

REGULATORY REQUIREMENTS FOR THE SUBMISSION OF NDA AS PER CDSCO IN
INDIA COMPARISON WITH INDONESIA

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ABSTRACT

A regulatory process is by which a person/organization/sponsor/innovator gets authorization to launch a drug products in the particular market region by following respective regulatory guidelines. Developing a new drug requires great amount of research work in chemistry, manufacturing, controls, preclinical sciences and clinical trials. Drug reviewers in regulatory agencies around the world bear the responsibility of evaluating whether the research data support the safety, effectiveness and quality control of new drug product to serve the public health. In general, a drug approval process comprises of various stages: application to conduct clinical trials, application to marketing authorization of drug and post marketing studies. Every country has its own regulatory authority, which is responsible to enforce the rules and regulations and issue the guidelines to regulate the marketing of the drugs. In the present scenario, different countries have to follow different regulatory requirements for Marketing Authorization Application (MAA) approval of new drug. In this article, we studied the new drug approval process and regulatory requirements in India and Indonesia according to their regulatory agencies.

KEYWORDS: Central Drugs Standard Control Organization (CDSCO), United States of Food and Drug Administration (USFDA), New Drug Approval, Marketing Authorization Application (MAA).

INTRODUCTION

The approval of a new drug involves two phases: the first phase focuses on clinical trials, while the second phase is for marketing authorization. Initially, non-clinical studies are completed to confirm the drug's efficacy and safety. After that, an application for conducting clinical trials is submitted to the competent authority in the relevant country. Once approved, clinical trials can be conducted, ranging from phase I to phase IV. These studies aim to assess the drug's efficacy, safety, and optimal dosing in humans. After completing the clinical trials, another application is submitted to the competent authority for marketing approval. The authority reviews the application and approves the drug only if it is found to be safe and effective in humans, or if its positive effects

outweigh its adverse effects. Even after a new drug receives approval, government oversight is essential to monitor its safety. Side effects may emerge when the drug is used by a larger population. It's also important to observe interactions with other drugs that were not tested in premarketing trials, as well as any adverse effects in specific populations. Currently, countries have varying regulatory requirements for new drug approval. Achieving a single regulatory approach for marketing authorization applications across different countries is challenging. Therefore, understanding the regulatory requirements for Marketing Authorization Applications in each country is important. The basic regulations for new drug approval are illustrated in Fig. 1.^[1]

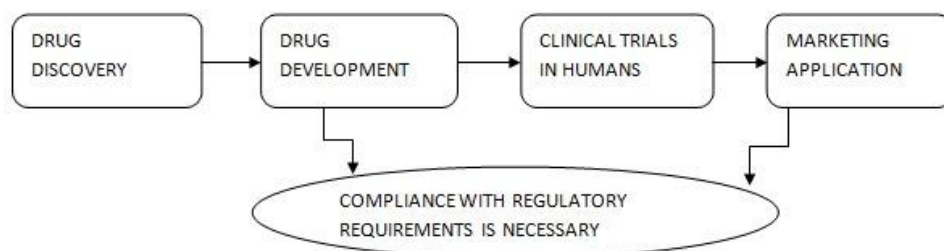


Figure no. 1: Regulation of Drug Approval Process.

2. REGULATIONS OF DRUG APPROVAL PROCESS

New Drug Application (NDA) is a request made to the relevant regulatory authority for permission to market a new drug. To get this permission, a sponsor submits preclinical and clinical test data, which includes information about the drug and a description of the manufacturing process. The clinical trials occur in different phases:

- Preclinical study: Mice, rats, rabbits, monkeys
- Phase I: Human pharmacology trial to estimate safety and tolerability
- Phase II: Exploratory trial to estimate effectiveness and short-term side effects
- Phase III: Confirmatory trial to confirm therapeutic benefits
- Phase IV: Post-marketing trial, which studies the drug after approval

Once the regulatory agency receives the NDA, it undergoes technical screening. This evaluation ensures that there is enough data and information in each area to justify the application being filed. At the end of the NDA review, there are three possible outcomes for the sponsor.

- Not approvable: This letter includes a list of deficiencies and explains the reasons.
- Approvable: This means the drug can be approved with minor deficiencies that can be corrected, like labeling changes or a commitment to conduct post-approval studies.
- Approval: This states that the drug is approved.

If the outcome is either approvable or not approvable, the regulatory body gives the applicant a chance to meet with the agency to discuss the deficiencies.

