International Research Journal of Pharmacy and Medical Sciences
ISSN (Online): 2581-3277

Drug Registration and Regulatory Approval Procedure in India

Sk. Shaheen[1], R. Venkidesh[1], N. Audinarayana[2], D. Jothieswari*
Sri Venkateshwara College of Pharmacy (Autonomous), Rvs Nagar, Chittor
Email address: drbaswarajpharma1@gmail.com

Abstract*—The drug approval process is the regulatory framework via which a person, organization, sponsor, or inventor is granted authorization to market a pharmaceutical product. The pharmaceutical approval process is often separated into many stages: application for clinical trial authorization, clinical trial execution, application for marketing authorization, and post-market research. Each nation has a regulatory body tasked with implementing laws and regulations while also providing guidance on pharmaceutical marketing regulation. The Drug and Cosmetics Act establishes State Authorities as the primary regulators of drug manufacturing, sales, and distribution, while Central Authorities are in charge of approving new drugs, supervising clinical trials, establishing drug standards, ensuring quality control of imported drugs, coordinating with State Drug Control Organizations, and providing expert guidance for consistent Act enforcement. The Central Drugs Standard Control Organization (CDSCO), overseen by the Drugs Controller General of India (DCGI), develops clinical trials, innovative pharmaceutical procedures, and laws. This guideline is based on the regulatory standards for pharmaceutical approval in India, as defined in the Drugs and Cosmetics Act, as well as any relevant rules or changes. This guideline describes the requirements for clinical trials and new medicine approval, as well as the CDSCO's procedures for reviewing technical dossiers associated with these applications*.

***Keywords*—** *Drug registration process, New Drug application, Clinical Trial application*.

I. INTRODUCTION

Countries now possess varying regulatory protocols for the authorization of a novel pharmaceutical. The unified regulatory framework for the marketing authorization application of an innovative pharmaceutical product, applicable across many countries based on a single dossier, is very intricate. Thus, understanding the specific and comprehensive regulatory requirements for marketing authorization applications of novel pharmaceutical products in each nation is essential for formulating a successful regulatory strategy.[1] The Drug and Cosmetic Act of 1940 and the Rules of 1945 were enacted by the Indian Parliament to oversee the importation, production, distribution, and sale of medicines and cosmetics.[2-3] The Central Drugs Standard Control Organization (CDSCO) and its head, the Drugs Controller General of India (DCGI), were founded. In 1988, the Indian government included Schedule Y into the Drug and Cosmetics Rules of 1945. Schedule Y delineates the criteria and conditions for clinical research, having been amended in 2005 to align with globally recognized norms. The revisions include the development of wording for Phase I-IV studies and the delineation of assigned tasks for investigators and sponsors. It is essential to validate the safety and effectiveness of the pharmaceutical product for human use prior to its approval for importation, production, or marketing inside the nation. Rules 122A, 122B, 122D, 122DA, 122DAA, and 122E of the Drugs and Cosmetics Rules, along with Appendices I, IA, and VI of Schedule Y, delineate the necessary information and data for the endorsement of clinical studies and the importation or production of new pharmaceuticals for commercialization within the country. The criteria for licensing clinical trials and novel medications may differ based on the characteristics of the substances.[4-6] This guideline document delineates the essential criteria for the endorsement of clinical studies and several categories of New Drugs, encompassing Investigational New Drugs, distinct drug components, augmented strengths, supplementary indications, and refined formulations, among others. This guideline will assist the industry in delivering essential information with more precision, hence enabling systematic assessment of applications by CDSCO evaluators. This organized application, with thorough and cohesive material, will improve the CDSCO's review process and promote operational efficiency, while also facilitating the preparation of future electronic submissions to CDSCO.[8-10] The Drug and Cosmetics Act assigns State authorities the primary responsibility for regulating the manufacture, sale, and distribution of drugs, whereas Central Authorities are tasked with approving new drugs, overseeing domestic clinical trials, establishing drug standards, ensuring quality control of imported drugs, coordinating State Drug Control Organizations, and providing expert guidance for the uniform enforcement of the Act. The Drug Controller General of India is tasked with issuing licenses for certain types of medicines, such as blood and blood products, intravenous fluids, vaccines, and sera.[10-12]

1.1. Functions:

1.1.1. Statutory Functions:

Quantitative quality evaluation of the majority of foreign medications present in the Indian market. Conducting analytical quality control of domestically manufactured pharmaceuticals and cosmetics for the Central and State Drug Controller Administrations. Serving as an appellate body on drug quality issues.

