INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Paper

CDSCO: pharmaceutical regulatory authority of India

Abhishek Deshmukh*, Tejas Sharma, Dr. Shivshankar Mhaske, Krushna Tayade, kasim Bhuriwale

Satyajeet College of Pharmacy, Mehkar, Dist- Buldana, Maharashtra

ARTICLE INFO

Published: 02 Feb. 2025
Keywords:
CDSCO, Responsibilities of DCGI, Drug approval process, Clinical trials
DOI:
10.5281/zenodo.14789469

ABSTRACT

Central Drug Standard Control Organization is Regulatory Authority in India. CDSCO Is responsible for conducting Clinical trials for new drug and provide approval to the New drug. CDSCO also monitors the Rules and Regulation regarding various medicinal Practices in India. Functions of CDSCO include ensuring the quality of drugs, Medical Devices and cosmetics sold in the country, approval of new drugs and regulating clinical Trials

INTRODUCTION

The Central drug standard control Organisation (CDSCO) of india is main regulatory body for regulation of pharmaceutical drug, medical Device and clinical trials.

The main head office of CDSCO is located in new Delhi and functioning under the control of Directorate General of Health services, ministry of health and family welfare government of india.

Drugs Controller General of India (DCGI)

- He is a responsible for approval of New Drugs, Medical devices and Clinical Trails to be Conducted in India.
- He is appointed by the central government under the DCGI the State drug control organization Will be functioning.
- The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).

The DCGI is responsible for handling matters of product approval and approval standards, Clinical trials, introduction of new drugs, and import licenses for new drugs. A drug may be Licensed for manufacturing in a state only once it has been approved by CDSCO. Drugs Controller General of India (DCGI) is the Head of department of the Central Drugs Standard. Control Organization of the Government of India Responsible for approval

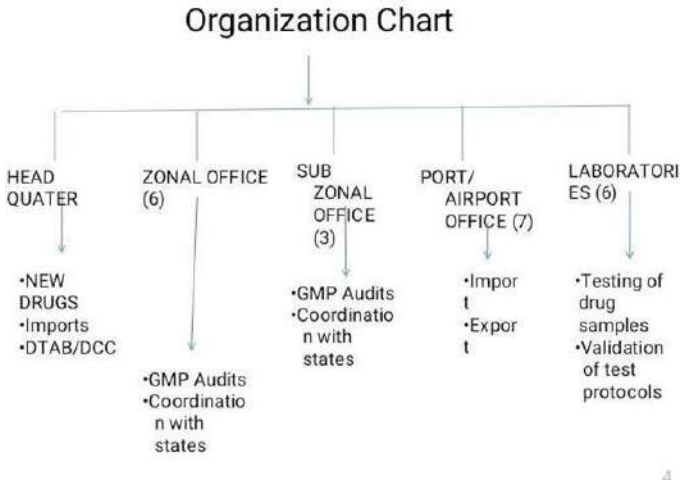
***Corresponding Author:** Abhishek Deshmukh
Address: *Satyajeet College of Pharmacy, Mehkar, Dist- Buldana, Maharashtra*
Email ✉: abhishekdeshmukh8010@gmail.com
Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

of licences of specified Categories of drugs such as blood and blood Products, IV fluids, vaccines, and sera in India. Drugs Controller General of India, comes under The Ministry of Health & Family Welfare. DCGI Also sets standards for manufacturing, sales, Import, and distribution of drugs in India. The Government on 14 August 2019 appointed Dr. VG Somani as Drug Controller General of India (DCGI). Dr. VG Somani unceded S Eswara Reddy, the interim DCGI who was appointed in February 2018. DCGI heads the Indian drug Regulatory body the Central Drugs Standard. Control Organisation (CDSCO), whose functions Include ensuring the quality of drugs and Cosmetics sold in the country, approval of new Drugs and regulating clinical trials. With the Notification of Medical Device Rules 2017 by the Government of India, DCGI will also act as Central Licensing Authority (CLA) for the Medical devices which fall under the purview of These rules. Out of four Classes of medical devices From Class A to Class D, DCGI will be the direct Licensing authority for Class C and Class D Devices, whereas it will coordinate licensing for Class A and B devices through State drug Controllers, who will act as State Licensing Authority .

Responsibilities of DCGI:

- DCGI lay down the standard and quality of Manufacturing, selling, import and Distribution of drugs in India.
- Acting as appellate authority in case of any Dispute regarding the quality of drugs.
- Preparation and maintenance of national Reference standard.
- To bring about the uniformity in the Enforcement of the Drugs and Cosmetics Act.
- Training of Drug Analysts deputed by State Drug Control Laboratories and other Institution
- Analysis of Cosmetics received as survey Samples from CDSCO (central drug standard Control organization).

