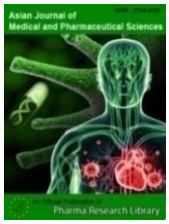

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A Study on New Regulations for Marketing and Authorization of Pharmaceutical Products in USA and India

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A B S T R A C T

The marketing authorization is given by CDSCO to different types of drugs under the provision of Drugs & Cosmetics Act 1940 and Rules 1945 and New Drugs and Clinical Trials Rules 2019. Any substance falling within the definition of drug (Section 3b of the Act) is required to be registered before import into the country. Not only drug but the manufacturing site needs to be registered for import. If the drugs, fall within the definition of New Drug (Rule 2 (w) of the Act), the new drug approval is the pre-requisite for submission of application for Registration and or import of drug. The study aims to assess the regulatory strategy for product development is essentially to be established before commencement of developmental work in order to avoid major surprises after submission of the application. The goal of ICH is to promote international harmonization by bringing together representatives from the three ICH regions (EU, Japan and USA) to discuss and establish common guidelines. Since year 2003, the authorities in the United States, the European Union (EU) and Japan ask for the Common Technical Document (CTD) format set out by the 2003 International Conference on Harmonization (ICH) which was agreed by the Regulatory Agencies of Europe, Japan and the US and the Research-based Industry and more recently, its electronic version - the electronic Common Technical Document (eCTD). Pharmaceutical product approval process should be seen as a critical step in ensuring access to safe and effective drugs. Although there is a continuous process of harmonization taking place all around the world, still we see a huge challenge, which is yet to be overcome by the Pharmaceutical industry in case of generic drug development and filing. Therefore, to meet these challenges, a lot of strategic planning is required before the development of any generic drug product.

Keywords: CDSCO, ICH, Common Technical Document, safe and effective drugs, generic drug product.

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

Import, manufacturing, sale and distribution of drugs in India is regulated under Drugs and Cosmetics Act 1940 and Drugs and Cosmetic Rules 1945 and New Drugs and Clinical Trials Rules 2019. At present, bulk drug and finished formulations are regulated under the said Act. A Marketing Authorization Applications an application submitted by a drug manufacturer seeking permission to bring a newly developed medicinal product (for example, a new medicine) to the market. It is a term used by the countries from the Europe Union seeking permission to bring a newly developed medicinal product to the market. In India, there is officially no term such as Marketing Authorization Holder. In the present scenario, India has stringent regulatory requirements for approval of a new

drug. The CDSCO is the national regulatory authority in India that evaluates safety, efficacy and quality of drugs in the country.

The marketing authorization is given by CDSCO to different types of drugs under the provision of Drugs & Cosmetics Act 1940 and Rules 1945 and New Drugs and Clinical Trials Rules 2019. Any substance falling within the definition of drug (Section 3b of the Act) is required to be registered before import into the country. Not only drug but the manufacturing site needs to be registered for import. If the drugs, fall within the definition of New Drug (Rule 2 (w) of the Act), the new drug approval is the pre-requisite for submission of application for Registration and or import of drug. An applicant is required to file application in Form CT-18/CT-21 along with prescribed fees in the form of Bharatkosh challan and all relevant data as per Second Schedule of New Drugs and Cosmetics Rules 2019, for seeking permission to import or manufacture of new drug substances and its formulations for marketing in the country or conduct of clinical trials in India. The pharmaceutical industry is one of the highly regulated industries, with many rules and regulations enforced by the government to protect the health and well-being of the public. Therefore, the aim of the pharmaceutical industry is to identify and develop a generic drug product which can be tailor made to meet the diverse market requirements[1-6].