1.1.2. Other Functions:

Acquisition, preservation, and distribution of International Standard Reference Materials Formulations of medicinal compounds. Creation and maintenance of National Reference Standards. Conservation of microbial habitats relevant to

Sk. Shaheen, R. Venkidesh, N. Audinarayana, and D. Jothieswari, "Drug Registration and Regulatory Approval Procedure in India," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 8, Issue 1, pp. 43-49, 2024.

pharmacological evaluation Distribution of standards and cultural norms to governmental quality control labs and pharmaceutical manufacturing establishments. Protocols for pharmaceutical analysers set by State Drug Control Laboratories and other organizations.

1.2. Central Drugs Laboratory (CDL):

The Central Medications Laboratory in Kolkata, established by the Indian Drug and Cosmetics Act of 1940, serves as the national statutory laboratory for the Government of India, responsible with the quality evaluation of pharmaceuticals and cosmetics. The Drug Control Authorities of India conduct operations at their oldest quality control laboratory at this location. It reports to the Director-General of Health Services under the Ministry of Health and Family Welfare and is subject to administrative oversight.

Testing Laboratories under CDSCO

1. CDL. Kolkata
2. CDTL, Mumbai
3. CDTL, Kasauli
4. CDTL, Hyderabad
5. CDTL, Chennai
6. RDTL, Chandigarh
7. RDTL, Guwahati

1.2.1. Central Drugs Testing Laboratory (CDTL) Chennai, Tamil Nadu

The Central Drug Testing Laboratory serves as one of four National Laboratory facilities in India dedicated to the testing and investigation of Drugs and Cosmetics in accordance with the Drug and Cosmetics Act of 1940.

1.2.2. Central Drugs Testing Laboratory (CDTL) Hyderabad, AP

The Central Drug Testing Laboratory is a newly formed entity in Andhra Pradesh, India, dedicated to the testing, research, and analysis of pharmaceuticals and cosmetics in accordance with the Drug and Cosmetics Act of 1940.

1.2.3. Central Drugs Testing Laboratory (CDTL) Mumbai

The Central Drugs Testing Laboratory in Mumbai is a national statutory laboratory of the Government of India, functioning under the administrative jurisdiction of the Drug Controller General (India), DGHS, Ministry of Health and Family Welfare. The laboratory's main responsibilities include assessing imported bulk medicines and formulations approved by ADCs in Mumbai, Nhava Sheva, and Chennai, as well as reviewing Survey and Watchers samples supplied by the Deputy Drugs Controller (India), West Zone. Recently, the Controller General of Medicines in India has begun citing innovative medications and formulations.

1.2.4Regional Drugs Testing Laboratory (RDTL) Guwahati

The Regional Drugs Testing Laboratory Guwahati is one of five National Laboratories created by the Government of India, tasked with the quality monitoring of Drugs and Cosmetics. It was founded according to the Indian Drugs & Cosmetics Act of 1940 and functions under the administrative supervision of the Drugs Controller General of India, an entity subject to the Directorate General of Health Services, Ministry of Health & Family Welfare. The laboratory was founded in 2002 to service the whole North Eastern area, including Sikkim, and is situated at its own building in Guwahati.

