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New Drug Approval Process in India: A Comprehensive Review of Regulatory Requirements and Procedures

Vaishnavi Bulhe, Sayali Pagire

Department of Pharmacy. JE's S.N.D. College of Pharmacy Bahulgoan Yeola
Vaishnavibulhe@gmail.com

ABSTRACT:-

(NDCT) Rules, 2019. Clinical development is generally conducted through Phase I, Phase II and Phase III studies to establish safety, tolerability, appropriate dosage and therapeutic efficacy. Ethical review, informed consent and protection of clinical-trial participants are important components of the process. Following successful clinical development, the regulatory authority evaluates quality, safety and efficacy data before granting permission for manufacture, import and marketing. The SUGAM portal facilitates online submission and regulatory communication. Post-marketing surveillance and pharmacovigilance continue after approval to identify rare or long-term safety concerns and maintain a favourable benefit–risk profile. Overall, the Indian regulatory framework provides an evidence-based approach for the development and approval of safe, effective and quality medicines. The new drug approval process in India is a systematic and highly regulated pathway designed to ensure that medicines introduced into the market meet acceptable standards of quality, safety, and efficacy. This review provides a comprehensive overview of the regulatory requirements and procedures involved in the development and approval of new drugs in India. The process begins with drug discovery and pharmaceutical development, followed by preclinical evaluation of pharmacological, pharmacokinetic and toxicological properties. After satisfactory preclinical results, permission for clinical trials is obtained from the Central Drugs Standard Control Organisation (CDSCO) under the New Drugs and Clinical Trials

1. Introduction :-

The development and approval of a new drug is a complex, lengthy and highly regulated process that is essential for ensuring the availability of medicines that are safe, effective and of acceptable quality for patients. Before a pharmaceutical product can be introduced into the Indian market, it must undergo systematic scientific evaluation involving pharmaceutical development, preclinical studies, clinical trials, regulatory assessment and post-marketing safety monitoring. The primary purpose of this regulatory process is to establish a favourable benefit–risk profile for the proposed medicine and to protect the health and rights of patients and clinical-trial participants. In India, the regulatory framework for new drugs and clinical trials has evolved considerably to address advances in pharmaceutical science, increasing complexity of drug products and the need for internationally compatible regulatory standards.

In India, the Central Drugs Standard Control Organisation (CDSCO) is the principal national regulatory authority responsible for important aspects of drug regulation. CDSCO functions under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. Its regulatory responsibilities include the evaluation of applications for new drugs, clinical trials and other related activities. The New Drugs Division of CDSCO processes applications for new drug approval and clinical trials and evaluates them according to the applicable regulatory requirements. CDSCO's current regulatory information describes its role in reviewing applications for new drug approval and clinical trials, including Phase I, II, III and IV studies and certain post-marketing surveillance studies.

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The regulatory framework governing new drugs and clinical trials in India is primarily based on the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945, and the New Drugs and Clinical Trials (NDCT) Rules, 2019. The NDCT Rules, 2019 were notified on 19 March 2019 and established a dedicated framework for the regulation of new drugs, investigational new drugs, clinical trials, bioavailability and bioequivalence studies, and related regulatory activities. The rules were framed under the powers of the Drugs and Cosmetics Act, 1940.

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The term "new drug" has a broad regulatory meaning. It can include a drug or active pharmaceutical ingredient that has not been used to a significant extent in India or has not been approved as safe and efficacious by the Central Licensing Authority for its proposed claims. It may also include an already approved drug proposed for a new indication, dosage, dosage form or route of administration, certain fixed-dose combinations, modified or sustained-

release preparations, novel drug-delivery systems and certain biological products. Therefore, regulatory approval is not limited only to completely new chemical entities; several modifications or new uses of existing drugs may also fall within the regulatory definition of a new drug.

