatory control over the quality of drugs, cosmetics and notified medical devices in the country

- It is the National Drug Regulatory Authority of the Government of India and is responsible for laying down the standards for Drugs, approval for Clinical Trials, control over quality of imported Drugs, coordination of activities of State Drug Control Organizations and providing expert advice with a view to bring about uniformity in the enforcement of the Drugs and Cosmetics Act as well as granting and renewal of licenses for specified critical categories

of Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera, r-DNA products and Medical devices. The Government of India is currently engaged in upgrading the quality of regulatory practices in the country and bring in a high degree of uniformity in these practices across the States.

A good regulatory system should help build a science based regulatory framework to support and promote Research and Development in country.

2.5. Functions of CDSCO

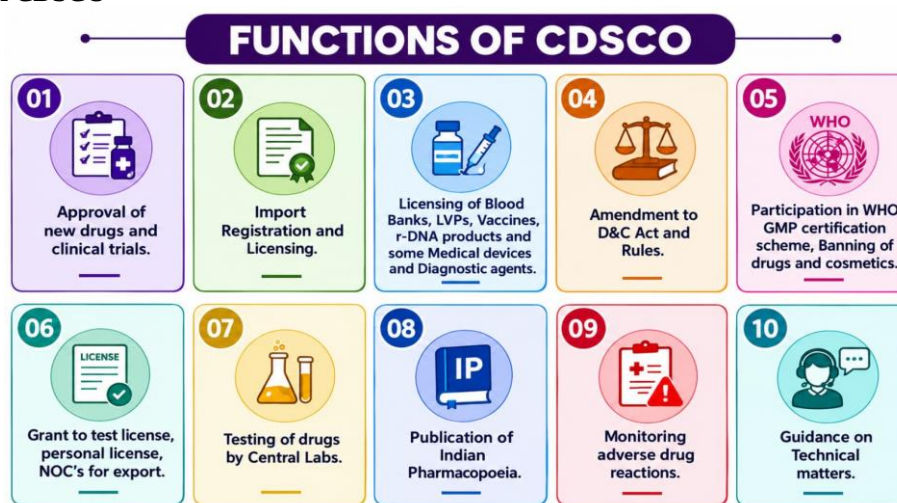


Figure no 4: Function of CDSCO.

2.6. Office of Drugs Controller General of India (CDSCO Offices/Labs)

- Zonal Offices: Mumbai, Ghaziabad, Chennai, Kolkata, Ahmedabad and Hyderabad.
- Sub Zonal Offices: Chandigarh, Bangalore, Jammu and Goa.

- Port Offices : Ahmedabad, Bangalore, Goa, Chennai (Sea and Air), Delhi, Kochi, Kolkata (Sea and Air), Mumbai (Sea and Air), Navasheva, Hyderabad.
- Central Drugs Laboratories: Mumbai, Chennai, Guwahati, Chandigarh, Kolkata, Hyderabad.

2.7. Five module of CTD AND eCTD

CTD Triangle

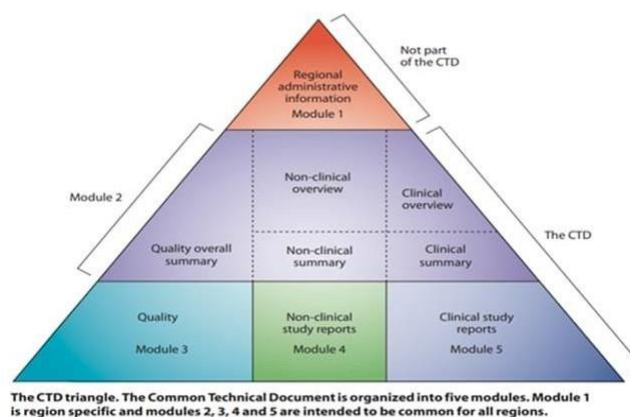


Figure no. 5: CTD Triangle.

- Module 1: General Information
- Module 2: CTD Summaries
- Module 3: Quality
- Module 4: Nonclinical Study Reports
- Module 5: Clinical Study Reports

2.7.1. Module 1: General Information

Module 1 is region specific due to which it is not strictly included in CTD. It contains administrative information, labeling information, and application forms. Different countries have different formats and content for Module 1.