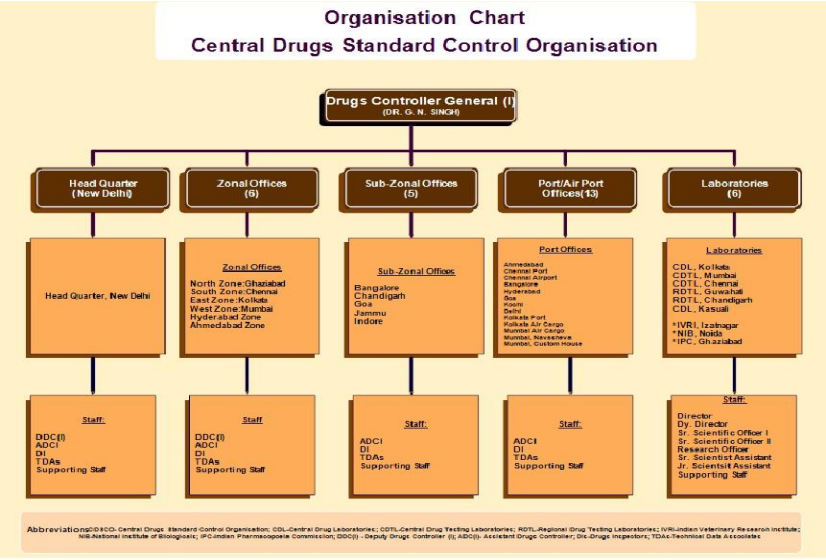
1.2.5. Regional Drugs Testing Laboratory (RDTL) Chandigarh

The Regional Drugs Testing Laboratory in Chandigarh has been operational since November 2007. The laboratory is currently evaluating an average of 50 drug samples each month, primarily to meet the needs of CDSCO (North Zone). The laboratory is enhancing its facilities and workers to improve testing capabilities.

1.2.6. Central Drug Laboratory, CRI Kasauli

The Central Drug Laboratory at CRI Kasauli is a centralized facility that conducts vaccine testing. The Central Drugs Laboratory is an officially designated laboratory according to the Drugs and Cosmetics Act of 1940. It evaluates the following pharmaceuticals or categories: i) Sera ii) Vaccines iii) Toxins iv) Antigens v) Anti-toxins vii) Sterilized surgical ligatures and sutures viii) Bacteriophages, encompassing the Oral Polio vaccination.

1.3. Central Drugs Standard Control Organisation Chart:



Sk. Shaheen, R. Venkidesh, N. Audinarayana, and D. Jothieswari, "Drug Registration and Regulatory Approval Procedure in India," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 8, Issue 1, pp. 43-49, 2024.

II. Objectives of the Work

1. Comprehending and complying with regulatory mandates is crucial for the effective development and promotion of medications. These suggestions relate to the endorsement of clinical studies and the permission for the production or importation of several categories of innovative medicines, including active pharmaceutical ingredients (API) and finished formulations.
2. This guideline specifies the requirements for the approval of clinical trials and new medicines, together with the procedure for assessing technical dossiers related to these applications by CDSCO and Schedule-Y of the Drugs and Cosmetics Rules.

The major objective is to

3. A foundational comprehension of the regulatory framework and processes overseeing the authorization of clinical trials, medicines, and medication marketing in India.

III. Methodology and Result &Discussions

Examining guidance documents and directives from health authority resources, together with compiling country-specific regulations in chronological sequence, is a significant problem. A strategy is essential to outline the whole process in many stages. The regulatory dimensions of the novel medicine development process must be meticulously examined. To optimize the laborious process, the whole study has been divided into five discrete stages, each including a simultaneous common phase. The five discrete stages of project execution.

Phase I – Definition
Phase II – Identification
Phase III – Accumulate
Phase IV – Analyze
Phase V – Compilation

The dominant phase happening simultaneously at each level is Assessment. Phase I (DEFINE): Research Objectives • Regions for Inclusion • Timelines required for each step.
Phase II (IDENTIFY): a) Data sources b) Primary submission domains Phase III (COLLECT): Acquisition of unrefined data from the sources. Information will be obtained from the websites of recognized health organizations. Stage IV (SCRUTINIZE): • Classification of data • Review of guidelines Phase V (COMPILE): Consolidation of the augmented data The data acquired from the health authority resource must be effectively analyzed to extract the critical information required for submissions throughout product development. The main challenge facing companies is the vast amount of detailed data needed for submission to the health department. Minor omissions in the plan may obstruct the approval process, negatively impacting the industry.

3.1. Registration and Regulatory Requirement for Drug Approval In India

Regulations dictate the endorsement of clinical studies and the permission for the production/importation for commercialization of various new medicines, including active pharmaceutical ingredients (APIs) and finished formulations, categorized as novel drugs under Rule 122E of the Drugs and Cosmetics Rules. The guideline specifies the requirements for the approval of clinical trials and new drugs, along with the procedure for assessing technical dossiers related to these applications by CDSCO, in compliance with Rule 122 A, 122B, 122DA, 122DAA, 122E, and Schedule-Y of the Drugs and Cosmetics Rules. This guideline does not apply to biologicals and vaccines.

