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Review Article

Indian Pharmaceutical Regulatory Authority: Review

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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 Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country. The Drugs & Cosmetics Act,1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics. It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well being of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics

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Act. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera.[1] The CDSCO has a good track record with the World Health Organization, it has also been accused of past collusion with independent medical experts and pharmaceutical companies. CDSCO plans to open an international office in Beijing, China. [2]

OBJECTIVE

- To upgrade knowledge of regulators and to increase consumer awareness.
- To interact and cooperate with the State, Central Government, Union Territories and non-governmental voluntary organizations with a view to improve the quality of healthcare facilities.
- To inculcate a sense of dedication amongst regulators, assist them to improve their professional excellence, to improve their effectiveness enabling them to serve and safeguard the interest of the consumers.
- To promote and advance, in the interest of public, the art of science and pharmaceutical technology and to develop highest standards for pharmaceutical and Medical Devices industry products with the use of technology.
- To offer better services to the public.
- To foster a science based, predictable and consistent regulatory framework to support and promote Research and Development in the country. [3]

Functions

- 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 License Approving 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.
- Guidance on technical matters\Participation in the

WHO GMP certification scheme.

- Monitoring adverse drug reactions (ADR).
- Conducting training programs for regulatory officials and Government Analysts.
- To ensure that no New Drug is imported into the country unless its import permitted by the Drugs Licensing Authority under Rules (Rules 122 A & 30-AA).
- To ensure that small quantities of drugs imported for Test, Examination and Analysis or clinical trials or for personal use are duly covered by Test License (11 or 11-A) or Permit License as (12 B) as the case may be.
- Maintenance of Statistics data regarding imports/export of all Drugs/cosmetics/medical devices and submit the same on monthly basis to the Deputy

Drugs Controller (India) of the respective zones and to other authorities as and when required.

- Co-ordination with the Commissioner of Customs – The Port Officers should have enough knowledge of the relevant portions for Customs Act and DGFT policies.
- Import of raw materials under Advance Licenses/100% EOU cases must be intimated

to the concerned State Drugs Controller to examine proper post-import check with a copy marked to the DDC(I) of the concerned Zone.

- Assist members of the trade with the information required.
- Preparation and forwarding of Quarterly and Annual Reports.
- Examination of post parcels couriers for import and export of drugs, cosmetics and medical devices.
- Coordination with the customs and other investigating agencies for the matters of violation of import/export under intimation to the DDC (I) of the concerned zone.
- To examine the re-import/re-export consignment as per the procedures.
- To draw samples from import/export and re-import consignment as per laid down procedures.
- To examine unclaimed/seized cargo when referred by customs and offer opinion as per procedure laid down.
- In case of drugs and cosmetics of not of standard quality/spurious, to be informed to all the port offices directly with a copy marked to the Deputy Drugs controller of the concerned zone.[3]

DCGI

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 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 or SLA.[4]

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).[9]

Organization Chart:

Zonal Office:

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.

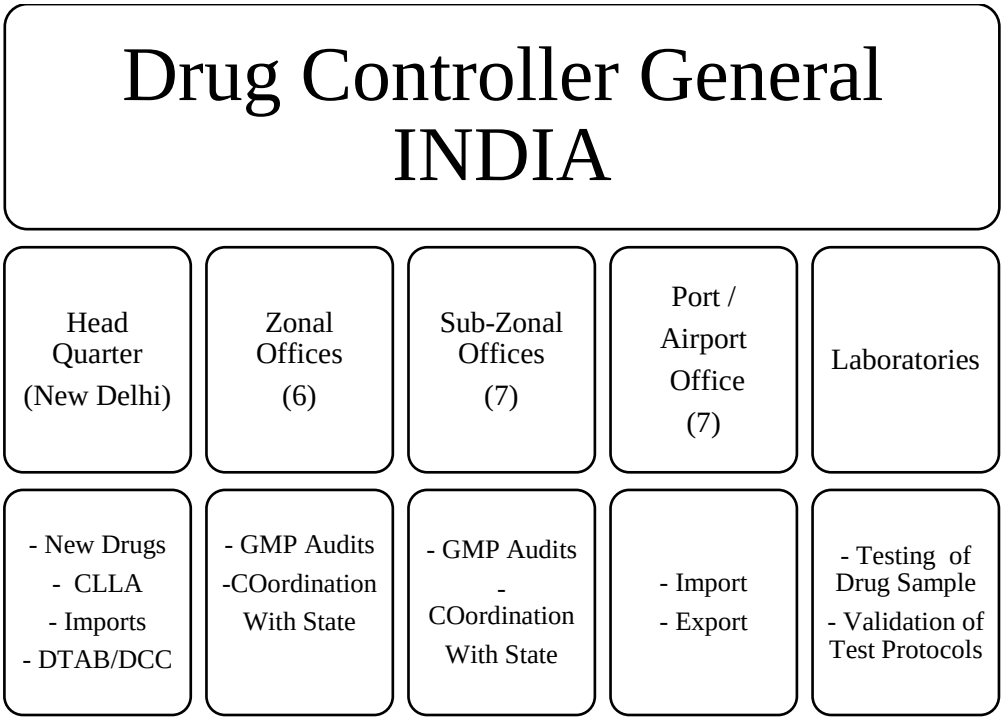
Sub-zonal Office:

Chandigarh, Jammu, Bangalore.

