

REGULATORY RECURRENCE FOR APPROVAL OF ANDA (GENERIC DRUG) AS PER CDSCO IN INDIA COMPARISON WITH JAPAN

Dr. P. Ashok Kumar*, Jeevan S, Darshan V. S., Lingaraja N. P., Hemanth M., Kirankumar B. R.

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block Mahalakshmi Nagar, Near Railway Gate, 80 Feet Road Batwadi, Tumkar - 572103, Karnataka, India.



***Corresponding Author: Dr. P. Ashok Kumar**

Department of Regulatory Affairs, Sree Siddaganga College of Pharmacy, 1st Left Cross, 3rd Block Mahalakshmi Nagar, Near Railway Gate, 80 Feet Road Batwadi, Tumkar - 572103, Karnataka, India.

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ABSTRACT

Generic medicines play an important role in providing safe, effective, quality and affordable healthcare. They are developed as equivalent alternatives to brand-name medicines and must meet regulatory requirements for quality, safety, efficacy and bio equivalence. Their availability reduces healthcare expenditure, improves access to essential medicines and promotes competition in the pharmaceutical market. The Abbreviated New Drug Application (ANDA) is an important pathway for generic drug approval. It allows manufacturers to demonstrate equivalence to a Reference Listed Drug without repeating the complete development programme of the original product. Major requirements include bioequivalence studies, pharmaceutical quality, Chemistry, Manufacturing and Controls (CMC), current Good Manufacturing Practices (cGMP), stability testing and impurity control. In India, generic medicines are regulated under the Drugs and Cosmetics Act, 1940, Drugs Rules, 1945 and applicable regulatory requirements. The Central Drugs Standard Control Organization (CDSCO) performs important functions related to drug quality, safety, efficacy, clinical trials, marketing authorization, imported drugs, pharmacovigilance and bioavailability/bioequivalence requirements. In Japan, the regulatory framework involves the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA). PMDA conducts scientific and technical reviews, inspections and post-marketing safety activities, while MHLW provides final regulatory authorization. This comparative study evaluates the generic drug approval systems of India and Japan, focusing on regulatory requirements, bioequivalence, quality standards, review procedures and patient safety. It highlights major similarities and differences between the two regulatory frameworks and their approaches to ensuring the availability of safe, effective and affordable generic medicines.

KEYWORDS: Generic drugs; ANDA; CDSCO; PMDA; MHLW; Bioequivalence.

INTRODUCTION

A generic drug is a medicine developed to be equivalent to an established brand-name drug. It contains the same active ingredients and is intended to provide a same therapeutic effect as the corresponding reference medicine.



Figure no 1: Generic medicine.

IMPORTANCE OF GENERIC DRUG

- Safety, effective and quality
- Reduce the cost of treatment
- Improve access to essential medicines
- Provide competition in the pharmaceutical market
- Maintain required quality standards^[1]

BIOEQUIVALENCE

A generic medication must demonstrate bioequivalence to gain regulatory approval

The generic formulation must release the exact quantity of the active ingredients of into the patients bloodstream at the identical rate as original brand-name reference listed drug (RLD)

Regulators permit a clinically negligible variation in absorption of approximately 3-5%, which mirrors the standard variance seen between different batches of the original brand-name drug.^[2]