As per global market trend, it is estimated that approximately $150 billion worth of drugs will be off-patented during the period 2010 to 2017, which will serve as a platform for pharmaceutical companies to develop generic drugs. The pharmaceutical industry in India has shown a remarkable growth which in turn has risen the economy of India. After the introduction of the product patent regime in India, there was a need for pharmaceutical companies both in India and abroad to explore newer markets. Indian pharma majors are entering new markets with global ambitions, mergers and acquisitions are in focus with a reason to enter new market. For sustained growth over the next few decades, firms have to concentrate on generic drug products. “Diseases that cannot be cured, diseases that have to be managed, provide great opportunities for generic drugs.” Government has the responsibility to protect their citizens. It is the responsibility of national governments to establish regulatory authorities with strong guidelines for quality assurance and drug regulations in the respective territories. Somewhat parallel with the ongoing harmonization and movement toward creating a common market for medicines inside the EU, the need for wider harmonization was felt by officials from Japan, EU, and US during International Conference of Drug Regulatory Authorities (ICDRA) organized by world health organization (WHO). The informal discussions had led to a need of the harmonization of requirements relating to the new innovative drugs and also subsequently paved the way to the establishment of International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH), a collaborative initiative between the EU, Japan, and the United States with observers from WHO, EFTA, and Canada. Efforts to harmonize various elements of drug regulatory activities have been initiated by various inter-governmental organizations at regional and inter-regional level in the past decade.

2. Methodology

Investigational New Drug (IND) Application

It’s an application filed to the FDA in order to start clinical trials in humans if the drug was found to be safe from the reports of Pre clinical trials. A firm or institution, called a Sponsor, is responsible for submitting the IND application. A pre - IND meeting can be arranged with the FDA to discuss a number of issues:

- The design of animal research, which is required to lend support to the clinical studies
- The intended protocol for conducting the clinical Trial
- The chemistry, manufacturing, and control of the investigational drug

New Drug Application (NDA): If clinical studies confirm that a new drug is relatively safe and effective, and risks to patients, the manufacturer files a New Drug Application (NDA),the actual request to manufacture and sell the drug in the United States[7].

Drug Approval Regulatory &Process In The United States: The United States represents the largest continental pharma market worldwide and holds around 45% global market. The pharmaceutical market in the United States was expected to increase from $354bn in 2015 to $497bn by 2020. The FDA is the main regulatory body that handles drug approval in the United States. Though markets like China and India have shown a massive leap in the pharma market, the United States and Europe are still the key players in the pharmaceutical industry. The United States has the world’s most stringent standards for approving drugs, and drug approval standards are considered the benchmark by many regulators worldwide.

Regulatory body for drug approval in the USA

The Food and Drug Administration (FDA) is responsible for protecting and promoting public health. The Center for Drug Evaluation and Research (CDER) is a division of the U.S. Food and Drug Administration (FDA) that monitors most drugs as defined in the Food, Drug, and Cosmetic Act. FDA approval process begins only after the submission of the Investigational New Drug (IND) application[8-9].

Who can submit IND, NDA & NDA 505(b)(2) drug applications: The applicant, or the applicant’s attorney, agent, or authorized official must sign the NDA. If the person signing the NDA does not reside or conduct business within the United States, the NDA is required to contain the name and address of, and be countersigned by, an attorney, agent, or an authorized official who resides or maintains a place of business within the United States.

The approval process for Investigational New Drug (IND): If the results prove safe in the preclinical trials, the sponsor can submit an Investigational New Drug (IND) application with the FDA to start clinical trials in humans. The sponsor is responsible for the submission of the IND application.

Table 1: Application forms and corresponding licenses for Indian regulator authorities to carry out development stage of products

Application types	Application Form No.	License Form No.	Regulator Y body	Validity	Timelines in Days
Import of drugs for the purpose of examination, test Or analysis	Form12	Form11	CDSCO	1Year	45
NOC for manufacture for The purpose of examination, test or analysis (Form 29)	-	NOC	CDSCO	-	60#
Manufacture for the purpose of examination, test or analysis	Form30	Form29	SLA	1Year	

- The role of the regulatory authorities is to ensure the quality, safety, and efficacy of all medicines in circulation in their country. It not only includes the process of regulating and monitoring the drugs but also the process of manufacturing, distribution, and promotion of it.
- This process involves the assessment of critical parameters during product development. Any drug/medicinal product have to be approved/ authorized by the respective regulatory authorities before it can be placed in the market.
- To get this approval/authorization, certain trials had to be conducted to prove the safety and efficacy of the drug/medicinal product.

