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Investigational New Drug (IND) approval process in India - Limitations, challenges and recommendations

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Abstract

Regulatory approval in India is a complex and ever-changing phenomenon governed primarily by the Central Drugs Standard Control Organization (CDSCO) under the guidance of the Drug Controller General of India (DCGI). It is a complex procedure that ensures all drugs meet the required norms of safety, efficacy, and quality before they are released into the market. It is a lengthy procedure for manufacturers and also poses a problem with the interpretation of the rules by different states. Moreover, the lack of harmonization with international regulatory systems also causes a delay in international collaborations. The lack of infrastructure for clinical trials and the need for a large number of trained regulatory experts also add to the problems. It not only delays the approval of drugs but also discourages foreign investors from investing in the country. In order to overcome these hurdles, India needs to focus more on regulatory transparency, digitalization of applications, and the use of a risk-based evaluation approach. Training of regulatory staff, the use of real-world evidence, and alignment with international best practices such as ICH and WHO guidelines can help speed up the regulatory approvals in India. This will, in turn, help India to become a more collaborative and technologically advanced regulatory environment, thereby promoting innovation, safety, and competitiveness in the field of pharmaceutical drug development globally.

Keywords: Regulatory Reforms; CDSCO And DCGI; Drug Approval Challenges

1. Introduction

India has one of the largest pharmaceutical industries globally, making a significant contribution towards the global supply of affordable generic medicines. It has earned the title of being the 'pharmacy of the world' because of its high manufacturing capacity, talent pool, and commitment towards making available affordable and accessible healthcare solutions globally. It has also played a pivotal role through the regulatory approval process, ensuring that only safe, effective, and high-quality drugs are made available for the end consumer. It has a structured evaluation process, undertaken by the Central Drugs Standard Control Organization (CDSCO) [13]and supervised by the Drugs Controller General of India (DCGI). It has always been a challenging task for the regulatory environment of the pharmaceutical industry in India, characterized by lengthy review procedures and a lack of harmonization between global regulatory requirements. It was a pivotal move by the government of India, introducing the New Drugs and Clinical Trials (NDCT) Rules, 2019, for the promotion of transparency, accountability, and timely approvals, while also promoting clinical research and innovation [12]. However, the practical implementation issues, capacity limitations, and divergent understanding of the regulation continue to pose barriers to the effective registration and commercialization of new drug entities and biologics. A comprehensive knowledge of the regulatory barriers is vital for pharmaceutical organizations, contract research organizations, and policymakers to ensure the best compliance practices for the

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smooth regulation process. Improving the level of convergence with global standards such as ICH, WHO, and US FDA [10][24] guidelines, and promoting evidence-based review practices can help accelerate the process [11]. This article critically evaluates the regulatory barriers faced by the pharmaceutical regulation process in India and suggests ways to ensure a stronger, more transparent, and innovative regulation process.

2. Regulatory framework in India

2.1. Central Drugs Standard Control Organization (CDSCO)

The Central Drugs Standards Control Organization (CDSCO) acts as the apex regulatory authority for the regulation of the approval of new drugs, clinical trials, medical devices, and pharmaceutical imports in the country. It ensures that all regulatory activities are carried out under the strict standards of safety, efficacy, and quality, as per the provisions of the country's regulations and international regulatory guidelines.[2]It also monitors the aspects of Pharmacovigilance, post-marketing surveillance, and enforcement of Good Manufacturing Practices (GMP) for the maintenance of public health standards.[14]

2.2. Drugs Controller General of India (DCGI)

The Drugs Controller General of India (DCGI), who heads CDSCO, has the power to grant permissions for the manufacture, import, and marketing of new drugs; to approve clinical trials; and to monitor adverse drug reactions through tools like PSURs. This DCGI also has an important role to play in achieving regulatory convergence to international regulations like ICH, WHO, and USFDA guidelines. This will enhance India's image as a hub for clinical research.

At the state level, the State Drug Control Authorities are responsible for regulating the licensing, manufacturing, distribution, and sale of drugs. They ensure that all the manufacturing units are in compliance with the state regulations and SOPs. They also ensure that the drugs are not adulterated and are not misbranded.