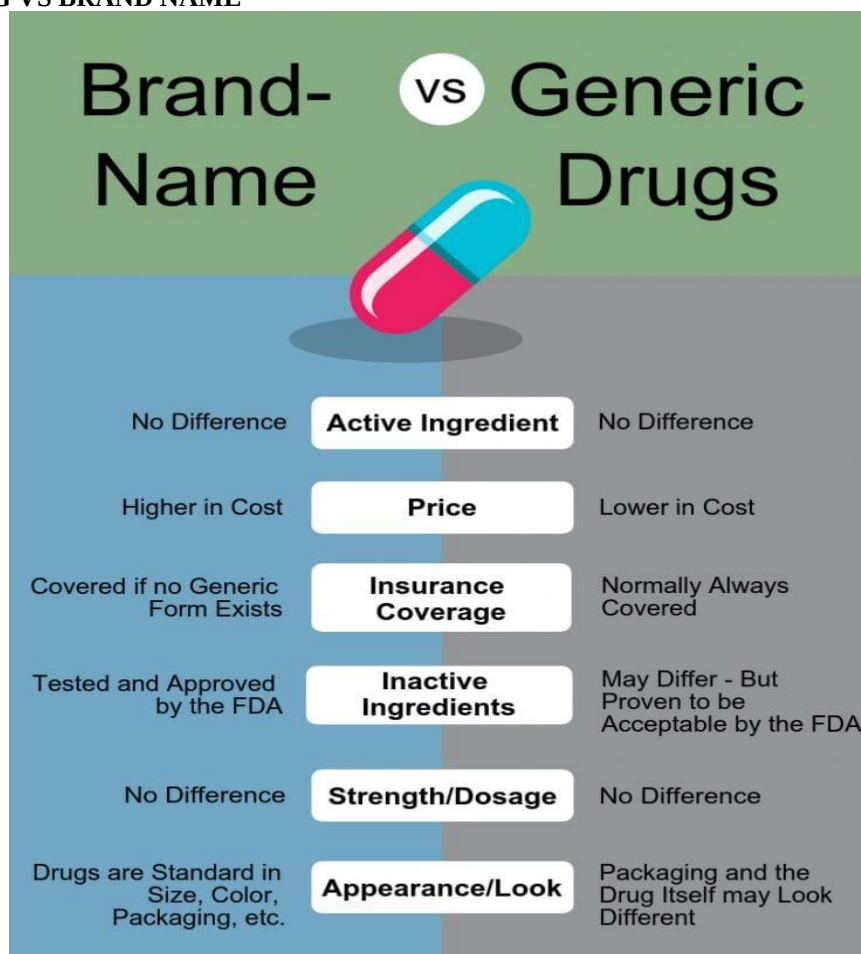
GENERIC DRUG VS BRAND NAME

Figure no 2: Difference between Brand name vs Generic name.

GENERIC NAME: The generic name is the common or scientific name of the active drug ingredients it is not a company specific name.

BRAND NAME: The brand name is the name given to a medicine by the pharmaceutical company for marketing and identification.

For example

Generic name: paracetamol

Brand name: crocin.^[1]

scientific proof of a drug's effectiveness by 1962. With safety and efficacy established, the 1984 Hatch-Waxman Act shifted the industry's focus toward affordability by clearing the path for cheaper generic alternatives. As major drug patents expired through the 1990s and 2000s, global reliance on these affordable options surged. Today, bolstered by strong production policies in countries like India, generic medicines dominate worldwide prescriptions, ensuring essential treatments remain accessible and cost-effective for the general public.^[3]

HISTORY GENERIC DRUG

Modern pharmaceutical regulation evolved from ensuring basic safety in 1938 to requiring rigorous

NEEDS FOR GENERIC DRUG

Affordable treatment: generic medicine can reduce treatment costs.

Improved access: More patients can obtain necessary medicines.

Competition: generic manufactures increases competition in pharmaceutical market.

Healthcare savings: increased generic use can reduce healthcare expenditure.

Availability of medicines: generic products can Improve the availability of commonly required medicines.

