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COMPARATIVE STUDY OF REGULATORY REQUIREMENTS FOR DRUG APPROVAL PROCESS IN UNITED STATE, INDIA AND EUROPE UNION

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ABSTRACT

The approval process for pharmaceutical drugs is important for ensuring safety, effectiveness, and quality of medicines prior to their commercialization. Every country has its own regulatory process based on science, law, and health care needs. This review gives an assessment of the regulatory requirements and the approval process adopted in the USA, EU, and India regulated by USFDA, EMA, and CDSCO respectively. Comparative assessment is made of the requirements for conducting clinical trials, submission of dossiers, pharmacovigilance programs, and review periods. Harmonization efforts are also assessed in the context of ICH and CTD. The USA follows a stringent centralized path through IND, NDA, ANDA, and BLA approvals. The EU operates under centralized, decentralized, mutual recognition, and national approaches coordinated by EMA. India has improved its regulation process through NDCTR 2019 and harmonizing with international practices.

KEYWORDS: USFDA, EMA, CDSCO, CTD, Drug Approval Process, Clinical Trials, Regulatory Affairs, Pharmacovigilance.

1. INTRODUCTION

"Comparative study of Regulatory Requirement for Drug Approval Process in United State, India., And Europe Union " Is a comparison of the regulatory framework used to assess and approve pharmaceutical drugs in various nations. This comparative study highlights the variation in time needed to authorize, document, and satisfy regulatory requirements from diverse jurisdictions, including those in the United States, Europe, and India. The regulatory bodies in each nation vary; for example, in the United States, there is the USFDA, while in Europe, it is the EMA. Likewise, in India, it is the Central Drugs Standard Control Organization CDSCO, operating in varying socio-cultural and legal environments. The United States drug approval process is well-known for its rigorous criteria, which call for extensive clinical trials and the provision of data using different applications like IND and NDA. However, the European Medicines Agency offers several avenues for drug approval, including the centralized procedure, which allows one application for the authorization of a drug across all EU nations.[1]

1.1 India

In India, the governance of drugs and cosmetics is managed by the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945. The Central Drugs Standard Control Organization (CDSCO), which is led by the Drug Controller General of India (DCGI), operates under the Ministry of Health and Family Welfare and is tasked with overseeing the approval, importation, production, distribution, and sale of pharmaceutical products in the country.[2] The guidelines concerning clinical trials can be found in Schedule Y of the Drugs and Cosmetics Rules and were notably revised in 2005 to comply with international standards. The introduction of the New Drugs and Clinical Trials Rules (NDCTR) in 2019

brought about a more clear and efficient regulatory structure. Significant aspects include faster approval timelines and updated guidelines for Ethics Committees (ECs).[3]

1.2 Discovery and Development of Drugs

The process of discovery of drugs is concerned with the research and development of new medicines through the study of disease, screening of molecules, drug repositioning, and modern scientific techniques like genetic engineering and targeted drug delivery system.[4] Even when thousands of potential medicines are identified, only a few go ahead for further evaluation after preliminary tests.[5]

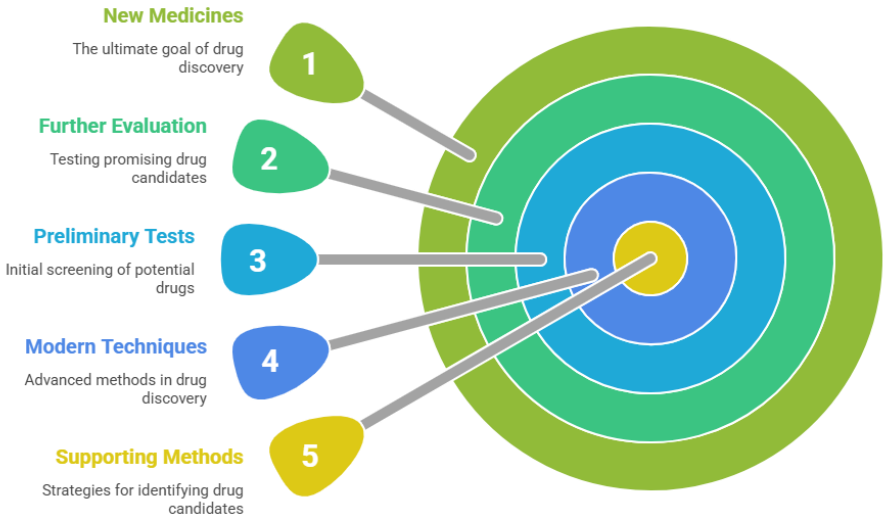


Figure 1: Drug Discovery and Development Process.