3. Results and Discussion

Regulatory dossier submission in ICH countries:

The complete name of ICH is the "International Conference on harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use". ICH is a joint initiative involving both regulators and research-based industry representatives of the European Union, Japan and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines. The goal of ICH is to promote international harmonization by bringing together representatives from the three ICH regions (EU, Japan and USA) to discuss and establish common guidelines. For example, since year 2003, the authorities in the United States, the European Union (EU) and Japan ask for the Common Technical Document (CTD) format set out by the 2003 International Conference on Harmonization (ICH) which was agreed by the Regulatory Agencies of Europe, Japan and the US and the Research-based Industry and more recently, its electronic version - the electronic Common Technical Document (eCTD). CTD provides a common format for the submission of information to the Regulatory Agencies for the registration of the pharmaceutical product.The CTD is organized into five modules as shown in Figure I. Module 1 is region specific and Modules 2, 3, 4 and 5 are intended to be common for all regions. The agreement to assemble all the Quality, Safety and Efficacy information in the CTD format has revolutionized the regulatory review processes, led to harmonized electronic submission that, in turn, enabled implementation of good review practices[10-16].

Module 1: Administrative Information and Prescribing Information

1.1 Table of Contents of the Submission Including Module
1.2 Documents Specific to Each Region e.g. the application forms, labeling etc.

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, not exceeding one page. Module 2 should contain 7 sections in the following order: CTD table of contents

- CTD introduction
- Quality overall summary
- Nonclinical overview
- Clinical overview
- Nonclinical written and tabulated summaries
- Clinical summary

Module3: Quality Information on Quality should be presented in the structured format as described below:

3.1 Table of Contents of Module 3
3.2 Body of Data
3.2. S Drug substance(s)
3.2. S.1 General Information
3.2. S.2 Manufacture of Drug Substance (name, manufacturer)
3.2. S.3 Characterization of Drug Substance (name, manufacturer)
3.2. S.4 Quality Control of Drug Substance (name, manufacturer)
3.2. S.5 Reference Standards or Materials (name, manufacturer)
3.2. S.6 Container Closure System (name, manufacturer)
3.2. S.7 Stability of Drug Substance (name, manufacturer)
3.2. P Drug product (name, dosage form)
3.2. P.1 Description and Composition of the Drug Product (name, dosage form)
3.2. P.2 Pharmaceutical Development (name, dosage form)
3.2. P.3 Manufacture of drug product (name, dosage form)
3.2. P.4 Controls of Excipients (name, dosage form)
3.2. P.5 Control of Drug Product (name, dosage form)
3.2. P.6 Reference Standards or Materials (name, dosage form)
3.2. P.7 Container Closure System (name, dosage form)
3.2. P.8 Stability (name, dosage form)

3.2. A Appendices
3.2. A.1 Facilities and Equipment (name, manufacturer)
3.2. A.2 Adventitious Agents for Safety Evaluation (name, dosage form, manufacturer)
3.2. A.3 Excipients
3.3 Literature References

Module 4: Nonclinical Study Reports

The nonclinical study reports should be presented in the order described below:
4.1 Table of contents of module 4
4.2 Study reports
4.2.1 Pharmacology
4.2.2 Pharmacokinetics
4.2.3 Toxicology
4.3 Literature references

Module 5: Clinical Study Reports

The human study reports and related information should be presented in the order described below:
5.1 Table of contents of module 5
5.2 Tabular listing of all clinical studies
5.3 Clinical study report
5.4 Literature References

The ASEAN Common Technical Document is organized into four parts.

Part I.

Table of Contents, Administrative Data and Product Information

Part I contains initially the overall Table of Contents of the whole ACTD to provide basically the information that could be looked through respectively. Secondly, the next content is the Administrative Data where required specific documentation in details is put together such as application forms, label, and package insert etc. The last section of this part is Product Information where necessary information includes prescribed information, mode of action, side effects etc.

A. Introduction
B. Table of Contents
C. Administrative Data and Product Information
1. Application Form
2. Letter of Authorization
3. Certifications
4. Labelling
5. Product Information

Part II. Quality Document

Part II should provide the Overall Summary followed by the Study Reports. The quality control document should be described in details as much as possible.