Quality assurance: regulatory approval ensures that product meet required standards.^[4]

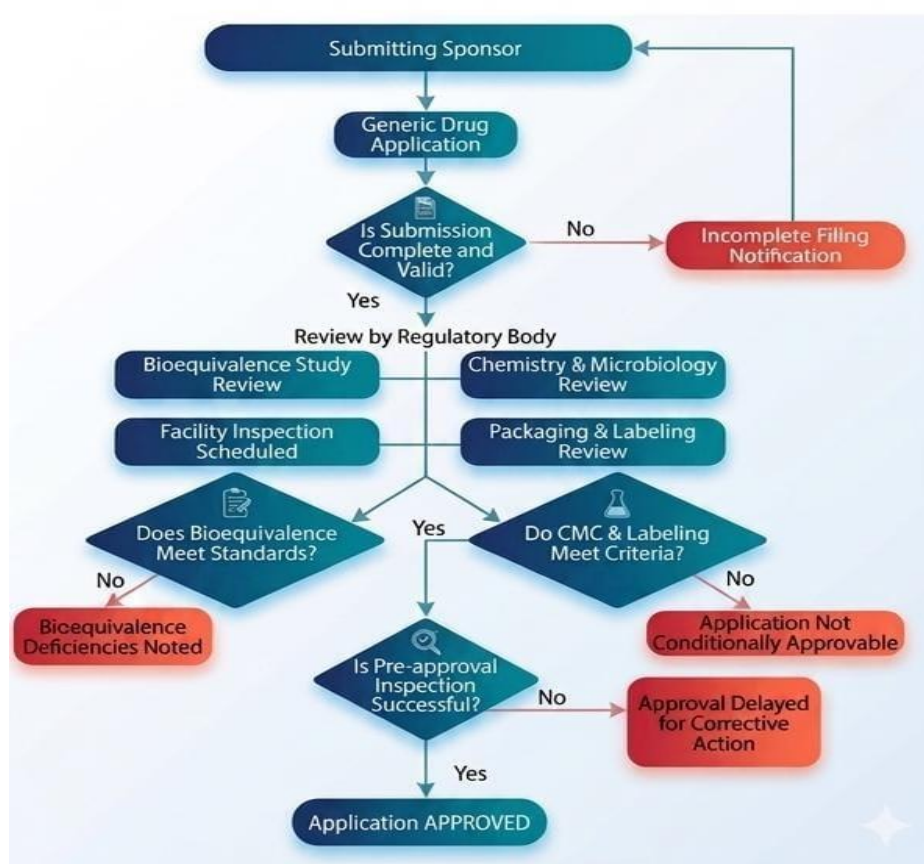
CHEMISTRY MANUFACTURING AND CONTROLS(CMC)

- cGMP compliance
- Stability testing
- Impurity profile^[5]

OBJECTIVES AND AIMS OF ANDA

To evaluate Pharmaceutical equivalence
To assess Pharmacrutilical Uniformity
To critique Manufacturing Integrity
To navigate the patent Landscape
To Reduce overall healthcare Expenditures
To Improve patient Adherence and Public Health Access
To Foster Healthy market Competition.^[6]

ANDA: ABBREVIATED NEW DRUG APPLICATION



^[7]figure no 3: ANDA approval process.

REGULATORY FRAMEWORK IN INDIA

Generic medicines in India are regulated under the country's pharmaceutical laws and regulatory requirements.

Important legal and regulatory instruments include:

- Drugs and Cosmetics Act, 1940
- Drugs Rules, 1945
- New Drugs and Clinical Trials Rules, 2019
- Applicable regulatory guidance and requirements

The Central Drugs Standard Control Organization (CDSCO) is the central regulatory authority involved in important aspects of drug regulation in India.

CDSCO is involved in areas such as drug quality, safety, efficacy, clinical trials, marketing authorization, imported drugs and pharmacovigilance.

It also has an important role in the regulatory oversight of bioavailability and bioequivalence studies.^[8]

OVERVIEW OF CDSCO

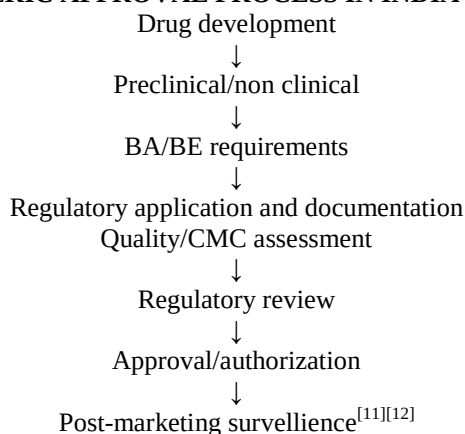
CDSCO – Central Drugs Standard Control Organization
CDSCO functions under the Ministry of Health and Family Welfare, Government of India.