These centres are coordinated with state drug control authorities under their jurisdiction for uniform standard of inspection and enforcement.

Central Drugs Testing Laboratories:

1. Central Drugs Laboratory, Kolkata.
2. Central Drugs Testing Laboratory, Mumbai.
3. Central Drugs Testing Laboratory, Chennai.
4. Central Drugs Laboratory, Kasauli..
5. Regional Drugs Testing Laboratory, Guwahati.
6. Regional Drugs Testing Laboratory, Chandigarh.[17]



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.[8,9]

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[8,9]

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 post-approval studies. Approval- it state that the drug is approved. [10-16]

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 [17].

Phases of Clinical Trials

Phase I or clinical pharmacology study:

Initial safety trials on a new medicine. An attempt is made to establish the dose range tolerated by volunteers for single and for multiple doses. Phase I trials are sometimes conducted in severely ill patients (e.g., in the field of cancer) or in less ill patients when pharmacokinetic issues are addressed (e.g. metabolism of a new antiepileptic medicine in stable epileptic patients whose microsomal liver enzymes have been induced by other antiepileptic medicines). Pharmacokinetic trials are usually considered Phase I trials regardless of when they are conducted during a medicine's development. [18-25]

Phase II or exploratory trials

Phase II a:

Pilot clinical trials to evaluate efficacy (and safety) in selected populations of patients with the disease or condition to be treated, diagnosed, or prevented. Objectives may focus on dose-response, type of patient, frequency of dosing, or numerous other characteristics of safety and efficacy.

Phase II b:

Well controlled trials to evaluate efficacy (and safety) in patients with the disease or condition to be treated, diagnosed, or prevented. These clinical trials usually represent the most rigorous demonstration of a medicine's efficacy. Sometimes referred to as pivotal trials. [11-13]

Phase III or confirmatory trials

Purpose is to obtain sufficient evidence about the efficacy and safety of the drug in a larger number of patients, generally in comparison with a standard drug and/or a placebo as appropriate. In this phase, the group is between 1000-3000 subjects. If the results are favourable, the data is presented to the licensing authorities for a commercial license to market the drug for use by the patient population for the specified and approved indication [12-14].

Phase IV trials or post-marketing phase

Studies or trials conducted after a medicine is marketed to provide additional details about the medicine's efficacy or safety profile. Different formulations, dosages, durations of treatment, medicine interactions, and other medicine comparisons may be evaluated. New age groups, races, and other types of patients can be studied. Detection and definition of previously unknown or inadequately quantified adverse reactions and related risk factors are an important aspect of many Phase IV studies. If a marketed medicine is to be evaluated for another (i.e., new) indication, then

those clinical trials are considered Phase II clinical trials. The term post-marketing surveillance is frequently used to describe those clinical studies in Phase IV (i.e., the period following marketing) that are primarily observational or non-experimental in nature, to distinguish them from well controlled Phase IV clinical trials or marketing studies. [18-25]

Cosmetics

The Ministry of Health and Family Welfare (MoHFW) has notified the Cosmetics Rules, 2020 under the Drugs and Cosmetics Act, 1940. This move is to streamline all functions and bring effective compliance in the cosmetic sector of India. The notification came to separately codify and update the rules relating to import, manufacture, labelling, sale, and distribution of cosmetics in India, which were earlier set out under the Drugs and Cosmetics Rules, 1945. The notification is as per section 12 and section 33 of the Drugs and Cosmetics (D&C) Act, 1940 (23 of 1940). These rules will apply to the cosmetic as defined in clause (aaa) of Section 3 of the D&C Act, 1940 (23 of 1940). Earlier, the Ministry had issued the draft rules and asked for comments and suggestions from the stakeholder. Finally, the Central Government notified the new Cosmetic Rules, 2020. [7]

Things to know about the new Cosmetics Rules, 2020

1. Form COS-2 : Import registration Certificate
2. Form COS-12 : Application for import or manufacturing of New Cosmetic
3. Form COS-4 : Application for importing cosmetics from manufacturer who already has Registration Certificate for said product
4. Form COS-4A : Registration Certificate for importing cosmetics from manufacturer who already has Registration Certificate for said product