3. CDSCO framework [7]

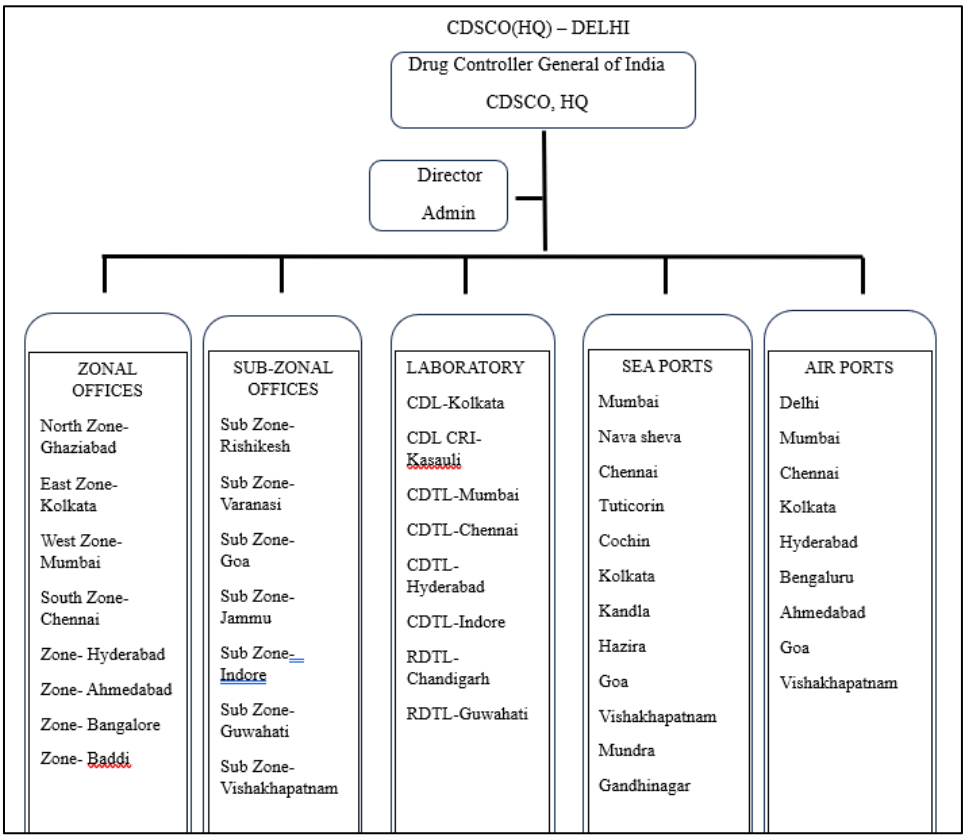

Figure 1 Organization of CDSCO

3.1. Investigational New Drug (IND)

An Investigational New Drug (IND) is a submission to the appropriate regulatory authority (such as CDSCO in India and FDA in the United States) to seek approval to conduct clinical trials on humans.[1] An IND application contains comprehensive information on the new drug, including the following:

- Drug Composition: This includes information on the chemical composition of the drug.
- Manufacturing Process: This includes information on the process of manufacture and compliance with GMP.
- Pre-clinical Data: This includes information on pharmacological studies, toxicological studies, and pharmacokinetic studies conducted on animals.
- Clinical Trial Protocols: This includes information on the objectives and design of the study.
- Investigator Information: Qualifications and facilities where the research will be conducted.[6]

The IND plays a bridging role between preclinical research and human research studies, ensuring patient safety and promoting the development of new therapeutic interventions. Approval of the IND is a requirement before commencing Phase I human studies.[9]

