INDIAN REGULATORY REQUIREMENTS

CONTENTS

INTRODUCTION- CDSCO is the main regulatory body of India for regulation of pharmaceutical medical devices & clinical trials.

CDSCO is the central drug authority for discharging function assigned to the central government under D&C act. Head office of CDSCO is in New Delhi & it is functioning under the control of Directorate of General of Health Services, Ministry of Health & Family Welfare, Government of India.

ORGANIZATION OF CDSCO

Vision-To protect & promote health in India.

Mission- To safeguard & enhance the public health by assuring the safety, efficacy & quality.

Ministry of Health

CDSCO

Drug Controller General of India

Deputy Drugs Co (India)

Assistant Drug Controller (India)

Medical Device division Diagnostic division

Drug Inspectors Technical Data Associate Drug Inspectors Technical Data Associate

Fig-1 Organization of CDSCO

ORGANISATION CHART-

Drugs Controller General (I)
(Dr. V. G. Somani)

Head Quarter	Zonal Offices (6)	Sub-Zonal Offices (7)	Port/Air Port Offices (13)	Laboratories (7)
New Delhi	North Zone-Ghaziabad	Bangalore	Ahmedabad	CDL Kolkata
	South Zone-Chennai	Varanasi	Chennai Port	CDTL Mumbai
	West Zone-Mumbai	Goa	Chennai Air Port	RDTL Guwahati
	East Zone-Kolkata	Jammu	Bangalore	RDTL Chandigarh
	Hyderabad Zone	Indore	Hyderabad	CDL Kasauli
	Ahmedabad Zone	Guwahati	Goa	CDTL Hyderabad
		Baddi	Kochi	CDTL Chennai
			Delhi	*IVRI Izatnagar
			Kolkata Port	*NIB Noida
			Kolkata Air Cargo	*IPC Gaziabad
			Mumbai Air Cargo	
			Mumbai Nhava Sheva	
			Mumbai Custom House	

Fig-2 Organization chart

1.Zonal Officer-These are involved in GMP audit & inspection of manufacturing unit of large volume parenteral, sera, vaccine & blood products.

I.	Mumbai	II.	Ahmedabad
III.	Kolkata	IV.	Hyderabad
V.	Chennai	VI.	Ghaziabad

2. Sub-zonal officer- These center co-ordinate with state drug control authorities under their jurisdiction for uniform standard of inspection.

I. Chandigarh II. Jammu III. Bangalore

3.Port-Airport office- The CDSCO is the central drug authority for discharging function assigned to the central government under D & C act.

I.	Delhi	II.	Mumbai port
III.	Chennai	IV.	Cochin port
V.	Indore port	VI.	Vishakhapatnam seaport
VII.	Kolkata port	VIII.	Krishanampattanam seaport

4. Laboratories- The function of the laboratory includes – Analysis of drugs & pharmaceuticals, cosmetics & medical devices manufactured in the country. Analysis of import drugs & cosmetic samples entering through the port offices of CDSCO.

I.	CDL (Kolkata)	II.	CDTL (Chennai)
III.	CDL (Kasauli)	IV.	RDTL (Chandigarh)
V.	CDTL (Mumbai)	VI.	RDTL (Guwahati)
VII.	CDTL (Hyderabad)		

FUNCTIONS OF CDSCO

- Approval of new drug & clinical trials
- Import registration & licensing
- License approving of blood banks, LVPs, vaccines, r-DNA products & some medical devices
- Amendment to D & C act & rules
- Banning of drugs & cosmetics
- Grant of test license , personal license, NOCs for export
- Testing of New drug

STATE LICENSING AUTHORITY SLAs

Functions -

- Licensing of manufacturing site for drug including API & finished product
- It gives approval of drug testing laboratory
- Monitoring of quality of drug & cosmetic; marketed in the country
- Licensing of establishment for sale or distribution of drug
- Pre- & post- licensing inspection
- Recall of sub-standard drugs

CENTRAL LICENSING AUTHORITY

Functions –

- Approval of new drug & clinical trials
- Banning of drug
- Grant of test licensing, personal license
- Import registration, licensing & approving of blood banks, vaccines, medical devices
- Testing of drugs by central lab

RESPONSIBILITIES OF STATE AUTHORITY

- Manufacturing, sales, distribution of drugs licensing drug testing laboratories
- Manufacturing, sales, distribution of drugs licensing drug testing laboratories
- Approving drug formulation for manufacture
- Carrying out pre & post licensing inspection