2.7.2. Module 2: CTD Summaries

This module should begin with a general introduction to the pharmaceutical, including its pharmacologic class, mode of action, and proposed clinical use.

2.7.3. Module 3: Quality

Module 3 provides information on the chemistry of drug product and drug substance, their manufacturing, and controls

2.7.4. Module 4: Nonclinical Study Reports

Module 4 describes the format and organization of the non-clinical (pharmacotoxicological) data relevant to the application

2.7.5. Module 5: Clinical Study Reports

Module 5 includes clinical data of a drug product required for marketing approval on its efficacy, safety, pharmacokinetic, pharmacodynamics, and other relevant data.

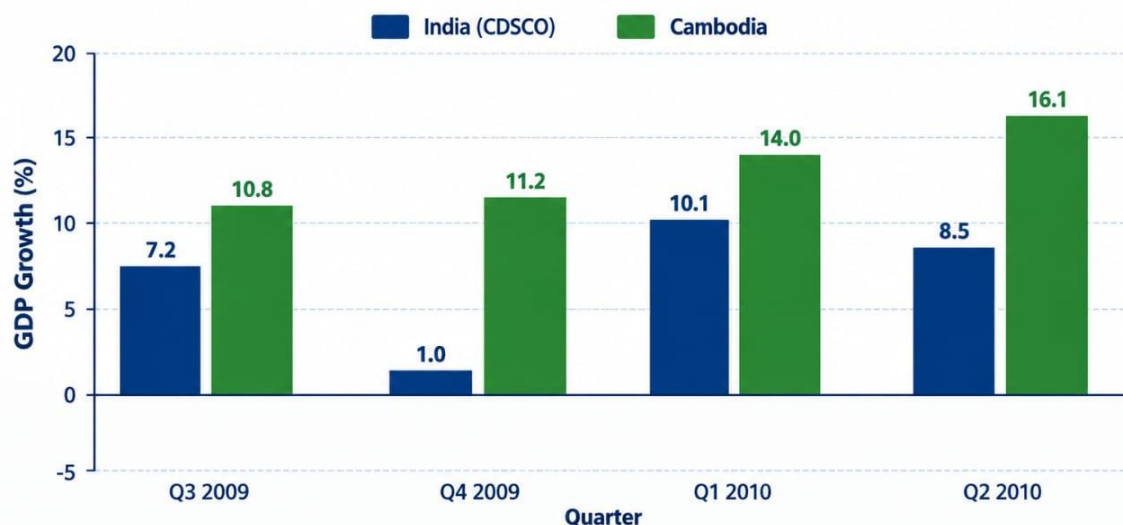
3. Comparison of India V/S Cambodia

Table 1: Comparison of CTD of India V/S Cambodia.

Filing a CTD in India	Filing a eCTD in Cambodia
Format :Paper -based or physical digital media (CDS/DVDS) with printed pages.	Format :Electronic files are governed by an XML backbone.
Lifecycle management : Cumbersome. Changing a document requires printing and submitting massive volumes of paper.	Lifecycle management : Highly efficient allows for precise tracking, replacement or deletion of specific files over the drug's cycle.
Navigation :Uses physical tabs, binders and a manual table of contents.	Navigation :Uses built- in PDF bookmarks, hyperlinks and automated XML directory trees for instant navigation.
Global Mandate : Mostly obsolete for primary submissions; still used in regions without eCTD capabilities.	Global Mandate : The mandatory submission standard for a major global authorities like the USFDA and the EMA.
Origin/Scope : ICH standards to harmonize dossiers across major regulators.	Origin/Scope :Digital evolution of CTD using the same five-module logic.
Structure :fivemodules:M1(regional)+M2-M5(summaries, quality, non-clinical, clinical).	Structure :Same five modules, but organized and referenced via XML backbone.
Module-2 (Summaries) :Module -2 holds high-level summaries for module 3-5.	Module-2 (Summaries) :Data Exclusivity: Brazil has its data protection regulations.
Geographic Acceptance :ICH regions and many others accept CTD for harmonized filings.	Geographic Acceptance : Mandatory or preferred in key markets (FDA, EMA); widely adopted globally
Updates and Versioning :Whole dossier replacements or manual updates; less automated.	Updates and Versioning :Incremental updates allowed; sequences track changes and lifestyle..
Primary Advantage : Global harmonization; Reduced duplication across regions.	Primary Advantage : Streamlined submissions, reviewer – friendly navigation, audit- ready.
Best Use care :Preparing a dossier for ICH markets or multi regions filings.	Best Use care : Any sponsor planning lifecycle management and multiply filings mandatory in many regions.
Accessibility and Search ability :CTD is paper-based, submissions are less accessible and searchable, making it more challenging for regulators to quickly locate and review specific information.	Accessibility and search ability :eCTD submissions are highly accessible and searchable, enabling regulators are easily navigate through the documents, search for specific information and expedite the review process.