3. PROCEDURE FOR NEW DRUG APPROVAL IN INDIA

The Drug and Cosmetic Act of 1940 and the Rules of 1945 were enacted by India's parliament to regulate the import, manufacture, distribution, and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) and its head, the Drugs Controller General of India (DCGI), were established. In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules of 1945. Schedule Y provides guidelines and requirements for clinical trials, which were revised in 2005 to match international standards. Changes included establishing definitions for Phase I to

IV trials and clarifying responsibilities for investigators and sponsors.

In 2006, clinical trials were further divided into two categories. Category A includes trials that can be conducted in markets with competent and mature regulatory systems. Category B includes all other trials. Category A trials (approved in the U.S., Britain, Switzerland, Australia, Canada, Germany, South Africa, Japan, and the European Union) are eligible for fast tracking in India and can be approved within eight weeks. Category B trials face more scrutiny and can take 16 to 18 weeks for approval.

To conduct clinical trials in India, an application must be submitted to the DCGI along with data on chemistry, manufacturing, control, and animal studies. Details about the trial protocol, investigator's brochures, and informed consent documents should also be included. A copy of the application must be sent to the ethical committee, and clinical trials can only happen after the DCGI and ethical committee approve them.

Phase I trials test the maximum tolerated dose and record adverse reactions in healthy human volunteers. Phase II trials determine therapeutic uses and effective dose ranges in 10 to 12 patients at each dose level. Phase III confirmatory trials involve roughly 100 patients across 3 to 4 centers to gather data on the drug's efficacy and safety. If the new drug is not marketed in any other country, Phase III trials should involve at least 500 patients across 10 to 15 centers.

After completing clinical trials, the new drug registration is applied for using form # 44, along with all preclinical and clinical testing information. Data on the drug's marketing status in other countries, along with safety and efficacy information, is also necessary. Additional documents, including prescription information, samples, testing protocols, product monograph, labels, and cartons, must be submitted.

The application review period is about 12 to 18 months. Once the NDA receives approval, the company can distribute and market the product, entering Phase IV trials, which explore new uses, long-term effects, and different populations.

The drug approval process varies by country. Some countries have a single regulatory body handling all tasks, like the FDA in the USA, while others, like India, divide these responsibilities between central and state authorities. Differences also arise in the approval time for clinical trial applications, the review period for marketing authorization applications, registration fees,

registration processes, and marketing exclusivity. Some countries have two review processes—normal and accelerated—as seen in the USA and China. Other countries, like India, only have one. The format for the drug approval dossier also varies. In some places, such as the USA, EU, and Japan, using the CTD format is mandatory, while in India it is optional.^[2,3]

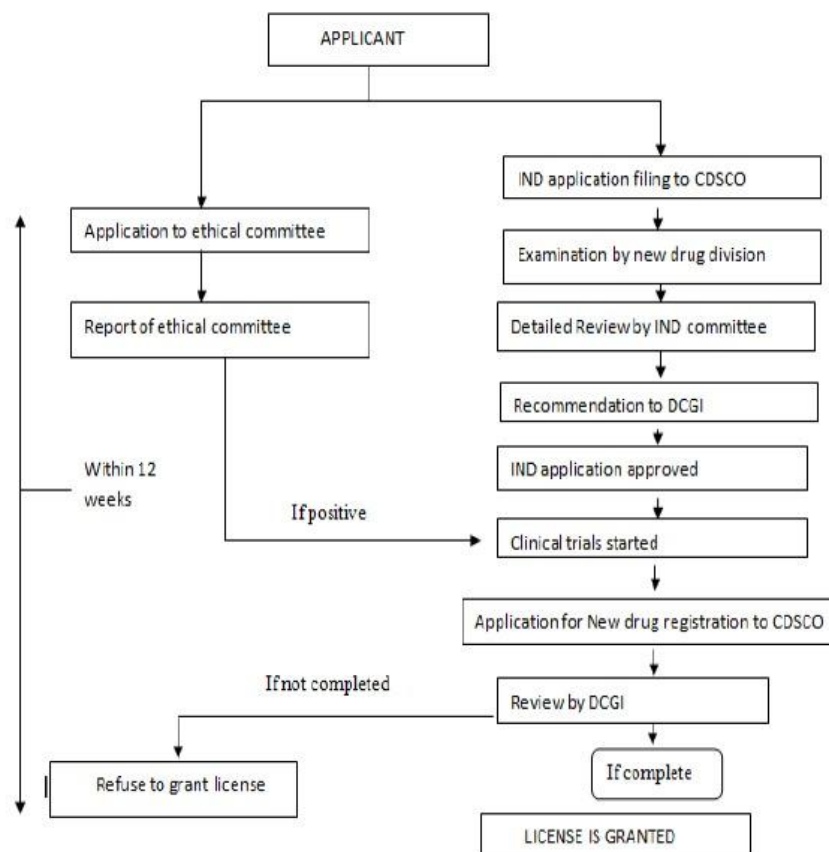


Figure no. 2: Drug approval process in INDIA.