Structure of CDSCO:



Zonal office:

Total zonal office of CDSCO are 6 in India which are located in different state of India

Mumbai

Kolkata

Chennai

Ghaziabad

Ahmedabad

Hyderabad

Mumbai, Kolkata, Chennai, Ghaziabad, Ahmadabad, Hyderabad. These centres are Involved in GMP audits and inspection of Manufacturing units of large volume, parental, Sera, vaccines and blood products.

Sub Zonal office:

Sub Zonal office are 3 in India which are located in 3 different regions of India
Chandigarh
Jammu
Bangalore
Chandigarh, Jammu, Bangalore. These centres are coordinated with state drug Control authorities under their jurisdiction for Uniform standard of inspectiont.

Central Drugs Testing Laboratories :

- Central Drug Laboratory, Kolkata
- Central Drug Testing Laboratory, Mumbai
- Central Drug Testing Laboratory, Chennai
- Central Drug Laboratory, Kasauli
- Regional Drug Testing Laboratory, Guwahati
- Regional Drug Testing Laboratory, Chandigarh

These laboratories are established under the Indian Drug and Cosmetic Act, 1940 and Responsible for quality control of drugs and cosmetics in the country.

Central Licensing Authority:

- Approval of new drugs and clinical trials.
- Import Registration and Licensing
- Licensing of Blood Banks, LVPs, Vaccines, r-DNA products and some Medical devices and Diagnostic agents.
- Amendment to D&C Act and Rules.
- Participation in WHO GMP certification Schemes.
- Banning of drugs and cosmetics.
- Grant to test license, personal license, NOC's For export.
- Testing of drugs by Central Labs.
- Publication of Indian Pharmacopoeia.
- Monitoring adverse drug reactions.
- Guidance on Technical matters

Function:

- Laying down standards of drugs, cosmetics, Diagnostics and devices.
- Laying down regulatory measures, Amendments to Acts and Rules.
- To grant marketing authorization of new Drugs.
- To regulate clinical trials in India.
- To approve licenses to manufacture certain Categories of drugs as Central LicenseApproving Authority
  i.e. for Blood Banks, Medical Devices, r-DNA drugs, Large Volume Parenteral and Vaccines & Sera.
- To regulate the standards of imported drugs
- Work relating to the Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC).
- Pharmacovigilance program of India.
- Coordinating activities of the State Drugs Control Organizations to achieve uniform Administration of the Act and providing policy Guidance.

State Licensing Authority:

State Licensing Authority means the Authority Created for the Purpose of regulating and Controlling the license of cultivation, Manufacture, Distribution and sale of medical marijuana in this State.

Function:

- Investigation and prosecution in respect of Contravention in respect of contravention of Legal provisions.
- Licensing of drug testing laboratories.
- Approval of drug formulation for Manufacture.
- Monitoring of quality of Drugs and cosmetics, Manufactured by respective state and those Marketed in the state.
- Investigation and prosecution in respect of Contravention in respect of contravention of Legal provisions.
- Administrative actions.
- Pre- and post- licensing inspection.

- Recall of sub-standard drugs

Drug Approval Process:

Approval of new drug in India

When a company in India wants to manufacture/ Import a new drug it has to apply to seek Permission from the licensing authority (DCGI) by Filing in Form 44 also submitting the data as given In Schedule Y of Drugs and Cosmetics Act 1940 And Rules 1945. In order to prove its efficacy and Safety in Indian population it has to conduct Clinical trials in accordance with the guidelines Specified in Schedule Y and submit the report of Such clinical trials in specified format. [10-16] But A provision is there in Rule- 122A of Drugs and Cosmetics Act 1940 and Rules 1945 that the Licensing authority may waive certain trails if he Considers that in the interest of public health he May grant permission for import of new drugs Basing on the data of the trials done in other Countries. Similarly, there is another provision in Rule – 122A which says that the clinical trials may Be waived in the case of new drugs which are Approved and being used for several years in other Countries. Section 2.4 (a) of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says for Those drug substances which are discovered in India all phases of clinical trials are required. Section 2.4 (b) of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 says that for Those drug substances which are discovered in Countries other than India; the applicant should Submit the data available from other countries and The licensing authority may require him to repeat All the studies or permit him to proceed from Phase III clinical trials. Section 2.8 of Schedule Y of Drugs and Cosmetics Act 1940 and Rules 1945 Says that the licensing authority may require Pharmacokinetic studies (Bioequivalence studies) First to show that the data generated in Indian Population is equal to data generated abroad and Then require him to proceed with Phase III trials. In summary, the exact requirements of Clinical Trials may change from case to case and depend on the extent to which licensing authority is satisfied About its safety and efficacy. Most countries have Adopted the Common Technical Document (CTD) Format. Hence, CDSCO has also decided to adopt CTD format for technical requirements for Registration of pharmaceutical products for human Use. New Drug Application (NDA) :- NDA is an Application submitted to the FDA for permission To market a new drug. To obtain this permission a Sponsor submits preclinical and clinical test data to NDA for analyzing the drug information, Description of manufacturing procedures. After NDA received by the agency, it undergoes a Technical screening. This evaluation ensures that Sufficient data and information have been Submitted in each area to justify "filing" the Application that is FDA formal review. At the Conclusion of FDA review of an NDA, there are 3 Possible actions that can send to sponsor: Not Approvable- in this letter list of deficiencies and Explain the reason. Approvable – it means that the Drug can be approved but minor deficiencies that Can be corrected like-labelling changes and Possible request commitment to do postapproval Studies. Approval- it state that the drug is Approved

Clinical Trial Process:

Schedule Y of drugs and cosmetics act explain the Guideline for grant of permission for conducting Clinical trials in India. The protocol for such trials Are examined by the office of DCGI before the Permission are granted. Office of DCGI also grants Permission for conducting bioequivalence studies.