GDP GROWTH COMPARISON: INDIA (CDSCO) vs CAMBODIA

Percent, Quarter-on-Quarter (Seasonally Adjusted Annual Rate)



India (CDSCO): GDP growth data as per CDSCO (Source: JP Morgan Global DataWatch)

Cambodia: GDP growth data (Source: World Bank)

Graph: GDP Growth Comparison – India (CDSCO) vs Cambodia

Fig. no. 6: GDP Growth Comparison.

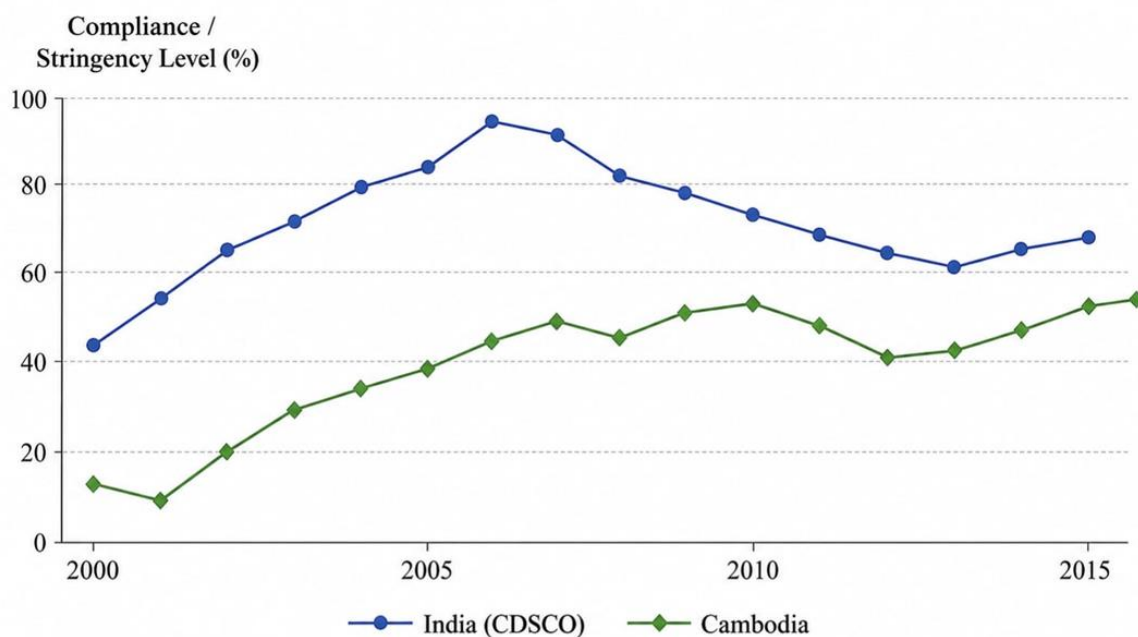


Fig. no. 7: Comparison graph of India v/s Cambodia.

4. CONCLUSION

In conclusion, the regulatory requirements for the preparation of Common Technical Document (CTD) and Electronic Common Technical Document (eCTD) submissions in India, governed by the Central drugs standard Control Organization (CDSCO) and those in Cambodia, overseen by the Department of Drugs and Food (DDF) have similarities and differences.

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