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Pharmaceutical regulatory agencies

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Abstract
As the pharmaceutical businesses throughout the world become more competitive, regulatory agencies are being formed in a variety of nations around the world. Regulatory authorities and organizations play an important part in meeting the legal requirements of a country's drug development process. Pharmaceuticals are currently one of the most heavily regulated businesses in the world. The regulatory body guarantees that all legal and regulatory elements of a medicine are followed. Every nation has its own regulatory authority, which is in charge of enforcing laws and regulations as well as issuing guidelines to govern the drug discovery process, licensing, registration, manufacturing, marketing, and labelling of pharmaceutical goods. The few regulatory agencies and organizations established in respective countries include the USFDA (USA), MHRA (UK), TGA (Australia), CDSCO (India), health Canada (Canada), MCC (South Africa), ANVISA (Brazil), EMEA (European Union), SFDA (China), NAFDAC (Nigeria), MEDSAFE (New Zealand), MHLW (Japan), MCAZ (Zimbabwe), SWISSMEDIC (Some of the international regulatory agencies and organizations that play an important role in all aspects of pharmaceutical regulations include the World Health Organization (WHO), Pan American Health Organization (PAHO), World Trade Organization (WTO), International Conference on Harmonization (ICH), and World Intellectual Property Organization (WIPO). The key problems for these regulatory authorities and organizations worldwide are to assure the safety, quality, and efficacy of medicines and medical devices, to harmonize legislative procedures connected to drug development, and to monitor and ensure compliance with statutory requirements. They also play an important role in ensuring and increasing regulatory implementation in non-regulated areas of the world to protect the safety of those who live there. The current research provides a brief overview of key developed and developing nations' regulatory bodies, as well as the scope and problems of such regulatory organizations in medication development and the delivery of safe and effective healthcare goods to citizens worldwide.

Keywords: Pharmaceutical, Harmonization, SWISSMEDIC, WTO, WIPO

Introduction

Pharmaceutical regulation

Pharmaceutical Regulation is the combination of governmental legislative, administrative, and technical procedures used to guarantee the effectiveness, safety, and quality of the product. A wide range of pharmaceutical operations are governed by the intricate system of rules known as pharmaceutical regulation [1].

Several essential elements of pharmaceutical laws include –
It includes

- Control over pharmaceutical and clinical research.
- Control over the creation of novel medications or health supplements.
- Control over the production of medicinal items.
- Control of clinical trials.
- Controls on the distribution and packaging of pharmacological supplements.
- Regulation to preserve the effectiveness and quality of medications.

Effective regulation of drug requires a variety of functions

- Guaranteeing the safety, efficacy and quality of drugs.
- Licensing of premises, persons and practices.
- Inspection of manufacturing facilities and distribution channels.
- Product assessment and registration.
- Adverse drug reaction monitoring.
- Quality control.
- Control of drug promotion and advertising.
- Most importantly, the process of drug regulation.

The drug regulation consists of:
1. Drug Laws
2. Drug Regulatory Agencies
3. Drug Regulatory Boards
4. Quality Control
5. Drug Information Centres [2].

Regulatory affairs

Regulatory affairs is a branch of work that verifies that foods, medicines, and other products are developed, produced, and distributed in conformity with the regulatory standards for human consumption.

Regulatory affairs is a field of work which confirm that food, pharmaceuticals, and medical items are designed, tested, developed, produced, and distributed in accordance with regulatory requirements for human use, regulatory affairs is a field of work [3, 4, 5].