Section A: Quality Overall Summary (QOS): Table I gives a view of the Quality Overall Summary of Part II of ACTD.

Section B: Table of Contents

Section C: Body of Data

Part III. Nonclinical Document

Part III should provide the Nonclinical Overview, followed by the Nonclinical Written Summaries and the Nonclinical Tabulated Summaries. The document of this part is not required for Generic Products, Minor Variation Products and some Major Variation Products. For ASEAN member countries, the Study Reports of this part may not be required for NCE, Biotechnological Products and other Major Variation Products if the Original Products are already registered and approved for market authorization in Reference Countries.

Section A: Table of Contents
Section B: Nonclinical overview
Overview of the Nonclinical Testing Strategy
Pharmacology
Pharmacokinetics
Toxicology
Integrated Overview and Conclusions
List of Literature Citations
Section C: Non clinical written and tabulated summaries
1. Introduction
2. Content of nonclinical written and tabulated summaries
Pharmacology
Pharmacokinetics
Toxicology
Section D: Nonclinical study reports

Part IV: Clinical Document

Part IV should provide the Clinical Overview and the Clinical Summary. The document of this part is not required for Generic Products, Minor Variation Products and some Major Variation Products. For ASEAN member countries, the Study Reports of this part may not be required for NCE, Biotechnological Products and other Major Variation Products if the Original Products are already registered and approved for market authorization in Reference Countries.

Section A. Table of contents
Section B. Clinical overview
Product Development Rationale
Overview of Biopharmaceutics
Overview of Clinical Pharmacology
Overview of Efficacy
Overview of Safety
Benefits and Risks Conclusions
Section C: Clinical summary
Summary of biopharmaceutic studies and associated analytical methods
Summary of clinical pharmacology studies
Summary of clinical efficacy
Summary of clinical safety
Synopsis of individual studies
Section D: Tabular listing of all clinical studies
Section E: Clinical study reports

OVERVIEWOF ICH – CTD AND ACTD

In the present section an attempt has been made to compare the drug regulatory approval procedure and requirements for the registration of pharmaceuticals for human use ICH countries and ASEAN. The main points of divergence are in the content and format of the registration dossier.

The ACTD consists of Parts I to IV which have subsections A to F whereas ICH – CTD has 5 Modules with subsections that are numbered. The administrative data of Part I is part of ACTD whereas Module 1 of ICH – CTD is purely country specific. The summaries of the quality (Part II), nonclinical (Part III) and clinical (Part IV) are located at the beginning of each part of the ACTD. The ICH – CTD dedicates these summaries in a separate Module 2. As the ACTD does not have such summary part, it consists of only 4 Parts and not 5. The main differences between the ICH - CTD and ACT Dare listed below in Table II.

The value of the global pharmaceutical market is expected to grow at 5 percent CAGR, to be USD 1trillion in 2014 according to Urch publishing. The pharmaceutical industry is one of the highly regulated industries, to protect the health and well-being of the public. The structures of drug regulation that exist today i.e. drug laws, drug regulatory agencies, drug evaluation boards, quality control laboratories, drug information centers, etc., have evolved over time in response both to the increasingly sophisticated pharmaceutical sector, and to the apparent needs of society.

In the present scenario, India has stringent regulatory requirements for approval of a new drug. The single regulatory approach for marketing authorization application (MAA) of a new drug product belonging to various categories of drugs (NCE, Biologicals, Controlled Drugs etc.) is utmost difficult. Therefore, the knowledge of precise and detailed regulatory requirements for MAA of different categories of drugs should be known to establish a suitable regulatory strategy.