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The new drug approval process begins much before the submission of an application to the regulatory authority. It generally starts with drug discovery and development, during which researchers identify a potential therapeutic target and develop a candidate molecule or biological product. The candidate is then subjected to pharmaceutical development and laboratory investigations to understand its physicochemical properties, formulation characteristics, pharmacological activity and potential toxicity. Once sufficient preliminary information is obtained, the drug candidate progresses to preclinical development. Preclinical studies provide important information regarding pharmacodynamics, pharmacokinetics, toxicity and other safety characteristics before the product is administered to human participants.

Preclinical evaluation is an important stage because exposure of humans to an inadequately characterized drug may result in unacceptable risks. Depending on the nature of the drug, studies may include acute and repeated-dose toxicity, safety pharmacology, genotoxicity, reproductive and developmental toxicity, local tolerance and other relevant investigations. The results of these studies form an important part of the scientific justification for progressing to human clinical trials. Regulatory authorities therefore evaluate non-clinical information together with pharmaceutical and other relevant data before allowing clinical development to proceed.

After adequate preclinical development, the sponsor or applicant submits an application for permission to conduct a clinical trial. Under the NDCT regulatory framework, the Investigational New Drug (IND) Division of CDSCO plays an important role in processing applications related to investigational new drugs and clinical trials. CDSCO states that an IND application is an important step before human exposure to an investigational new drug and that applications for clinical-trial permission and related activities are submitted through the SUGAM online portal with the required documents and applicable fees.

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Clinical trials are conducted in a series of phases, with each phase designed to answer different scientific and clinical questions. Phase I clinical trials primarily provide information about safety, tolerability, pharmacokinetics and, where appropriate, pharmacodynamic effects. These studies generally involve a relatively small number of participants. Phase II studies are generally conducted in patients with the target disease and are designed to obtain preliminary evidence of therapeutic efficacy while further evaluating safety and identifying appropriate doses. Phase III clinical trials generally involve larger patient populations and provide confirmatory evidence regarding efficacy and safety. The results from these studies form an important basis for evaluating whether the benefits of the drug outweigh its potential risks.

The protection of human participants is a fundamental component of the clinical development process. Clinical trials require appropriate ethical review, informed consent and measures to protect the rights, safety and well-being of participants. Ethics Committees play an important role in reviewing clinical research proposals. CDSCO maintains regulatory provisions and registration-related information concerning Ethics Committees involved in clinical trials and bioavailability/bioequivalence studies.

2.Defination :-

New Drug Approval Process in India can be defined as

“A systematic regulatory process through which a new drug is scientifically evaluated for its quality, safety and efficacy by the competent regulatory authority in India, particularly the Central Drugs Standard Control Organisation (CDSCO), before permission is granted for its clinical use, manufacture, import or marketing.”

3. Objectives :-

1. To ensure quality of pharmaceutical products.
2. To establish safety in humans.
3. To demonstrate efficacy for the proposed indication.
4. To evaluate the benefit–risk profile of the drug.
5. To protect clinical-trial participants.
6. To ensure ethical conduct of clinical research.
7. To monitor drug safety after marketing.

4. Regulatory Authority in India:-

Central Drugs Standard Control Organisation (CDSCO)

CDSCO is India's central regulatory authority for drugs and clinical trials. Its New Drugs Division evaluates applications for new drug approval and clinical trials and may seek expert recommendations through Subject Expert Committees (SECs) and other regulatory committees.

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The Investigational New Drug (IND) Division specifically handles applications concerning investigational new drugs and clinical trials. Applications are submitted through the SUGAM portal with the required documents and fees

5. New Drug Approval process in India :-

The overall process can be represented as:

Drug discovery → Preclinical studies → Regulatory submission → Clinical trial permission → Phase I → Phase II → Phase III → New drug application → Regulatory review → Approval → Marketing → Post-marketing surveillance

Step 1: Drug Discovery and Development

The process begins with identification of a potential drug candidate.

Activities may include:

1.Target identification

2.Lead identification

3.Lead optimization

4.Pharmacological evaluation

5.Toxicological evaluation

6.Development of dosage form

Step 2: Preclinical Studies

Before administration to humans, the candidate drug undergoes laboratory and animal studies.