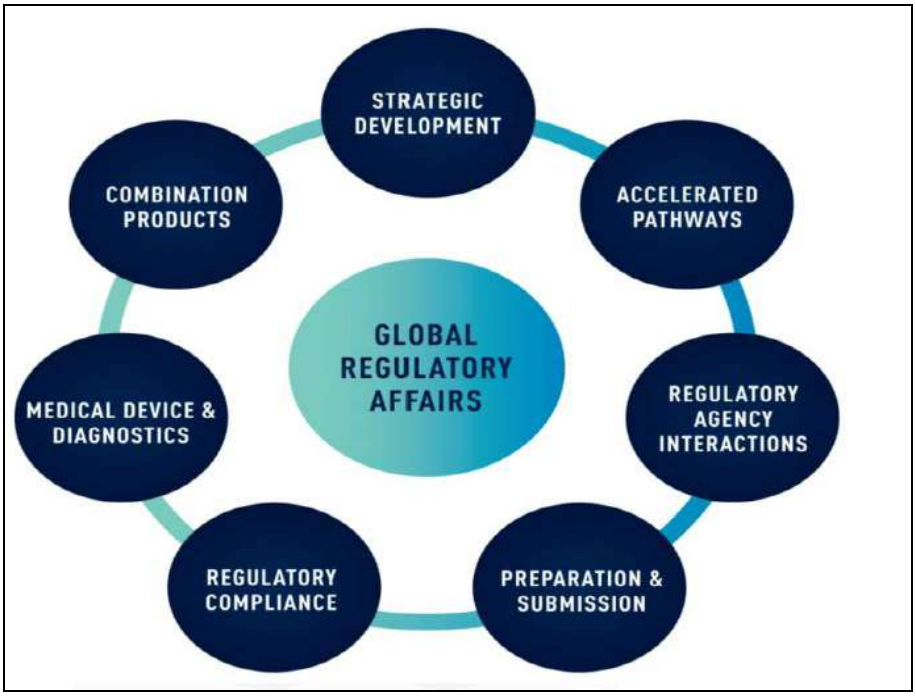

Fig 1: Global Regulatory Affairs [6]

2.1 Regulatory Affairs Focus Areas

Regulatory focus area shows the major points and fields where regulatory affairs are applicable to authorize and quality management of pharmaceutical products and supplements.

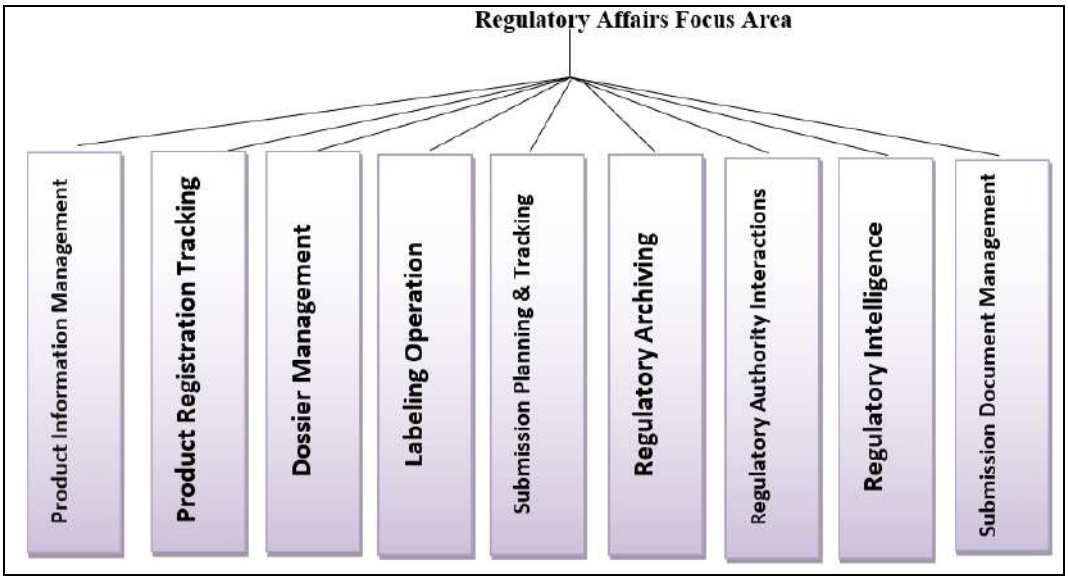

Fig 2: Regulatory Affairs Focus Area

Pharmaceutical regulatory agencies

Pharmaceutical regulatory Agencies are Regulatory bodies or authorities which have control over evolution, development, Improvement, preparation, manufacture, production, quality and efficacy management of any pharmaceutical supplements. There is no medicine products are entirely safe or effective under all conditions, but there is a moral and legal expectation that the proper measures be taken to assure the best possible quality, safety, and effectiveness. To speed up the development and delivery of safe and effective healthcare products to people all over the world, regulatory authorities administer strategic, tactic, operational, and practical data, direction, and support.