The new drug approval process has been made into three phases for simplification in understanding - the first phase is pre-marketing meant for discovery, development and clinical studies, second phase for marketing authorization of drug and third is for post marketing. Firstly, preclinical studies of a drug are completed to ensure efficacy and safety, and then application for conduct of clinical trials is submitted to the CDSCO. Thereafter, the clinical trials can be conducted (phase I to phase IV). These studies are performed to ensure the efficacy, safety and optimizing the dose of drug in human beings. After the completion of clinical studies of the drug, then an application to the competent authority of India for the approval of drug for marketing is submitted. The competent authority reviews the application and approve the drug for marketing only if the drug is found to be safe and effective in human being or the drug have more desirable effect as compare to the risk. Even after the approval of new drug, marketing authorization holder should monitor and report to CDSCO its safety, quality changes from time to time as part of quality and regulatory compliance[17].

Import of drugs for examination, test or analysis in Form 11: Test license or Form 11 license is obtained for the import of small quantities of drugs, which is otherwise prohibited under section 10 of the Drugs and Cosmetics Act and Rules, 1945, for the purpose of examination, test or analysis. The application to be submitted in Form 12, requisite fee Rs. 100/- for single drug Rs. 50 for each additional drugs along with the supporting documents to CDSCO for approval in Form 11 having validity of 1 year. The following conditions to be considered by the applicant as laid down in the D&C act and Rules:

- No drug shall be imported for such purpose except under a license in Form 11.
- The licensee shall use the substances imported under the license exclusively for purposes of examination, test or analysis and shall carry on such examination, test or analysis in the place specified in the license, or in such other places as the licensing authority may from time to time authorize;
- The licensee shall allow Drug Inspector authorized by the licensing authority in this behalf to enter, with or without prior notice, the premises where the substances are kept, and to inspect the premises, and investigate the manner in which the substances are being used and to take samples thereof;
- The licensee shall keep a record of, and shall report to the licensing authority, the substances imported under the license, together with the quantities imported, the date of importation and the name of the manufacturer;
- The licensee shall comply with such further requirements, if any, applicable to the holders of licenses for examination, test or analysis as may be specified in any rules subsequently made under Chapter III of the Act and of which the licensing authority has given to him not less than one month's notice.

Manufacture of drugs for examination, test or analysis in Form 29: For development of any new drug the applicant is required to obtain license in Form-29 from State Licensing Authority based on NOC obtained from CDSCO. No objection certificate (NOC) to be sought from the CDSCO zonal office by submitting the application in prescribed format which comprise of product general information, manufacturing facility details, technical staff. Application in Form 30 along with prescribed fee Rs. 250/- for single product to be submitted to SLA for grant of form 29, upon receipt of NOC from zonal.

Approval Mechanism and Recent Updates for Clinical Trials in India: For Clinical trials application, the data should be submitted in form 44 along with requisite fee and supportive details such as chemical and pharmaceutical data; generic & chemical name; dosage form; composition; animal pharmacology & toxicity data; animal toxicology and clinical data; as well as phase I, II, III & IV data to the DCGI. The protocol of the clinical trial with a consent form is also submitted. The authority also needs to know about the regulatory status of the drug in other countries, including names of countries where the drug is approved, and international package insert or the place where Investigational New Drug (IND) application is filed. Applicants have to report any Suspected or Unexpected Serious Adverse Reaction (SUSAR) from other participating countries, if any. Further, it is necessary to submit an affidavit from the sponsor stating that the study has not been discontinued in any country. In case of discontinuation, reasons for the same must be communicated to the DCGI. Furthermore, a letter of undertaking for compensation as per appendix XII of schedule Y and marketing authorization application submission to CSDCO once approved in country of origin. For comprehensive details applicant can refer Schedule Y of the Drugs and Cosmetics Act 1940, and the rules therein, pre-screening checklist displayed on CDSCO website (www.cdsco.in).Clinical trials can be initiated only upon

receipt of approval from CDSCO and concerned ethics committee.

All the trials have to be registered prior to the initiation of clinical trials in Indian Council of Medical Research (ICMR) clinical trial registry which is mandatory since June 2009 onwards. Recent amendments pertaining to clinical trials in India: The CDSCO has issued number of guidelines, circulars to strengthen clinical trial regulations in India from time to time.