3.2. General Considerations

The guideline is founded on the regulatory criteria for drug approval in India as specified by the Drugs and Cosmetics Act, together with its associated rules and modifications. The applicant must get a Form-29 license from the State Licensing Authority, contingent upon obtaining a No Objection Certificate (NOC) from the CDSCO for the development of any new pharmaceutical product. The production of test batches for new pharmaceuticals intended for research and data creation should commence only after acquiring the license in Form-29. A proposal for clinical study approval or marketing permission may contain entirely original data. Completely sourced from the books. Primary data combined with literature-derived data ("hybrid"). Hybrid submissions are expected to become the predominant approach for novel medications. Chemical and medical data must be original unless well supported by existing literature demonstrating that specific data is not original. The DCG (I) office authorizes the manufacturing or importation of novel pharmaceuticals for domestic marketing. This agency is tasked with granting authorization for the execution of clinical trials for novel pharmaceuticals, including Investigational New Drugs (IND). New pharmaceuticals, as defined by Rule 122-E of the Pharmaceuticals and Cosmetics Rules, include unapproved medications, modified or novel claims concerning indications, dosage forms (such as sustained release formulations), routes of administration for previously authorized drugs, and combinations of multiple drugs. A medicine will be classified as unique for four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever occurs first. No clinical research for a novel medicine, whether for clinical investigation or any clinical trial by any institution, may be done without written clearance from the Licensing Authority as specified in paragraph (b) of Rule 21.

3.3. Further Clarifications

Source of active medicinal components for final formulation manufacture Documentation required about the origin of bulk drug(s) or raw material(s) when the applicant seeks approval only for the production of final formulations. If available, please provide a copy of the production permission for bulk medicines from the applicant. Alternatively, include the consent letter from the designated authority for the supply of supplies. Explanation: If the applicant does not possess permission from the DCGI to manufacture the Active Pharmaceutical Ingredient(s) (API), the applicant may: •

Sk. Shaheen, R. Venkidesh, N. Audinarayana, and D. Jothieswari, "Drug Registration and Regulatory Approval Procedure in India," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 8, Issue 1, pp. 43-49, 2024.

Import the API: The applicant must provide all relevant information and documentation and comply with supplementary import regulations for the API. The applicant must provide all relevant information and documentation and comply with supplementary manufacturing criteria for the API. Obtain the API from a different manufacturer that has not yet secured permission from the DCGI. The relevant manufacturer of the API must submit an independent application using Form 44, together with a treasury challan for the requisite amount and all necessary paperwork. The authorization for the manufacture of the new drug API will depend on the approval of its finalized formulation.