It performs important regulatory functions relating to pharmaceutical products.

Major Functions

- Regulation of drugs and pharmaceutical products.
- Evaluation of applications according to applicable requirements.
- Oversight of clinical trials.
- Regulation of imported drugs.
- Monitoring of drug quality.
- Bioavailability and bioequivalence oversight.
- Pharmacovigilance-related activities.
- Coordination with other regulatory bodies.
- Implementation of applicable drug laws and rules.
- Promotion of safety, quality and efficacy of medicines.^{[9][10]}

GENERIC APPROVAL PROCESS IN INDIA



REGULATORY REQUIREMENTS FOR GENERIC DRUGS IN INDIA

Pharmaceutical Quality: The generic product should meet established specifications, identity, strength, purity and other relevant quality attributes.

Bioequivalence: The generic product may need to demonstrate bioequivalence with the reference product according to applicable requirements.

CMC: Chemistry, Manufacturing and Controls information describes the drug substance, drug product, manufacturing process and controls.

GMP: Manufacturing should comply with applicable Good Manufacturing Practice requirements.

Stability: Stability studies provide information about the quality of the product during storage.

Impurity Control: Impurities should be appropriately identified, controlled and monitored. Packaging and Labelling.

The product should have appropriate packaging and regulatory information.

These requirements collectively support the quality, safety and consistency of generic medicines.^{[11][12]}

REGULATORY FRAMEWORK IN JAPAN

Japan has an established regulatory system for pharmaceutical products.

The major organizations involved in pharmaceutical regulation are:

MHLW – Ministry of Health, Labour and Welfare

PMDA – Pharmaceuticals and Medical Devices Agency

Japan regulates pharmaceutical products under the Pharmaceuticals and Medical Devices Act (PMD Act)

PMDA performs scientific and technical evaluation, inspections and post-marketing safety activities, while MHLW has responsibility for formal regulatory authorization.

The Japanese system emphasizes

- Quality
- Safety
- Efficacy
- Scientific evaluation
- Manufacturing quality
- Bioequivalence
- Post-marketing safety.^[13]

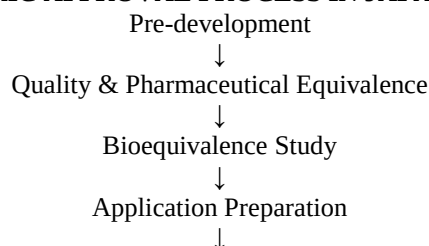
OVERVIEW OF PMDA

PMDA is an important organization in Japan's pharmaceutical regulatory system.

Major Responsibilities

- Scientific evaluation of pharmaceutical applications.
- Evaluation of generic drugs.
- Evaluation of quality and manufacturing information.
- Inspection and compliance activities.
- Scientific and regulatory consultation.
- Post-marketing safety monitoring.
- Collection and evaluation of adverse drug reaction information.
- Risk-minimization activities.
- International regulatory cooperation.^{[14][15]}