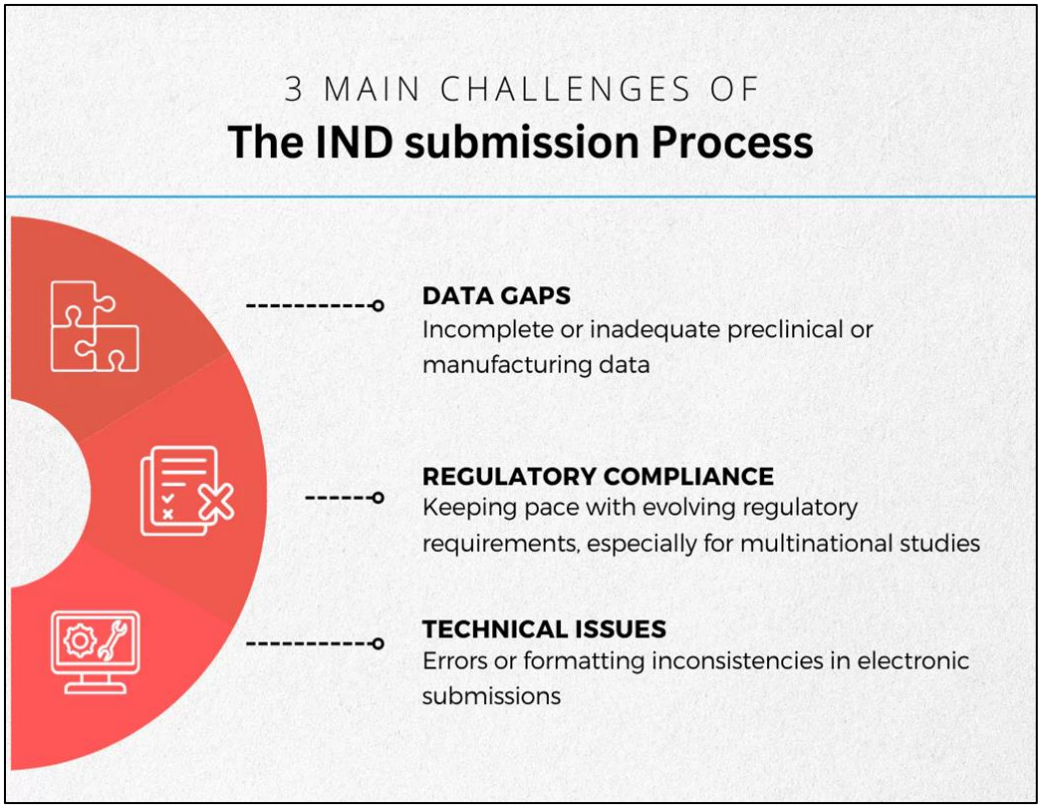

Figure 2 Challenges in IND Submission

4. Limitations And Challenges in IND Submission

4.1. Incomplete or Insufficient Preclinical Data

- Regulatory authorities demand substantial data on pharmacology, toxicology, and pharmacokinetics.[21]
- Lack of data or inconsistencies may demand additional studies.

4.2. Manufacturing and Quality Challenges

- Data on the synthesis of the drug, formulation, sterility, and stability must be provided.
- Lack of proper documentation may demand additional action prior to the acceptance of the IND.

4.3. Protocol Challenges

- The protocol must clearly state the objectives, methodology, patient population, dose, and endpoints.
- Lack of a proper protocol or failure to comply with the regulatory requirements may demand a revision of the protocol.[25]

4.4. Regulatory Compliance Complexity

- The regulatory authorities demand strict compliance with the guidelines on the format and content of the IND.
- The regulatory authorities at the state level may demand additional information than those at the central level.[17][27]

4.5. Ethical and Safety Considerations

- The preclinical safety profile must support human safety.
- Novel therapies, biologics, or advanced drug delivery systems may demand additional scrutiny.[18]

4.6. Communication and Review Delays

- The backlogs and lack of a standardized format may delay the review.
- Miscommunication or failure to properly address the questions posed by the regulatory authorities may delay the start of the clinical trial.