RESPONSIBILITIES OF CENTRAL AUTHORITY-

- Approval of new drugs
- Control over the quality of imported drugs
- Co-ordination of the activities of state drug
- Laying down the standard for drugs

JOINT RESPONSIBILITIES OF CDSCO & SLAs

- Licensing of Specialized Product

✓ Vaccine & Sera, Blood & It's Component, LVP's, rDNA Products, Medical Devices

Certificate of pharmaceutical product (COPP)

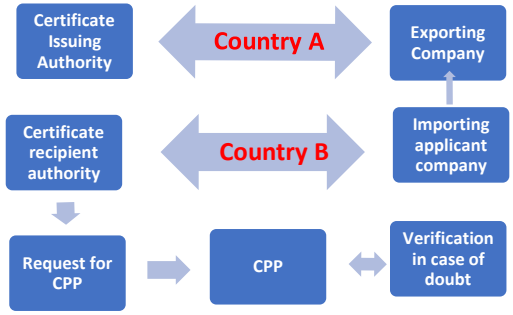

Fig 3-COPP

REGULATORY REQUIREMENTS

Requirements for permission of new drug approval

The manufacturing has to submit application on form 44 for permission of new drug approval under provision of D&C act 1945 & rules.

There are 5 modules of CTD

Module- I Administration /Legal information

✓ Contain document specific to each region

✓ Example-Application form or proposed label for region

Module-II Summaries

✓ General introduction to pharmaceutical in that pharmacological class, mode of action & clinical use

✓ Introduction should include propriety name, non-proprietary name of drug substance, company name, dosage form, strength, route of administration

✓ CTD summaries for quality, safety and efficacy

✓ Very short introduction of quality overall summary, non-clinical overview, clinical overview, non-clinical written and tabulated summaries for pharmacology, pharmacokinetics and toxicology

Module – III Quality information (Chemical, Pharmaceutical & Biological)

✓ Information of quality in structure format

✓ Documents provide guidance on format of registration application

✓ Contain all quality document for chemistry manufacture and control of substance and the drug product

Module IV – Non-clinical information

✓ Information on safety in structure format

✓ Section is present in analysis of non-clinical data pertinent to safety

- ✓ Analysis considers all relevant data either positive or negative
- ✓ Final copy of all final non-clinical study report

Module V – Clinical information

- ✓ Information of efficacy in structure format
- ✓ Clinical summary i.e Biopharmaceutics, PK and PD , clinical pharmacological studies, clinical efficacy, clinical safety, synopsis of individual studies and final copy of detail clinical study report

APPROVAL PROCEDURE FOR NEW DRUG

Definition of new drug- Drug that has not been declared safe, effective by qualified expert under the condition prescribed, recommended, or suggested in the label & that may be new chemical formula or an established drug prescribed for use in new way.

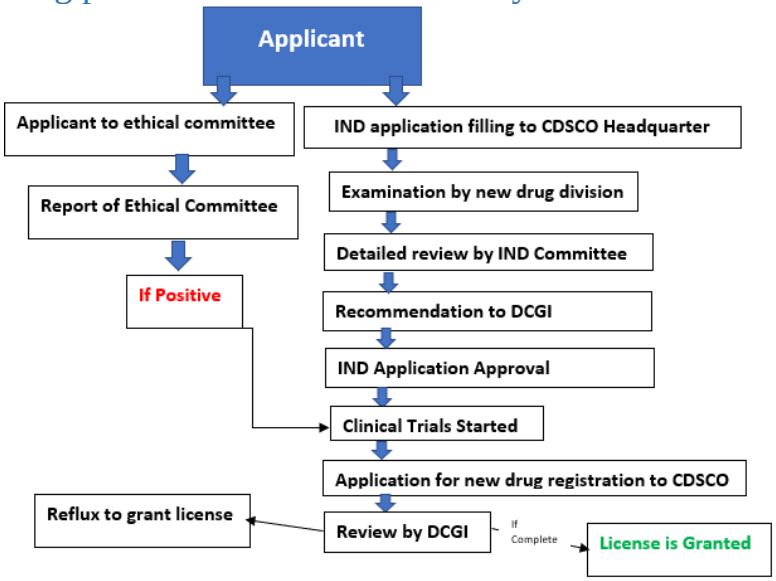

Fig-4 Approval procedure of new drug

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