Important studies include:

1.Pharmacodynamic studies

2.Pharmacokinetic study

3.Acute toxicity studies

4.Repeated-dose toxicity studies

5.Genotoxicity studies

6.Reproductive toxicity, where applicable

7.Safety pharmacology

8.Local tolerance studies

Step 3: Application for Clinical Trial

An applicant intending to conduct a clinical trial of a new drug or investigational new drug submits an application to the Central Licensing Authority in Form CT-04, accompanied by required documents and applicable fees under the NDCT Rules, 2019.

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The application contains relevant information concerning:

1.Drug substance and drug product

2.Pharmaceutical development

3.Manufacturing and quality information

4.Preclinical data

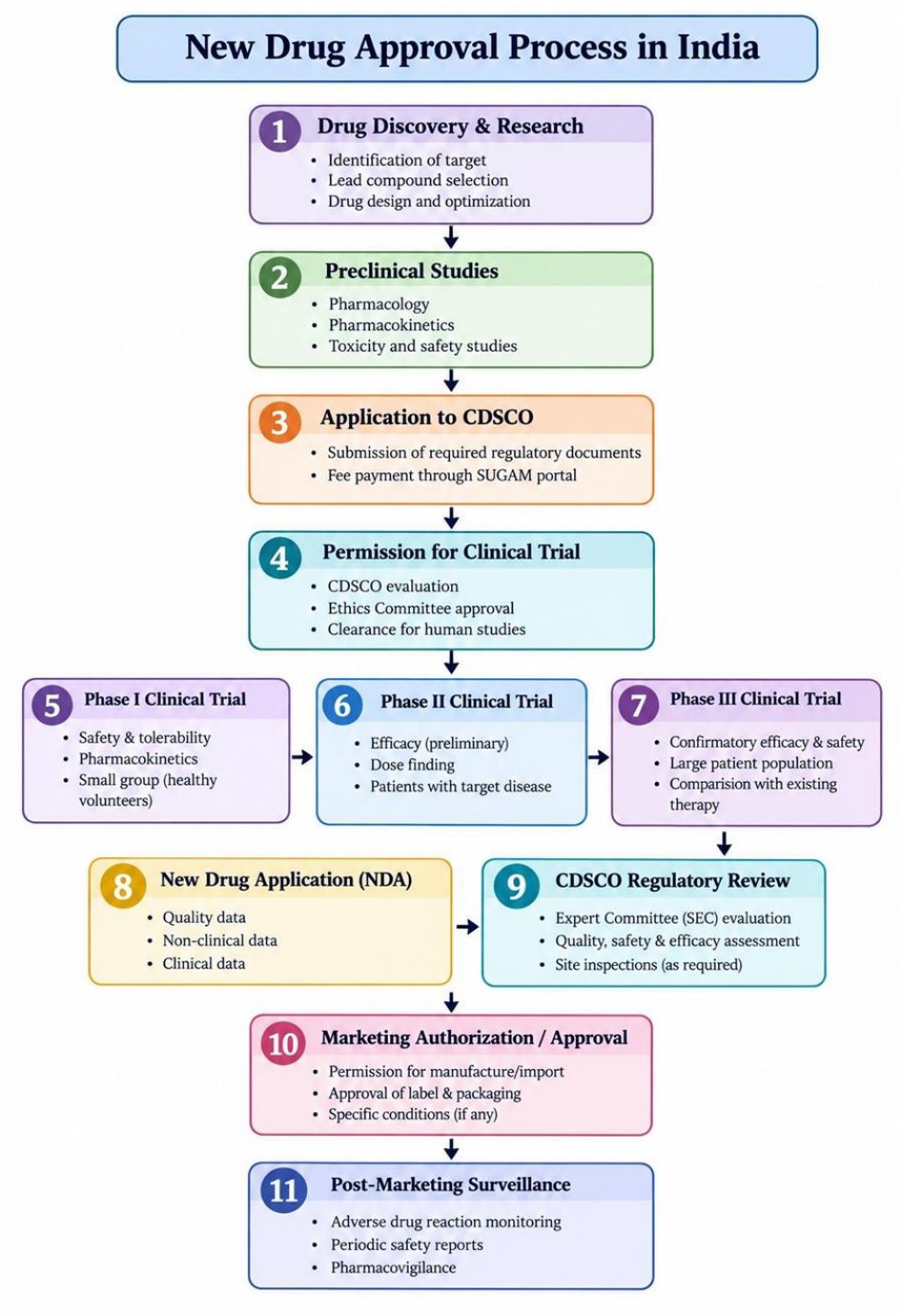
5.Proposed clinical protocol

6.Investigator information

7.Safety information

8.Informed consent documents

9.Ethics Committee information



Example: Suppose a pharmaceutical company develops a new medicine for the treatment of a particular disease. The company first performs preclinical studies to evaluate its pharmacological activity and toxicity. After obtaining sufficient data, it applies to CDSCO for permission to conduct clinical trials. The drug then undergoes Phase I, Phase II and Phase III clinical trials to establish safety, dosage and efficacy. After successful clinical development, the company submits the required new drug application containing quality, safety and efficacy data. CDSCO evaluates the application, including expert

review where applicable. If the benefit–risk profile is acceptable and regulatory requirements are fulfilled, permission for manufacture/import and marketing may be granted. After approval, the drug continues to be monitored through post-marketing surveillance and pharmacovigilance

6.Clinical Trial Phases:-

Phase I – Safety and Tolerability

Phase I is generally conducted in a small number of participants.

Main objectives include:

a.Evaluating safety

b.Determining tolerability

c.Studying pharmacokinetics

d.Identifying appropriate dose ranges

e.Studying pharmacodynamic e

Phase II – Efficacy and Dose Finding

Phase II generally involves patients with the target disease.

Objectives include:

a.Preliminary evaluation of efficacy

b.Dose optimization

c.Further safety assessment

d.Identification of adverse effectsffects where appropriate