- Registration of clinical trials has been made Mandatory with centralized clinical trial Registry of ICMR with effect from 15th 2009.
- Drug and Cosmetic rules are being amended To make mandatory the registration of clinical Research organizations.

- Drug and Cosmetic act is proposed to be Amended to include a separate chapter on Clinical trials.[17]

Approval for Clinical Trials:

1. Approval for clinical trials and application to Conduct clinical trials in India shouldbe be Submitted along with the date of chemistry, Manufacturing, control and animal studies to DCGI.
2. The data regarding the trail protocol Investigators brochures and informed consent Documents should also be attached.
3. A copy of the application must be submitted To the ethical committee and the clinical trials Are conducted only the after approval of DCGI And ethical committee.

Approval of Clinical trials, Import and Manufacture of New Drugs:

Requirements and Guidelines:

Schedule Y

Rule 122A – Permission to import new drug.

Rule 112B – Permission to manufacture new Drug.

Rule 122DA – Definition of clinical trials.

Rule 122E – Definition of new Drugs.

1. New substance having therapeutic Indication.
2. Modified on new claims, new route of Administration for already approved drug.
3. Fixed dose combination

Medical Devices:

Definition of "Medical Devices" According to the Definition Notification as Notified in the Gazette Notification on February 11, 2020, the Ministry amended the definition of "medical devices" under Section 3(b)(iv) of the Drugs and Cosmetics Act, 2020 as follows: All devices including an instrument, apparatus, Appliance, implant, material or other article, Whether used alone or in combination, including a Software or an accessory, intended by its Manufacturer to be used specially for human Beings or animals which does not achieve the Primary intended action in or on human body or Animals by any pharmacological or immunological Or metabolic means, but which may assist in its Intended function by such means for one or more Of the specific purposes of —

a. Diagnosis, prevention, monitoring, Treatment or alleviation of any disease or Disorder;
b. Diagnosis, monitoring, treatment, Alleviation or assistance for, any injury or Disability;
c. Investigation, replacement or modification Or support of the anatomy or of a Physiological process;Supporting or sustaining life; Disinfection of medical devices;
d. Control of conception

CONCLUSION:

The clinical studies reports and related information For process of approval of new drug in India with Emphasis on clinical trials should follow the Schedule Y, the Drug and Cosmetics Rules 1945 Rules given by the CDSCO. From the above review It can be concluded that, all clinical studies reports And related information regarding the approval of New drug in India should provide the necessary Requirements along with the NDA to FDA

REFERENCES

1. Introduction of CDSCO [Last Accessed on 2024 Feb 8] https://cdsco.gov.in/opencms/opencms/en/Home/
2. Central Drugs Control Organization [Last Accessed on 2021 JAN 1] https://en.m.wikipedia.org/wiki/Central_Drugs_Standard_Control_Organisation
3. Government of India Ministry of Health & Family Welfare central drugs standard control Organization Induction Programme For Assistant Drugs Inspectors Oct 05, 2015 to Dec 31, 2015 Page No. 2 Objective & Function
4. Drug Controller General of India [Last Accessed on 2021 JAN 2] https://en.m.wikipedia.org/wiki/Drugs_Controller_General_of_India

5. Medical Devices – A Perspective & Medical Devices (Amendment) Rules, 2020 https://taxguru.in/corporate-law/medical-devices-perspective-medical-devices-amendment- rules2020.html Medical Devices
6. Central and State Regulatory Bodies in India By Sonali Phadke https://www.slideshare.net/sonaliph/central-and-state-regulatory-bodies Dcgi
7. The New Drug Approval Process. Available At http://www.fda.gov/cder/handbook. Accessed on Dec 19, 2020.
8. Clinical Trial & Global Clinical Trial. Available at http://cdsco.nic.in/clinical_trial.htm Accessed on Dec, 2020.
9. https://cdsco.gov.in/opencms/opencms/en/About-us/Laboratories/
10. https://cdsco.gov.in/opencms/opencms/en/Zonal-office/

HOW TO CITE: Abhishek Deshmukh*, Tejas Sharma, Dr. Shivshankar Mhaske, Krushna Tayade, kasim Bhuriwale, CDSCO: pharmaceutical regulatory authority of India, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 2, 101-106. https://doi.org/10.5281/zenodo.14789469