Preclinical Studies

Preclinical tests are undertaken to establish the safety and toxicity profile, pharmacodynamics, and pharmacokinetics of drugs prior to clinical trials.[6] The experiments are carried out both in vitro and in vivo and encompass one-time and multiple-dose toxicology studies, carcinogenicity, reproductive toxicity, and safety pharmacology testing.[7]

Clinical Trials

Clinical trials are scientific experiments performed on human subjects to determine the efficacy and safety of an experimental drug.[8] Clinical trials follow a specific protocol that describes objectives, methodology, inclusion criteria for subjects, dosages, statistical analysis, and safety monitoring. Clinical trials usually occur in four phases[9]

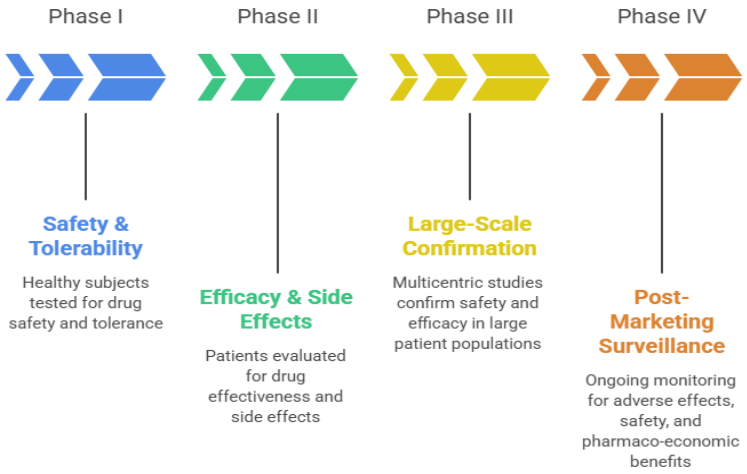


Figure 2: Clinical Trial Phases for Drug Development.

The sponsors have to provide comprehensive information on the investigational drug in terms of physiochemical properties, production process, toxicity study, clinical trial protocol, and adverse event reporting plan.[10] Clinical trials in India need to register with the Indian Clinical Trial Registry (CTRI).[11]

1.3 United States (US)

The United States is among countries with the most rigorous regulation of drugs, which is under the supervision of the United States Food and Drug Administration (USFDA). Approval of new drugs is mainly based on their evaluation through clinical trials and thereafter submission of New Drug Application (NDA).[12] The United States Pharmacopeia (USP), founded in 1820, laid down standards with regard to purity and strength of drugs. Important legislation in the field includes the Food and Drugs Act of 1906, the Federal Food, Drug and Cosmetic Act of 1938, the Kefauver-Harris Amendments of 1962, the Orphan Drug Act of 1973, the Generic Drug Enforcement Act of 1992, and the FDA Modernization Act of 1997.[13]

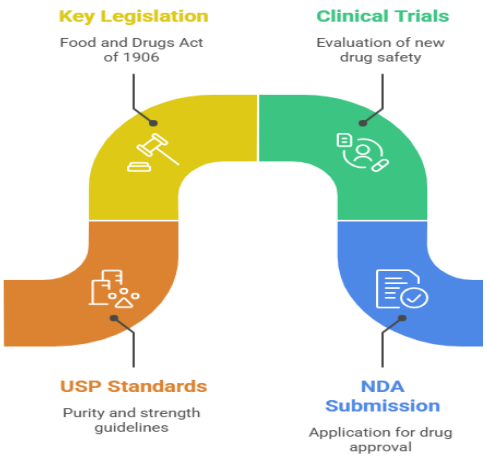


Figure 3: US Drug Regulation Evolution.

1.4 European union

In order for a drug to be authorized for marketing in Europe, it is subjected to the same regulatory process as in the United States. The two regulatory steps that the drug must pass in Europe include the clinical trial application and the marketing authorization application. There are 28 member countries in the European Union (as of July, 2013); Clinical Trial Applications are authorized by individual member countries whereas marketing authorization applications are approved by the individual members and central authorities.[14]

Centralized Procedure

Through the Centralized Procedure, a firm is allowed to receive one marketing authorization that covers all EU Member States, including Norway, Iceland, and Liechtenstein. The evaluation process under this method involves EMA, with the help of a designated Rapporteur. The approval process usually takes 210 days. The Centralized Procedure is a mandatory option when developing certain types of drugs, including biotechnological products and orphan drugs.[15]

Mutual Recognition

Under the Mutual Recognition procedure, the applicant can receive the market authorization in the Concerned member states (CMS) that are not the Reference member state (RMS), in which the drug has already received authorization.

The applicant sends an identical dossier to the entire European Union members states where they want authorization.[16]

As soon as one Member State decides to review the medicine (now it will be considered "RMS"), it informs other Member States (they will be "CMS") about its decision. The RMS prepares a report for other Member States based on its findings. The generic industry is a frequent user of this procedure for authorization of drugs. Time required to authorize drugs under this procedure can be up to 390 days.[7]

National Procedure

Under the National Procedure, a firm can receive marketing authorization for its product in just one EU country at once. The application is made to the national drug regulator, and the review time normally amounts to around 210 days.[17]

Decentralized Procedure

Through the Decentralized Procedure, a company can make simultaneous applications for marketing authorization across various member states in the EU regarding drugs that have never been licensed before in the EU. This procedure involves conducting an assessment of the drug product in the Reference Member State (RMS), followed by review by the Concerned Member States (CMS).[18]