GENERIC APPROVAL PROCESS IN JAPAN



Submission to PMDA
↓
PMDA Review
↓
MHLW Approval

↓
NHI Listing
↓
Post-Marketing Surveillance^{[16][17][18]}

JAPANS PHARMACEUTICAL REGULATORY ECOSYSTEM AUTHORITIES, ROLES, AND RESPONSIBILITIES

Table no 1: Roles and Responsibility of PMDA.^{[17][18]}

Functional area	Pharmaceuticals and medical devices agency(PMDA)	Ministry of health
Product approval	Scientific review & evolution: conducts the rigorous technical review of new drug application (NDAs) generic equivalents, and biosimilars to judge data integrity, clinical efficacy, and safety profile.	Final Legal Authorization: Formally grants or denies product marketing licenses. Acts officially on recommendations passed down from the PMDA and its own specialized advisory councils (Miyazawa et al.,2024)
Facility inspection	Compliance Audits: Executes global and domestic on-site compliance inspections to verify adherence to Good Manufacturing Practice(GMP), Good Clinical Practice(GCP), and Good Laboratory Practice(GLP) environments.	Licensing Enforcement: Formally issues or revokes manufacturing business licenses for domestic factories and officially accredits foreign manufacturing facilities based on data from PMDA inspections.
Post marketing safety	Data Collection & Analysis: Collects and processes Individual Case safety Reports (ICSRs) and adverse drug reactions (ADRs). Manage prompt electronic safety communication alerts via the 'PMDA medi-navi' network.	Regulatory Action: Issues mandatory administrative actions based on analyzed safety data, such as ordering text revisions for drug package inserts, releasing safety letters, or executing market withdrawals.

The Three Core Pillers Of PMDA

The PMDA's unique regulatory identity is built around three integrated service pillars, often referred to as operational safety portfolio.

- ❖ **Product Review(efficiency/quality)**
- ❖ **Post marketing safety Measures(Safety)**
- ❖ **Relief Services for adverse Health Effects**

COMPARITIVE STUDY OF INDIA VS JAPAN

Table no 2: Comparitive study of India vs Japan.^[19]

Parameter	India	Japan
Regulatory Authority	Central Drugs Standard Control Organization (CDSCO)	Pharmaceutical and Devices agency (PMDA)
Term	Similar Biologics Products	Follow-on Biologics
Definition	Biosimilars as defined as officially approved new versions of innovator biotherapeutic products for which the patent has expired.	A biosimilar product is a biotechnological drug product developed by a different company to be comparable to an approved biotechnology-derived innovator product.
Laws and Regulation	Review Committee on generic manipulation (RCGM) and Genetic Engineering Approval Committee (GEAC) of central Drugs Standard Control Organization(CDSCO)	Ministry For Health, Labor and Welfare (MHLW)
Reference product	Authorized in India	Authorized in Japan
Data Exclusivity	Not specified	Not specified
Approval Pathway	Biologic License Application (BLA)	New Drug Application (NDA) with biosimilar-specific data
Pre-Litigation Procedure	Absent	Absent

Jurisdiction	Not defined	Not defined
Interchangeability	Absent	Absent
Data requirement	Biological activity, clinical studies, preclinical studies, and Immunogenicity studies	Clinical studies, Preclinical studies, and Immunogenicity studies
Reference-Product Requirement	Must be approved in India or another recognized market	Must be approved in Japan or another recognized market
Guidance	Published guidance under CDSCO	Published guidance under MHLW
Stability Requirement	Long-term and accelerated	Not necessary

FUTURE SCOPE

Future opportunities identified in the project include greater alignment with international standards such as ICH, increased use of digital regulatory submission, stronger oversight of bioequivalence studies and data integrity, application of Quality-by-Design and advanced manufacturing approaches, and efforts to reduce unnecessary regulatory delays.

Greater scientific cooperation between India and Japan may support more consistent regulatory approaches and facilitate international development and registration of generic medicines. Improved regulatory efficiency should be balanced with continued protection of medicine quality and patient safety.^[20]

CONCLUSION

India and Japan Have established but structurally different regulatory system for generic medicines. India operates through CDSCO within the applicable India drug-regulatory framework, while Japan uses a specialized review structure involving PMDA and MHLW. The project material indicates that both countries emphasize quality, safety, efficacy and bioequivalence.

The comparison suggests that regulatory harmonization, digitalization, improved bioequivalence assessment, quality-by-design and scientific cooperation could contribute to more efficient generic -drug development and approval. Maintaining rigorous quality and safety standards remains essential while improving access to affordable medicines.^[20]

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