3.1. Timelines for NDA

Time for regulatory approval of CTA/IND application is 16-18 weeks. Time for evaluation of MAA is 8-12 weeks. MAA fees is 50000 INR.

3.2. Drug Approval Stages in India

	Clinical Trials						FDA	12 total	Phase IV
	Preclinical testing		Phase I	Phase II	Phase III				
Years	3.5		1	2	3		2.5		Additional Post marketing testing required by FDA
Test Population	Laboratory and animal studies	File IND at FDA	20- 80 Healthy volunteer determine safety and dosage	100-300 patient volunteers	1000-3000 patient volunteers	File NDA at FDA	Review process / Approval		
Purpose	Assess safety and biological activity								
Success Rate	5,000 compounds evaluated		5 enter trials				1 approved		

Figure no. 3: Drug Approval Stages in India.

4. REGULATIONS OF DRUG APPROVAL IN INDONESIA

The pharmaceutical sector is growing rapidly to address new medical conditions. As unmet medical needs increase, more drugs will be released. The National Agency of Drug and Food Control (NADFC), also known as BPOM (Badan Pengawas Obat dan Makanan), is the regulatory authority in Indonesia. BPOM is responsible for overseeing pharmaceuticals and related activities in the country. They have introduced several regulations that must be followed for registering and marketing pharmaceuticals in Indonesia. Their main focus is on consumer safety, ensuring that safe and quality medicines are available to the public. Continue reading to learn about key regulations, the registration process, necessary documents, and more.^[4]

5. PROCEDURE FOR NEW DRUG APPROVAL IN INDONESIA

5.1 Process flow of pre-registration of drugs

The applicant must create an account with NADFC/BPOM. BPOM will then verify and activate the account. Once this is done, you can log in and request a product ID.

- After paying the fees and uploading the proof of payment, BPOM will verify it. You will receive a payment notice via email.
- Fill out the pre-registration form and submit the documents. The evaluation process will start, and the applicant can track the status of the application.
- If all the requirements are met, HPR (pre-registration result) approval is granted.

5.2 Process flow for registration of drugs

- The applicant must complete the registration form after selecting the drug to be registered from the HPR data.
- After verifying the registration form, BPOM will issue an SPB (order to pay) registration. Once you make the payment, upload the proof of payment. After verification, you will obtain the product ID.
- Now upload all the required registration documents. They will be evaluated. You can track the application status online. BPOM may either request additional information or reject the application if the documents do not meet the requirements.
- If the requirements are met, you will receive an approval letter and an NIE (marketing permit number).