4.7. Special Considerations for Innovative Therapies

- INDs for NDDS, gene therapy, and biologics may require additional information on stability, bioavailability, and risk mitigation.
- Regulators may ask for adaptive designs and/or phased approval to ensure safety.[5]
- Documentation and Reporting Requirements
- All studies, manufacturing processes, and designs must be well-documented.
- Any deviation in this may pose problems in the approval process.[3][16]

4.8. Recommendations for IND Submission Challenges

4.8.1. Strengthen Preclinical Data

- Conduct pharmacology, toxicology, and PK/PD studies under GLP.
- Must be consistent with ICH guidelines; pre-IND meeting is a must.[8]
- Bridging studies need to be conducted if required.[22]

4.8.2. Improve Manufacturing and Quality (CMC)

- GMP principles need to be adopted at the earliest.[23]
- CMC documents need to be developed with complete synthesis, formulation, validation, sterility, and stability data.
- Pilot-scale batches need to be manufactured for reproducibility.[19]

4.8.3. Develop Clear and Compliant Clinical Protocols

- Must be consistent with ICH GCP guidelines.[28]
- Clear objectives, endpoints, sample size, methodology, and safety considerations need to be clearly defined.
- Statistical review is a must; also use validated protocol templates.

4.8.4. Manage Regulatory Complexity

- Must be consistent with the regulatory requirements of CDSCO/FDA/ICH.
- Must be updated with the latest regulatory guidelines.
- Must be reviewed by experienced regulatory affairs personnel.

4.8.5. Address Ethical and Safety Requirements

- Must include thorough risk-benefit analysis with justification.
- Must include additional safety studies for biologics, NDDS, gene therapy, and other novel drug platforms.

- Must be consistent with ethics committee approval; also consistent with ICMR guidelines.[15]

4.8.6. Enhance Regulatory Communication

- Must be consistent with pre-IND and follow-up meetings.
- Must be submitted with clear and organized documents with appropriate indexing.
- Must be responded to with complete and accurate information within 24-48 hours.

4.8.7. Prepare Additional Data for Innovative Therapies

- Provide immunogenicity, biodistribution, compatibility, and degradation studies.
- Provide risk mitigation strategies, DSMB, and adaptive designs if necessary.
- Provide long-term safety and stability for NDDS and biological systems.[20]

4.8.8. Ensure Complete Documentation

- Maintain a centralized electronic system for documentation (eTMF) with version control.
- Perform internal QA audits prior to submission to ensure complete information.
- Ensure all reports, records, and certificates are signed, dated, and traceable [4][26]

Table 1 Strategies to Reduce Drug Regulatory Approval Timelines

Strategy	Description
Pre-submission Consultation	Engage with regulatory authorities prior to submission to clarify requirements and reduce major queries.
Complete and Validated Dossiers	Ensure all modules, data, and certificates are thoroughly prepared and validated to minimize review delays.
Compliance with NDCT 2019	Follow prescribed timelines and formats for clinical trials, new drugs, and generics to accelerate approvals.
Robust Preclinical and Clinical Studies	Conduct high-quality, statistically sound studies to reduce safety, efficacy, or bioequivalence queries.
Early Resolution of Regulatory Queries	Promptly address deficiencies or questions raised by authorities to prevent delays.
Use of Online Submission Portals	Utilize SUGAM or similar platforms for faster document submission, tracking, and communication.
Accelerated Pathways for Special Cases	Apply under priority or accelerated review programs for orphan drugs, rare diseases, or urgent therapies.
Engagement of Regulatory Experts	Involve experienced consultants to navigate procedural complexities efficiently.

5. Conclusion

The pharmaceutical system in India has made considerable progress in the field but still faces critical issues in clarity, transparency, and capability. These issues have to be addressed to further strengthen India's position in the pharmaceutical industry on a global scale. Clarification in the process for new drugs, biologics, and advanced therapy medications may reduce ambiguity in the process. Increasing transparency in the system using dashboards and feedback may also increase the overall trust in the system. Improving infrastructure in CDSCO labs and digital submissions may also speed up the evaluation process. Setting time limits for approvals and implementing a digital single-window clearance system may also reduce the overall time in the process. Providing funding or reducing fees for small and medium enterprises may also encourage more players to participate in the clinical development process. Holding regular training workshops and providing consultations and panels may also help in overcoming the hurdles in the process. Maintaining a stable policy environment with predictable guidelines helps in reducing uncertainty and promoting long-term investment. By carefully balancing patient safety with innovation facilitation in India, faster access to high-quality medicines can be ensured, and India can continue to be a leader in pharmaceutical development

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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