Following are the compilation of these guideline to have overall understanding on the same. The recent amendments in schedule Y are

- Introduction of Rule 122DAB ¬- Specifying the procedures for payment of compensation to the subjects of the trial in cases of injury or death
- Introduction of Rule 122DAC - Specifying various conditions for conduct and inspection of clinical trials
- Introduction of Rule 122DD - Specifying the detailed guidelines for registration of Ethics Committee. System for the pre-screening of the applications for registration of ethics committees. IEC in respect of periodic review of ongoing clinical trials
- Drugs and Cosmetics (Amendment) Bill 2013 - Yet to be introduced

Audio-Visual Recording of Consent: Gazette Notification for Audio-Visual recording of informed consent. Audio-Video recording of informed consent has become mandatory

Prof. Ranjit Roy Chaudhary Report: Recently Prof. Ranjit Roy Chaudhary committee has submitted reports which discuss about practices for conducive environment for growth of clinical trial industry also meeting the regulatory standards. Actions on the recommendations of Prof. Ranjit Roy Chaudhury expert committee to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs. On 03 Jul 2014, DCGI has issued circulars pertaining to the acceptance of Prof. Ranjit Roy Chaudhury Expert Committee's.

SAE Reporting and Compensation: The process of SAEs reporting in case of injury/death has been revised in recent Schedule Y amendments and below is required information to be submitted along with the SAEs report. System of Pre-screening for submission of reports of SAEs to CDSCO. Panel of expert for reviewing of SAE of death. Formula to determine the quantum of compensation in the cases of clinical trial related serious adverse events (SAEs) of deaths occurring during clinical trials.

New Drug Approval Process

Schedule Y deals with regulations pertaining to clinical trial requirements for import, manufacture and obtaining marketing approval for a new drug in India.

Rule 122 A -Application for permission to import new drug.

Rule 122 B -Application for permission to manufacture new drug.

Rule 122 D -Application for permission to import /manufacture FDC

Rule 122 DA –Application for permission to conduct clinical trials

Rule 122 E –Definition of New Drugs

- New Substance having therapeutic indication
- Modified or new claims, indications, dosage, dosage form and new route of administration for already approved drug.
- Fixed Dose Combination, individually approved earlier now for modified claim
- Vaccines are new drugs unless otherwise certified
- Considered new drug for 4 years from date of first approval

Table 1: Quality Overall Summary of Part II of ACTD

S DRUG SUBSTANCE	P DRUG PRODUCT
S1 General Information	P1 Description and Composition
S2 Manufacture	P2 Pharmaceutical Development
S3 Characterization	P3 Manufacture
S4 Control of Drug Substance	P4 Control of excipients
S5 Reference Standards or Materials	P5 Control of Finished Product
S6 Container Closure	P6 Reference Standards or Materials
S7 Stability	P7 Container Closure
	P8 Stability
	P9 Product Interchangeability Equivalence evidence

Table 2: Overview of ICH – CTD and ACTD

DOCUMENTS	ICH - CTD	ACTD
Administrative Documents and Product Information	Module 1	Part I
CTD Overview and Summaries	Module 2	Incorporated in parts II, III & IV
Quality Documents	Module 3	Part II
Non – clinical Documents	Module 4	Part III
Clinical Documents	Module 5	Part IV

4. Conclusion

The study concludes that the drug approvals in the US, India are the most demanding in the world. The primary purpose of the rules governing medicinal products in US, India is to safeguard public health. Public regulatory authorities to ensures that pharmaceutical companies comply with regulations. Regulatory environment, it is difficult to adopt single marketing approval strategy for different categories of drugs[18-19]. This facilitates the optimization of projects through minimization in timelines for drug approvals and subsequent launch, and reduces overall cost of research and development. Finally, there needs to be a reaffirmation and fine balance between the tenacities of gaining market access of pharmaceuticals is to protect the public health and facilitate healthy growth of pharmaceutical manufacturers. Pharmaceutical product approval process should be seen as a critical step in ensuring access to safe and effective drugs. Although there is a continuous process of harmonization taking place all around the world, still we see a huge challenge, which is yet to be overcome by the Pharmaceutical industry in case of generic drug development and filing. Therefore, to meet these challenges, a lot of strategic planning is required before the development of any generic drug product.

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