The validity of the import registration certificate is 5 years. The validity of Form COS-4A is 3 years. Moreover, there are a total of 80 categories mentioned in the Fourth Schedule. According to 2020 Rules, "Actual manufacturer" concerning the import of cosmetics means a person who manufactures cosmetics at his manufacturing site in a country other than India approved by the National Regulatory Authority or any authority. The Central Licensing Authority may cancel or suspend the registration certificate for a period if the manufacturer or authorized agent or importer fails to comply with any of the Registration Certificate conditions as it thinks fit either wholly or in respect of some of the cosmetics to which it relates. Further, if the cosmetics are manufactured at more than one site, applicant must pay an additional 500 USD for each site where the products are actually being manufactured. [7]

Renewal of cosmetic import license

If there is the failure of payment of registration certificate retention fee on or before the due date, the registration certificate holder is liable to pay the registration certificate retention fee and a late fee. The late fee is calculated at the rate of two percent of the registration certificate retention fee for every month or part thereof within one hundred and eighty days. Otherwise non-payment of such fee during that period, the registration certificate shall be deemed to have been cancelled.

Change in constitution

Suppose there is a change in the constitution of a registration holder or overseas manufacturer after the grant of registration for grant of new registration within a time period of one hundred and eighty days from the change in rules and the existing registration shall be valid till such time. In that case, fresh registration is given, or the application is rejected by the Central Licensing Authority. In the Drugs and Cosmetics Rules, 1945 is amended as per Thirteenth Schedule of the 2020 Rules to the extent that the word cosmetics is

omitted from various provisions. In spite of the non-applicability of the Drugs and Cosmetics Rules, 1945, all issuance under the provisions of the Act and the 1945 rules including approvals, permissions, licenses and certificates in respect of cosmetics prior to commencement of the new 2020 cosmetic Rules, will be deemed valid for all purpose till its expiry or for a period of 18 months from the date of notification of the new rules, whichever is later, under the corresponding provisions of said rules. [7]

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;
d. Supporting or sustaining life;
e. Disinfection of medical devices; and
f. Control of conception. [7]

THE MEDICAL DEVICES (AMENDMENT) RULES, 2020

On February 11, 2020 the Ministry of Health and Family Welfare, after consultation with the Drugs Technical Advisory Board notified to amend the Medical Devices Rules, 2017 and specified that these rules may be called The Medical Devices (Amendment) Rules, 2020 and shall come into force on April 1, 2020. Chapter IIIA has been added in the Medical Devices Rules, 2017 which requires all devices notified under Section 3(b)(iv) of the Drugs and Cosmetics Act, except the devices notified under Schedule Eight of the rules, to be registered under the provisions of Chapter IIIA of the Rules, as per the newly added Rules 19A to 19F.

Key features of the Amendment

The Medical Devices as specified under the Amendment shall be voluntarily registered for a period of 18 months from 1 April, 2020 with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control Organisation. Thereafter, the registration shall be made mandatory.The manufacturer of a medical device shall be required to upload the information with regard to the details of the medical device for registration on the "Online System for Medical Devices" established by the Central Drugs Standard Control Organisation. Such as the details of the manufacturing entity of the device, the certificate of compliance with respect to ISO 13485 and the duly signed undertaking by the manufacturer stating that the information furnished is true and authentic. Those who import any medical device as per the amended Rules shall be required to furnish the basic details of the medical device as specified hereinabove, and in addition to the same shall be required to furnish the free sale certificate from country of origin and the details as specified in Rule 19D (2) (ii).

After uploading the aforementioned information on the "Online System for Medical Devices", the manufacturer is required to furnish the registration number on the label of the medical device. The Central Licensing Authority may verify the documents at any point of time and investigate quality or safety related failure or complaints. The procedure to be followed by the Central Licensing Authority in case the registrant fails to comply with any provision of these rules is also provided by in the amendment. A new list of Medical Devices has also been added in the form of an Annexure to the Rule 19A. [6]\

SUGAM Online licensing portal

An online licensing portal of Central Drugs Standard Control Organization (CDSCO) has been implemented on January 2016 and has been named "SUGAM" to file applications for various services like Application Submission, Processing and Grant of permission for quick delivery of services.[5]

SUGAM Portal allows the applicants to a following services :

1. Online Submission
2. Review
3. Grant of NOC/Permission

SUGAM Benefits:

1. Applicant can apply for licence under Import & Registration Division to CDSCO.
2. Track the status of submitted application.
3. Answer Back to the Raised Queries
4. Applicant can also upload essential documents for Registration, Import Licence and other related activities

Key Points:

1. The form should be filled by the Authorized Signatory or Responsible Person of the organization. After submitting the registration form, user will receive E-mail verification
2. Submit undertaking and address proof document in hard copy to CDSCO office.
3. After evaluation of the submitted documents only registration will be approved. Check your registered Email-id for all communications. [5]

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. Generally, the drug approval process comprised mainly the two steps, application to conduct clinical trial and application to the regulatory authority for marketing authorization of drug. The academic investigator needs to be up to speed in reading, understanding and applying regulations and work in tandem with the pharmaceutical industry for greater patient benefit.

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