Phase III – Confirmatory Studies

Phase III involves a larger patient population.

It provides evidence regarding:

a.Therapeutic efficacy

b.Safety

c.Dose and dosage regimen

d.Benefit–risk relationship

e.Comparison with existing therapy where applicable

Phase IV – Post-Marketing Studies

After marketing approval, additional studies may be performed to obtain information regarding:

a.Long-term safety

b.Rare adverse reactions

c.Additional indications

d.Real-world use

e.Post-marketing safety

7. Ethics Committee Review :-

Clinical research must also undergo ethical review. Ethics Committees registered under the applicable regulatory framework review clinical trial proposals to protect the rights, safety and well-being of trial participants.

Important ethical considerations include:

a.Informed consent

b.Confidentiality

c.Risk–benefit assessment

d.Protection of vulnerable participants

e.Compensation where applicable

f.Scientific validity of the study

8.Regulatory Review of the New Drug Application:-

After adequate clinical development, the sponsor submits the relevant application for permission to manufacture/import and market the new drug.

Examples of New Drugs Approved in India
(As per CDSCO Records)

Sr. No.	Drug Name	Therapeutic Indication	Date of CDSCO Approval (India)	Key Highlights
1	**Tirzepatide**	Type 2 diabetes mellitus (improving glycaemic control)	19 January 2024	• First-in-class dual GIP and GLP-1 receptor agonist • Approved for use in adults with type 2 diabetes, along with diet and exercise
2	**Fexuprazan**	Erosive esophagitis	10 February 2025	• Potassium-competitive acid blocker (P-CAB) • Used for treatment of acid-related disorders
3	**Edoxaban**	Stroke and systemic embolism prevention; DVT/PE	20 February 2025	• Oral anticoagulant (Factor Xa inhibitor) • Used for prevention of thromboembolic events
4	**Letermovir**	CMV prophylaxis in specified transplant patients	17 January 2025	• Antiviral (CMV DNA terminase inhibitor) • Reduces risk of cytomegalovirus infection in high-risk patients
5	**Remdesivir**	COVID-19 (in specified hospitalized patients)	1 June 2020	• Nucleoside analogue antiviral • Used for moderate to severe COVID-19 (during pandemic period)

Note: The above examples are based on CDSCO's list of new drugs approved in India. The regulatory pathway may vary depending on the drug, indication, category and special provisions.