3.4. Guidelines on Data Required to be Submitted for Approval of Clinical Trials (Phase-I/II/III/IV).

Clinical trials for newly found therapeutic compounds in India must commence in India at Phase I. Applications for new medicinal compounds discovered outside of India must contain Phase I data as required. Upon submission of Phase I data generated outside India to the Licensing Authority, approval may be granted to repeat Phase I studies and/or commence Phase II trials, subsequently followed by simultaneous Phase III trials with other global trials for that medication. Phase III studies are required in India before securing marketing permission for the medication; the necessary data will differ according to the aims of the new drug application. The number of study participants and sites involved in the clinical trial will depend on the nature and goals of the inquiry. Phase I clinical trials should generally be done by investigators skilled in clinical pharmacology and with the necessary tools to carefully observe and monitor participants. These may be executed at one or two sites. Each dose must include at least two persons. Phase II clinical studies should generally include 10 to 12 subjects at each dose level. These studies should generally be performed at 3-4 centers by physicians proficient in the relevant therapy domains and have the necessary resources to conduct efficacy and safety assessments. When a drug is already approved or marketed in other countries, phase III data should generally be gathered from at least 100 patients across 3-4 centers, primarily to corroborate the drug's efficacy and safety in Indian patients, in accordance with the guidelines specified in the product monograph for the claims made. For a new pharmaceutical compound discovered in India and unavailable in other countries, phase III data should generally be gathered from at least 500 patients across 10 to 15 locations. Authorization to perform these investigations will often be given progressively, considering the outcomes derived from prior rounds. The CDSCO will conduct an initial evaluation of these applications; if any particular data is inadequate, the applicant will be informed. Alternatively, the applications will be presented to the members of the Investigational novel Drugs (IND) committee or the New Drug Advisory Committee (NDAC) for novel chemical entities, as relevant. CDSCO will examine applications for authorization to undertake clinical trials involving novel dosage forms, new indications, or alternative methods of administration for current pharmaceuticals. Such applications may be assessed alongside specialists or expert committees as required. The data required for executing clinical trials with a novel medication will be comparable to that outlined in Appendix I of Schedule Y. Clause 1(3) of Schedule Y of the Drugs & Cosmetics Rules permits the Licensing Authority to abbreviate, defer, or omit toxicological and clinical data requirements for drugs intended for life-threatening or serious diseases, or diseases of particular significance to Indian health. The Drugs & Cosmetics Act and Rules do not include a definition for "life-threatening/serious diseases" nor an enumerated list of such diseases or disorders. "Life-threatening" diseases are often characterized as conditions with a significant likelihood of death unless the development of the disease is stopped, along with those that may lead to fatal outcomes. Conditions such as cancer and AIDS are often considered severe or life-threatening. In cases of life-threatening or severe diseases, it is beneficial to expedite the creation, evaluation, and commercialization of new therapies for patients, especially when no sufficient alternative therapy exists. In these cases, patients and physicians often demonstrate an increased readiness to accept heightened risks or adverse consequences from therapies for life-threatening or severe conditions in contrast to those for less critical ailments. Exemption requests from toxicological and clinical data standards will undergo evaluation via a comprehensive assessment of data adequacy alongside specialists or expert committees. Investigations in Animal Pharmacology and Animal Toxicology must adhere to Appendix IV and Appendix III of Schedule Y of the Drugs and Cosmetics Rules, respectively. Amendments to the aforementioned criteria may be implemented in accordance with the attributes of novel pharmaceuticals and specific ailments. The paperwork required for the approval of such clinical investigations is as follows, Form 44 Treasury Challan of INR 50,000 (for Phase I) / INR 25,000 (for Phase II/III clinical trials). Source of bulk medications and raw ingredients. Clarification: Applicants may import a restricted quantity of the API using Form-11, necessitating a subsequent application via Form-12, accompanied by the Treasury Challan and other relevant documentation. The applicant may manufacture restricted amounts of the API under a license obtained in Form-29 from the State Licensing Authority. Obtain the API from an unauthorized manufacturer as per the DCGI; in this case, the manufacturer must file a supplementary application for a NOC to produce restricted quantities for clinical study purposes. A NOC from the CDSCO license in Form-29 must be secured from the appropriate State Licensing Authority before the production of trial batches. Data about chemicals and drugs, encompassing: Information on active constituents: Pharmaceutical information (Generic Name, Chemical Name or INN) and physicochemical properties, including: i. Chemical designation and structure - empirical formula, molecular weight. ii. Analytical Data: Elemental analysis, mass spectrometry, nuclear magnetic resonance spectroscopy, infrared spectroscopy, ultraviolet spectroscopy, polymorphic characterization. Stability Studies: Documentation evidencing stability inside the specified container closure system for the duration of the clinical trial.

Sk. Shaheen, R. Venkidesh, N. Audinarayana, and D. Jothieswari, “Drug Registration and Regulatory Approval Procedure in India,” *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 8, Issue 1, pp. 43-49, 2024.

3.5.Guidelines On Data Required For Approval For Marketing Of New Drug No new medication may be imported (Rule 122 A) or manufactured (Rule 122 B) without the license from the Licensing Authority, as specified in clause (b) of Rule 21 (i.e., DCGI). To secure authorization for the importation or production of novel drug substances and their formulations for domestic marketing, the applicant must submit an application using Form 44, accompanied by the necessary fees via treasury Challan, along with all relevant information as specified in Schedule Y of the Drugs and Cosmetics Rules. This encompasses chemical and pharmaceutical information, pharmacological and toxicological data pertaining to animals, clinical safety and effectiveness data, regulatory status in other nations, and outcomes of clinical studies performed on the local populace. However, for newly licensed pharmaceuticals in other countries, the need to provide findings from local clinical trials for approval may be exempted if the licensing authority concludes, in the public interest, that authorization may be given based on data from other countries.

