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REGULATORY REQUIREMENTS FOR DOSSIER SUBMISSION IN INDIA AS PER CDSCO IN COMPARISION WITH SRILANKA

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ABSTRACT

Drug Regulatory Authority is defined as an authority or a government body appointed by the government to administer the granting of marketing authorization/approval of pharmaceutical products and biologicals in a country. It is also called as the Licensing Authority or Marketing Authority. The Drug Regulatory Authority of India is the Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare (MOHFW). Pharmaceutical Dossier of India is the major document required for the process of marketing approval of the pharmaceutical products and biologicals in India. Its content and format follow the Common Technical Document (CTD) as set out by the International Conference on Harmonization (ICH). The CTD of India is organized into 5 Modules. The information required under each module is suitably detailed in this article.

KEYWORDS: CDSCO, CTD, India, Pharmaceutical Dossier, Pharmaceutical product, Module.

INTRODUCTION

Many new pharmaceutical products have flourished and trade in the pharmaceutical industry has taken on an international domain. At the same time, however, the circulation of adulterated, substandard and counterfeit drugs on the national and international market has increased. Therefore, there is a strong need for improvement in the approval process of a new drug, demonstration of its safety, efficacy and quality before it could be approved for commercialization in the market. All these problems can be tackled effectively only by establishing an effective drug regulatory system. Drug Regulation is defined as the totality of all the measures - legal administrative and technical which the Government takes to ensure the safety, efficacy, and quality of drugs, as well as the relevance and accuracy of product information.[1] The development, production, importation, exportation, distribution and registration/approval of the drugs must be regulated via a proper channel to ensure that they meet the required prescribed standards.

MATERIALS AND METHODS

1. Covering letter:

A formal letter introducing the submission.

2. Application Form:

Completed application form as per CDSCO guidelines.

3. Pharmaceutical documentation:

Drug Master File (DMF), if applicable.
Information on the manufacturing process.
Analytical data on the product.
Stability data.
Batch records.
Quality control testing methods and results.
Details of packaging materials.

4. Clinical data:

Clinical trial protocols and results.
Investigator's brochure.
Pharmacovigilance data.

5. Non clinical data:

Pre-clinical studies data.
Toxicology reports.
Animal pharmacology data.

6. Regulatory document:

Certificates of pharmaceutical product (CPP)
GMP certificate.
Drug approval from the country of origin, if applicable.

7. Legal documents:

Power of Attorney.
Declaration of the applicant.
Authorization for the regulatory agent.

8. User Fee:

Pay the prescribed user Fee.

9. Other relevant documents:

Any additional documents required by CDSCO based on the specific product.

- Submitting a dossier for (e.g., New Drug, Generic Drug, Medical Device) and ensure that you have the appropriate application form.