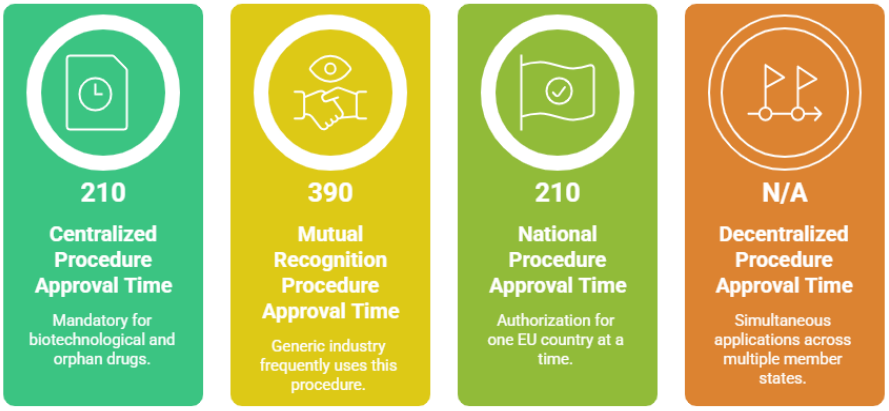


Figure 4: EU Marketing Authorization Procedures.

2. RESULT AND DISCUSSION

Table 1: Principal differences between US, EU & INDIA.

Requirements	United States (USFDA)	European Union (EMA)	India (CDSCO/DCGI)
Regulatory Body	Single regulatory body – USFDA	EMA with national regulatory authorities	Single regulatory body – DSCO/DCGI
Approval Process	Single approval process	Centralized, Decentralized, Mutual Recognition, and National procedures	Single approval process
TSE/BSE Data	Not required	Required	Required
Braille Labelling	Not required	Required	Not required
Post-Approval Changes	Minor, Moderate, Major changes	Type IA, IB, II Variations	Major and Moderate quality changes

Table 2: Administrative Requirements.

Requirements	United States (USFDA)	European Union (EMA)	India (CDSCO)
Application Type	ANDA / NDA	MAA	MAA
Debarment Classification	Yes	No	No
Number of Copies	3	1	1
Approval Timeline	Around 18 months	Around 12 months	12–18 months
Application Cost	NDA: < $2 million; ANDA: $51,520	National Application: £103,059;	Comparatively lower

		Decentralized Procedure: £99,500	

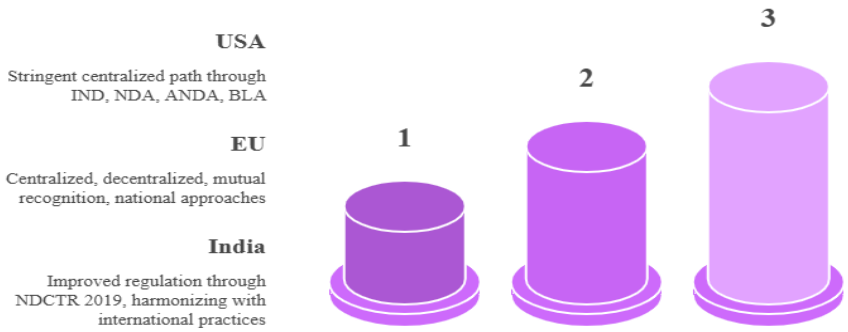
Table 3: Comparative analysis.

Parameters	India	Europe	United States
Language of Clinical Trial	English	English	English
Documents Submitted	Dossier, ICF, IB, CRF, CTA	Dossier, ICF, IB, CRF, CTA	Dossier, ICF, IB, CRF, CTA
Clinical Trial Registry	CTRI	EudraCT	ClinicalTrials.gov
Registration Process	Single process	Multiple processes	Single process
Registration Fees	Not required	Not required	Not required
Submission Format	Paper-based	e-CTD	e-CTD / Paper
Regulatory Authority	CDSCO / DCGI	EMA / CHMP / National Agencies	USFDA
Protocol Approval Fee	Required	Required	Not required
Regulatory Review Timeline	45 days	45 days	Within 30 days
Ethics Committee Review	4–8 weeks	Around 76 days	As per institutional policy
Process Validation	Required	Required	Not required
EC Registration Renewal	Every 5 years	Every 4 years	Every 3 years
Initial SAE Reporting	Within 24 hours	Within 7 days	Within 7 days

3. DISCUSSION

The paper highlights the drug approval processes at USFDA, EMA, and CDSCO. Even though all three organizations have the same goal of ensuring that drugs are safe, efficacious, and of good quality, there are differences in the drug approval process. USFDA uses an efficient centralized process, whereas EMA offers different drug approval processes within EU member countries. CDSCO has advanced significantly due to NDCTR 2019 and ICH harmonization. The implementation of CTD/eCTD and the harmonization of clinical trial process has made drug development more efficient. However, despite all this, there are still differences between various regulatory processes.

4. CONCLUSION



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