The criteria for assessing the "public interest" clause may include the following:

1. If the drug is indicated for critical or life-threatening conditions.
2. If the drug is justified for a condition of specific importance to the Indian health setting.

The drug is recommended for a condition with few or no appropriate therapeutic options.

4. If the treatment is intended for a rare disease or a condition with a restricted patient demographic, conducting a clinical trial may need a longer timeframe.
5. Existence of significant unmet medical needs or major public health issues

The medication in question offers significant advantages compared to existing therapy alternatives for a specific illness.

The submission of requirements for animal toxicology, reproductive studies, teratogenic studies, perinatal studies, mutagenicity, and carcinogenicity data may be modified or exempted for new drugs that have been approved and marketed for several years in other countries, contingent upon the availability of adequate published evidence concerning the drug's safety. The Drugs & Cosmetics Rules do not explicitly delineate the marketing duration for a new drug in foreign jurisdictions, which may be construed as "several years." However, it is clarified that to obtain relaxation or modification of the animal toxicology data requirements for a new drug, the drug must be marketed in other countries for a duration exceeding two years, and adequate evidence of its safety must be submitted to CDSCO via published journals. The CDSCO will assess any decrease or modification of toxicological data requirements individually, in collaboration with experts or an expert committee.

Clause 1(3) of Schedule Y of the Drugs & Cosmetics Rules stipulates that for drugs intended for life-threatening or serious diseases, or diseases of particular importance to Indian health, the toxicological and clinical data requirements may be abbreviated, deferred, or omitted at the discretion of the Licensing Authority (Schedule Y at URL Schedule%20Y(ammended%20version)%20-%20CDSCO.htm accessed on 15/7/2011).

The Drugs and Cosmetics Act and Rules do not include a definition for "life-threatening/serious diseases" nor an enumerated list of such diseases or disorders. "Life-threatening" diseases are often characterized as conditions with a significant likelihood of death unless the development of the disease is stopped, as well as those that may result in fatal outcomes. Conditions such as cancer and AIDS are often considered severe or life-threatening.

In cases of life-threatening or severe diseases, it is essential to expedite the development, evaluation, and commercialization of innovative therapies for patient care, especially when no sufficient alternative exists. In such cases, patients and doctors often demonstrate an increased readiness to accept risks or side effects linked to treatments for life-threatening or severe conditions, as opposed to those for less critical illnesses.

The CDSCO will conduct an initial evaluation of these applications; if any particular data is lacking, the applicant will be informed. Alternatively, the applications will be presented to the members of the Investigational novel Drugs (IND) committee or to the members of the New Drug Advisory Committee (NDAC) for novel chemical entities, except INDs, and new fixed-dose combinations (FDCs). The Central Drugs Standard Control Organization (CDSCO) will assess applications for the approval of novel dosage forms, indications, and modes of administration for approved drugs. These applications may be evaluated alongside specialists or expert panels as required.

Furthermore, all requests for exemption from toxicological and clinical data obligations shall be evaluated based on the assessment of data sufficiency and in conjunction with experts or expert committees.

The applicant (a qualified individual from the Company) must provide a legal affidavit affirming that the data provided with the application is scientifically genuine and true.

New pharmaceuticals may be categorized into the following types, and the requisite data for marketing clearance is delineated below: New Chemical Entity - created in India as an Investigational New Drug and not commercialized globally. New Chemical Entities licensed and commercialized in other countries but not authorized in India. New Chemical Entity in development in other nations and not commercially available globally. A medicine previously sanctioned by the Licensing Authority specified in Rule 21 for certain claims is now proposed for marketing with altered or novel claims, including indications, dosage, dosage form (such as sustained release dosage form), and method of administration. A newly authorized medicine inside the nation (within four years following the approval of new pharmaceuticals).