CDSCO reviews information related to:

A. Quality

- Drug substance

- Drug product

- Manufacturing process

- Specifications

- Analytical methods

- Stability studies

- Packaging

- Quality control

B. Safety

- Preclinical safety data

- Clinical safety data

- Adverse events

- Serious adverse events

- Special safety concerns

C. Efficacy

- Clinical trial results

- Statistical analysis

- Primary and secondary endpoints

9.Expert Committee Evaluation:-

Applications may be considered by Subject Expert Committees (SECs) comprising experts in relevant scientific and medical disciplines.

The expert evaluation can consider:

-Quality data

-Non-clinical data

-Clinical efficacy

-Clinical safety

-Unmet medical need

-Benefit–risk profile

-Proposed indication

-Dosage and administration

10. Regulatory Decision:-

After evaluation, the regulatory authority may:

Grant permission/approval.

Request additional information or clarification.

Ask for additional studies.

Impose specific conditions.

Reject the application if regulatory requirements are not satisfactorily fulfilled.

For clinical-trial applications, the NDCT Rules specify a formal review process. For example, under Rule 22, the Central Licensing Authority may grant permission, communicate deficiencies, or reject the application with reasons; the rule specifies a 90-working-day decision period for such applications, subject to the provisions of the Rules.

11. Marketing Authorization:-

Once the necessary regulatory requirements have been fulfilled, permission may be granted for manufacture/import and marketing according to the applicable regulatory pathway.

The approval specifies important information such as:

- Approved indication
- Dosage
- Route of administration
- Strength
- Patient population
- Safety information

- Labeling requirements

12. Post-Marketing Surveillance:-

Drug safety monitoring does not end after approval.

Post-marketing activities include:

- Adverse drug reaction monitoring
- Periodic safety reporting
- Detection of safety signals
- Risk–benefit reassessment
- Updating prescribing information
- Additional safety studies where necessary

CDSCO's New Drugs Division also handles safety monitoring of approved medicinal products using information such as safety reports and periodic safety data.

13. Role of SUGAM Portal:-

The SUGAM portal is CDSCO’s online regulatory submission platform. It is used for several applications related to new drugs and clinical trials.

The CDSCO IND Division states that applications including CT-04, CT-05, CT-18 and CT-21 are processed through the online SUGAM portal.

This digital system helps improve:

- Online submission
- Application tracking
- Regulatory communication
- Document management
- Transparency of regulatory processes

14. Challenges in New Drug Approval in India:-

Some important challenges include:

- Long development timelines
- High cost of clinical research
- Complex regulatory documentation
- Requirement for extensive safety and efficacy data
- Recruitment of suitable clinical-trial participants
- Maintaining GCP compliance
- Coordination between multiple stakeholders
- Increasing complexity of biologics, biosimilars and advanced therapies
- Continuous post-marketing safety monitoring

15. Recent Regulatory Developments:-

The NDCT Rules, 2019 continue to be an important regulatory framework, and CDSCO has issued subsequent amendments and notifications. The CDSCO's official NDCT page lists amendments and updates, including changes made in 2022 and 2023.

CDSCO has also continued to update its guidance and FAQs. Its current New Drugs page lists FAQs on the NDCT Rules dated 24 September 2025, indicating continued regulatory clarification and development.

16. Conclusion:-

The new drug approval process in India is a structured, evidence-based regulatory pathway intended to ensure that medicines entering the Indian market have acceptable quality, safety and efficacy. CDSCO plays a central role in evaluating new drugs, clinical trials and regulatory submissions. The implementation of the New Drugs and Clinical Trials Rules, 2019 has provided a dedicated framework for clinical research and new drug regulation. The process begins with preclinical research and progresses through clinical development, regulatory evaluation and marketing authorization, followed by continuous post-marketing safety monitoring. Effective regulatory affairs professionals are therefore essential for preparing accurate submissions, maintaining compliance and facilitating the development of safe and effective medicines.

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