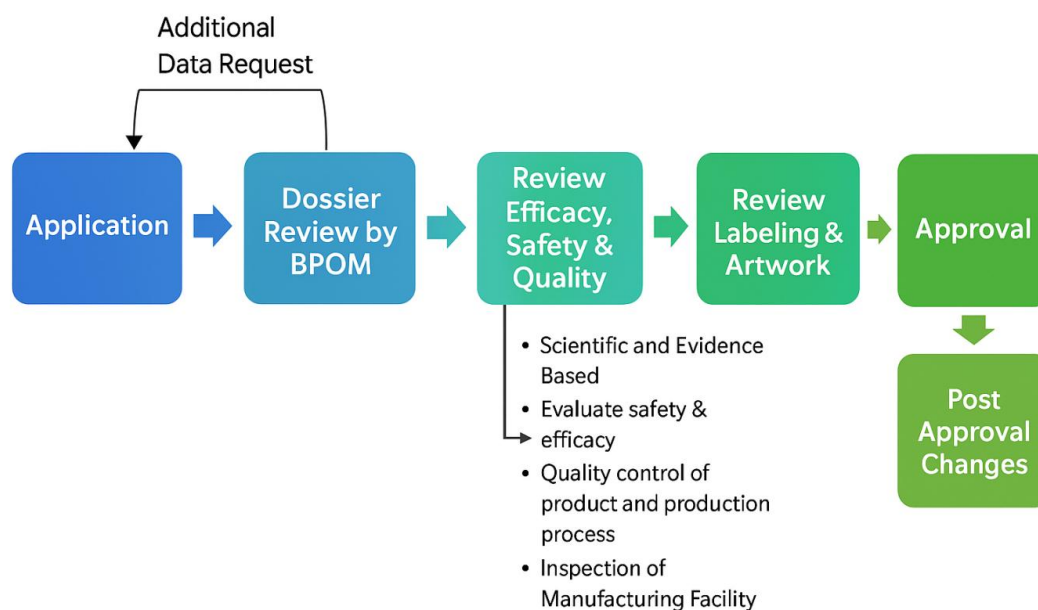


Figure no. 4: Drug Pharmaceutical Registration Process in Indonesia.

5.3 NADFC/BPOM

Documentation and CTD Requirements for Pharmaceuticals in Indonesia Registration documents are submitted and prepared in the ACTD format. The documents consists of.

- Part I: Administrative documents, product information and labels
- Part II: Quality Documents
- Part III: Non-clinical documents
- Part IV: Clinical documents

- Annex IV, V, VI, VII, VIII, IX & X of the BPOM regulation (no: 24, 2017) explains about the documents to be contained in each part.^[5,6]

5.4 TIMELINES OF INDIA

Fees for New Drugs is 10 million to 20 million (USD 650–1,300) and evaluation time for new chemical entities, biologics, or innovative drugs is Up to 300 WD (week days).

6. NDA Regulatory Requirements – India vs Indonesia

Key Requirement	India – CDSCO	Indonesia – BPOM
1. Authority & Legal Framework	CDSCO under Drugs & Cosmetics Act, 1940; New Drugs & Clinical Trials Rules (NDCTR) 2019	BPOM (National Agency of Drug and Food Control) under Ministry of Health regulations
2. Application Process	Online submission via SUGAM portal ; requires pre-NDA meeting, Form CT-21/CT-18, fees, and manufacturing/import license	Requires local Indonesian representative , importer ID (API), GMP/Free Sale Certificate, documents in Bahasa
3. Clinical Data Requirements	Preclinical + clinical trial data (including Indian population data); waivers possible if drug already approved abroad (per NDCTR 2019)	Pre- and post-marketing clinical trials need BPOM approval; trials valid for 2 years
4. Review & Approval Timeline	Reviewed by Subject Expert Committee (SEC); processing ~90 days after NOC; total NDA approval 12–18 months	Market Authorization approval usually 3–4 months (cosmetics) or up to 5 years validity (drugs)
5. Labelling Rules	Must follow CDSCO labelling norms (as per Drugs & Cosmetics Rules); English permitted	Labels must be in Bahasa Indonesia ; must include BPOM number, 2D barcode, warnings, expiry, halal if applicable
6. Validity & Renewal	Approval is permanent unless withdrawn/cancelled; no fixed “validity” period for NDA	Marketing Authorization valid 5 years ; renewal required 12–2 months before expiry

7. CONCLUSION

The comparison of CDSCO (India) and BPOM (Indonesia) shows that both regulatory bodies aim to ensure the safety, effectiveness, and quality of drugs. However, their frameworks differ in regulatory structure, submission requirements, evaluation timelines, and post-approval monitoring systems.

- CDSCO works under the Ministry of Health & Family Welfare and is based on the Drugs and Cosmetics Act of 1940. It follows practices influenced by ICH and WHO. The system is centralized but supported by states, emphasizing clinical trial regulation, drug safety monitoring, and fast-tracking approvals for new medicines.

- BPOM operates as an independent national body under the Indonesian government. It oversees not just drugs, but also food, cosmetics, and health supplements. Its rules focus on local clinical trial data, halal compliance, and traditional medicines. This reflects Indonesia's healthcare needs and cultural context. Both agencies are increasingly moving toward global regulatory standards and encouraging digital submission systems for better efficiency. Still, there are differences in data needs, timelines, and dependence on international approvals. In short, CDSCO acts as a regulator within a growing pharmaceutical center, prioritizing alignment with global markets. Meanwhile, BPOM focuses on national healthcare needs, traditional medicines, and public health. For multinational companies, understanding these regional regulatory differences is essential for successful drug approval and market access.

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