3.6.New Chemical Entity being developed in other countries and not marketed anywhere in world: Approval for the marketing of novel pharmaceuticals requires the submission of data similar to that outlined in Appendix I of Schedule Y, which corresponds to the data needed for any new chemical entity (NCE). Generally, newly licensed medications in countries such as the USA, UK, Canada, the European Union,

Japan, and Australia will qualify for manufacture, importation, and marketing authorization, except for certain exclusions detailed below: The drug is indicated for critical or life-threatening conditions. The drug is recommended for a condition of notable importance within the Indian health environment. The drug is administered for a condition with limited or insufficient therapeutic options. The medicine is administered for a rare disease or a condition affecting a small patient group, necessitating a prolonged term to complete a clinical research. Existence of significant unmet medical need or serious public health issues The medication in question offers significant advantages compared to existing therapy alternatives for a specific illness. Phase III studies for innovative pharmaceuticals must be executed locally to demonstrate their efficacy and safety in Indian patients when used as per the recommended guidelines. Prior to commencing Phase III studies with Indian subjects, the Licensing Authority may need pharmacokinetic assessments to ensure that the data gathered from the Indian population is consistent with the data previously acquired globally. Under the Drugs & Cosmetics Rules, the submission of local clinical trial findings may be deemed superfluous if the licensing body, in the interest of public welfare, decides to provide authorization based on data from other jurisdictions. Applicants seeking a waiver for local clinical trials of innovative pharmaceuticals must submit a formal request to CDSCO, together with enough justification and evidence. The CDSCO will first evaluate these applications; if any particular data is lacking, the applicant will be informed; otherwise, the applications will be sent to the members of the New Drug Advisory Committee (NDAC). The decision regarding petitions for exemptions of local clinical trials before the authorization of new drugs for market entry in the country will rely on the recommendations of the NDAC. The paperwork required for the approval of such New Drugs is as follows: Form 44 Treasury Challan for INR 50,000. Source of bulk medications and raw ingredients.

Clarification: The applicant may import or independently generate the API or get it from another domestic source. The applicant must submit an application together with all relevant papers and comply with extra rules for the importing of the API. The applicant must submit an application together with all relevant papers and comply with supplementary requirements for the production of the API. Obtain the API from an unauthorized producer by the DCGI. In this situation, the manufacturer is needed to file a fresh application using Form 44, together with a treasury Challan for the necessary amount and further relevant documents. The application will be processed simultaneously with the application for the finalized formulation. The API's clearance will depend on the endorsement of its formulation.

IV. Summary and Conclusions

The drug approval process is divided into two stages: the application for clinical trials and the application to the regulatory body for marketing authorization of the medicine. Many nations' pharmaceutical approval regimes have similarities while also differing. In most counties, the sponsor first submits an application to conduct a clinical trial, and only after receiving regulatory approval does the applicant proceed with the clinical studies and then submit a marketing authorization application for the medication to the regulatory authority. Across all nations, the data presented to regulatory agencies about medication quality, safety, and effectiveness is comparable; nevertheless, the schedules, costs, and assessment procedures for clinical trials and marketing license applications varied. The International Conference on Harmonization (ICH) has made significant strides in pushing for the consistent interpretation and implementation of technical ideas and criteria aimed at harmonization. This approach will eventually eliminate the need to duplicate efforts in the research and development of new medications. Thus, the ICH or WHO may perform worldwide standardization of pharmaceutical approval procedures.

Acknowledgement

One of the authors SS expresses thank to the Department of Pharmaceutical Sciences, Sri Venkateshwara College Of Pharmacy (Autonomous), Rvs Nagar, Chittor providing necessary facilities. Authors thank the Principal, Professor, Department of Pharmaceutical Analysis & Chemistry, Sri Venkateshwara College Of Pharmacy (Autonomous)for providing necessary facilities.