- ❖ Collect Documentation: Gather all necessary documents and data required for your submission. This typically includes,
- o Administrative Documents,
- ❖ Application form.
- ❖ Cover letter summarizing the submission.
- ❖ Letter of Authorization if the applicant is not the manufacturer.
- o Common Technical Document (CTD): Organize your dossier according to the CTD format, which typically includes Modules 1 through 5.
- ❖ Module 1: Administrative information.
- ❖ Module 2: Quality overall summary, nonclinical study reports, clinical study reports.
- ❖ Module 3: Pharmaceutical quality data (CMC data).
- ❖ Module 4: Nonclinical study reports.
- ❖ Module 5: Clinical study reports.
- o Module 6: Literature references.
- o Module 7: Other documents, which may include stability data, bioequivalence or bioavailability studies, risk management plans, etc.
- o Module 8: Product information, including labelling, packaging, and patient information leaflets.
- o Module 9: Regulatory status in other countries (if applicable).
- ❖ Compile Quality Data:
- ❖ For pharmaceutical products, ensure that you have comprehensive chemistry, manufacturing, and controls (CMC) data, including information on the drug substance, drug product, and associated materials.
- ❖ Compile Nonclinical Data.
- ❖ Gather data from pharmacology, toxicology, and other nonclinical studies. Ensure that these studies comply with Good Laboratory Practices (GLP).
- ❖ Compile Clinical Data.
- ❖ Collect detailed information on the clinical trials conducted to establish the safety and efficacy of the product. Include data on study design, patient populations, adverse events, and statistical analyses.
- ❖ Literature References.
- ❖ List references related to the product, including published articles, reports, and other relevant literature.
- ❖ Product Information.
- ❖ Prepare comprehensive labelling, packaging, and patient information leaflets for your product.
- ❖ Regulatory Status in Other Countries.
- ❖ Provide information about the regulatory status of the product in other countries, including approvals, rejections, or ongoing applications.
- ❖ Electronic Submission.
- ❖ Submit the dossier electronically in the prescribed format specified by the CDSCO. Ensure that all files are in the required format, typically in PDF or electronic Common Technical Document (eCTD) format.
- ❖ Payment of Fees.
- ❖ Ensure that all required fees are paid as per the CDSCO's fee schedule.
- ❖ Declaration of Commitment.
- ❖ Include a declaration of commitment to comply with all regulatory requirements.
- ❖ Submit the Dossier.
- ❖ Follow the CDSCO's specific submission process, which may involve online submission portals or physical submission, depending on their current guidelines.
- ❖ Follow-Up and Communication.
- ❖ Stay in contact with the CDSCO throughout the review process. Be prepared to respond to any queries or requests for additional information.

RESULTS AND DISCUSSIONS

- ✓ Determine the Type of Dossier: Understand the type of product you are submitting a dossier for (e.g., New Drug, Generic Drug, Medical Device) and ensure that you have the appropriate application form.
- ✓ Collect Documentation: Gather all necessary documents and data required for your submission. This typically includes.
- o Administrative Documents.
- ✓ Application form.
- ✓ Cover letter summarizing the submission.
- ✓ Letter of Authorization if the applicant is not the manufacturer.
- o Common Technical Document (CTD): Organize your dossier according to the CTD format, which typically includes Modules 1 through 5:
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COMPARISION OF DOSSIER SUBMISSION BETWEEN INDIA AND SRILANKA

	Dossier submission India	Dossier submission Sri Lanka
Authority	CDSCO	NMRA
CTD Modules	5 modules to be submitted	5 modules to be submitted
Applicant part	The drug regulatory agencies have established a proper content and format for filing of dossiers by the drug applicant	Indicate clearly weather the drug substance is purchased based on specification with a certificate of analysis/tested by applicant
Requirements	Includes detailed information on drug quality, safety, efficacy, clinical trail data, pharmacology, toxicology, and other relevant data	Include information on product quality, safety, efficacy, clinical data and manufacturing practices
Filing	PDs, CTD, eCTD	eCTD
Review time	The review time for dossier submission in India can vary depending on the specific regulatory authority, type of submission, and the complexity of the application	The review time for dossier submission in Sri Lanka vary depending on the specific regulatory authority, and also type of submission
Pharmacopoeia	Indian Pharmacopoeia	British Pharmacopoeia
Reference standard	Indian Pharmacopoeia Common Technical Document	The National Medicines Regulatory Authority (NMRA)

CONCLUSION

- ➢ The Common Technical Document (CTD) format is the reference standard for dossier submission in India as per the Central Drugs Standard Control Organization (CDSCO) guidelines.
- ➢ The CDSCO has published guidelines on the CTD format, which include requirements for submission methodology, labelling of documents, and the number of copies to be submitted.
- ➢ The CDSCO requires the submission of one hard copy and three soft copies of the dossier in PDF format on a Compact Disc (CD).
- ➢ The CDSCO also requires the submission of a Form 40 for the registration certificate and issuing license for the import of drugs into India.
- ➢ The CDSCO has introduced an online portal called SUGAM, which enables submissions, reviews, and permission or Notice of Compliance (NOC) granting through fast electronic servicing.
- ➢ If the CDSCO is satisfied with the regulatory documents, it will issue an approval letter, which is valid for three years

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