References

1. Vibcare, How to export medicines from India to other countries. Available from: https://vibcare.co.in/export-medicines-from-india/ Accessed on- 06 Jan 2020.
2. IBEF, Infographic on the growth of pharmaceutical industry in India. Available from: https://www.ibef.org/industry/pharmaceutical-india/infographic Accessed on- 05 Jan 2020.
3. Badjatya J K, Bodla R, Musyuni P. Export registration of pharmaceuticals in rest of world countries (ROW).
4. slideshare.net/irish1234/indian-pharma-market-key-exportdestinations-51845191
5. Annual report 2017-18 Government of India. Available from: https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202017-18.pdf Accessed on- 25 Jan 2020.
6. V. Senthil, Priyadharshini B. Regulatory process for import and export of drugs in india. 2015.
7. Basak S. Pharmaceutical Market and Regulatory Contents for Export of Pharmaceutical Products to Latin American Countries 2018.
8. Choudhary A, Preparation of master formula record, Available from: https://www.pharmaguideline.com/2016/07/preparation-ofmfr-for-pharmaceuticals.html Accessed on- 26 Jan 2020.
9. http://pharmacentral.in/preparation-of-mfr-for-pharmaceuticals/.
10. GMP ASEAN guideline. Available from: https://asean.org/storage/2012/10/ASEAN-TMHS-GMP-TrainingChapter-5-Annex-5-Sample-Batch-Manufacturing-Record.pdf https://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelCertificateAnalysisTRS902Annex10.pdf?ua=1.
12. Dr. Zeine C, Reference materials: Certificate of analysis. Available from: http://www.seishinsyoji.co.jp/files/libs/50/201604181140271489.pdf Accessed on 05 Feb 2020.
13. Pooja M, Certificate of pharmaceutical product COPP. www.rjptonline.org. 2015.
14. Pooja et al. Dmf filing in us, Europe and Canada. IJDRA.2015; volume 3(issue 4).
15. FDA, Types of drug master files. Available from: https://www.fda.gov/drugs/drug-master-files-dmfs/types-drugmaster-files-dmfs Accessed on 28 Feb 2020.
16. Yamini kanti S P et al, Filing of DMF in US, Canada and Europe. PDRAJ, Volume 2; issue (1). Available from: https://medwinpublishers.com/PDRAJ/PDRAJ16000108.pdf.

17. Inside story for review of DMF and Dossiers by regulatory authorities. Available from: http://www.perfectdossier.com/pdf/Inside%20Story%20for%20Review%20of%20DMF%20&%20Dossiers%20by%20Regulatory%20 Authorities.pdf. Accessed on 20 March 2020 18. US FDA, New requirements for the electronic submissions of MFs Available from: https://www.fda.gov/media/98898/download. Accessed on 25 Feb 2020.
19. https://www.pharmatutor.org/articles/pharmaceutical-regulatoryagencies-andorganizations-around-world-scope-challenges-indrug-development.20https://www.ddfcambodia.com/ Accessed on 26 Feb 2020.
20. https://www.pharmatutor.org/articles/a-study-of-procedures-fordossier-preparation-and-their%20marketing-authorisation-indifferent-countries-of-selected-drug?page=2.
21. European medicines agency, Common technical document for the registration of pharmaceuticals for human use- quality. Available from: https://www.ema.europa.eu/en/documents/scientificguideline/ich-m-4-common-technical-document-registrationpharmaceuticals-human-use-organisation-ctd-step-5_en.pdf. Accessed on 27 March 2020.
22. https://www.nuventra.com/resources/blog/regulatory-submissionsectd.
23. Guidance for industry M2 eCTD: electronic common technical document specification. Available from: https://www.fda.gov/media/71513/download. Accessed on 23 Feb 2020.
24. Government of Canada, Guidance document: preparation of drug regulatory activities in the eCTD format. Available from: https://www.canada.ca/en/health-canada/services/drugs-healthproducts/drug-products/applications submissions/guidancedocuments/ectd/preparation-drug-submissions-electronic-commontechnical-document.html. Accessed on 29 March 2020.
25. CTD 247, Benefits of electronic eCTD submission. Available from: https://ectd247.com/ectd-benefits/. Accessed on 05 March 2020.
26. Asian regulatory authorities. Available from: https://www.reginfo.com/other/asia/. Accessed on 08 Feb 2020.
27. ASEAN common technical dossier. Available from: https://asean.org/storage/2017/03/68.-December-2016-ACTD.pdf. Accessed on 07 March 2020.
28. Chakraborty S, eCTD submissions. Available from: https://www.slideshare.net/saikatck/ectd-submissions. Accessed on 06 March 2020.

Sk. Shaheen, R. Venkidesh, N. Audinarayana, and D. Jothieswari, "Drug Registration and Regulatory Approval Procedure in India," *International Research Journal of Pharmacy and Medical Sciences (IRJPMS)*, Volume 8, Issue 1, pp. 43-49, 2024.