Regulatory organization grant various organizations, licenses and authorization to manufacture, develop, and deliver different pharmaceuticals. With the proper calibre, safety, and effectiveness of their impact on the intended ailment. This body of literature demonstrates how nations with various administrative traditions have adapted the regulatory agency institutional model and created new institutions that are more in line with their respective traditions. Regarding the participation of society and the bureaucratic independence of organizations [8].

Classification of Pharmaceutical regulatory agencies

Pharmaceutical Regulatory Agencies

On the basis of working territory and effectivity

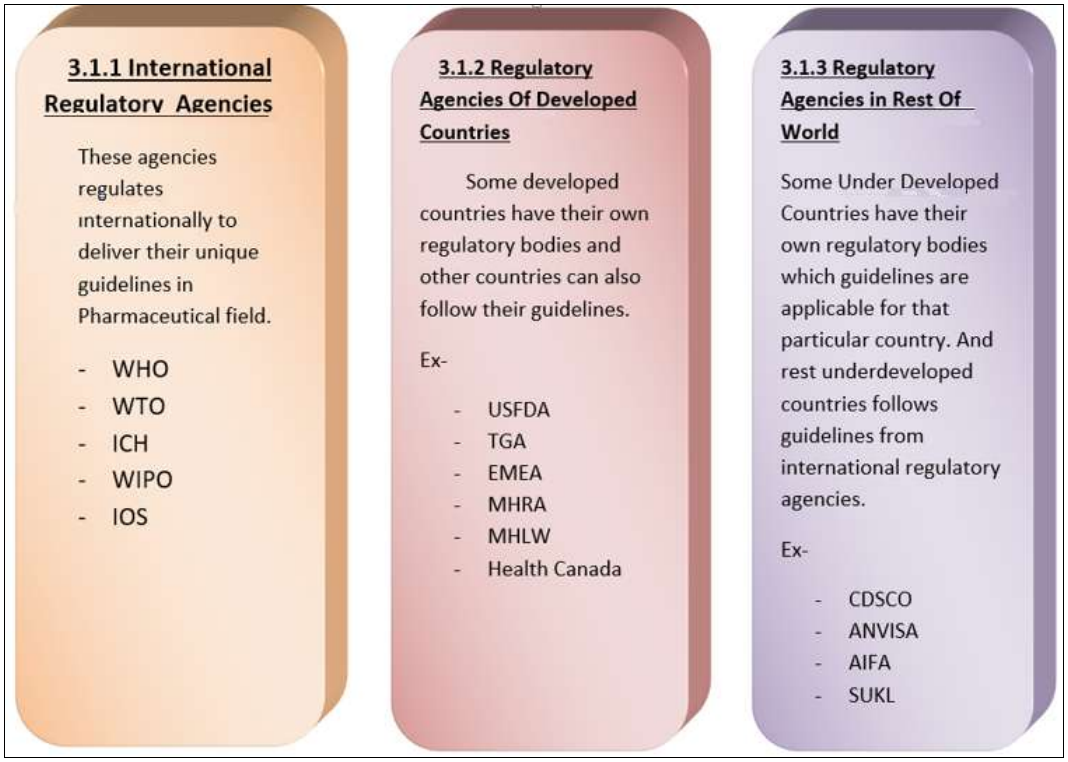

Fig 3: Classification of Regulatory Agencies

International Regulatory agencies

Some regulatory bodies regulates internationally to delivers their unique guidelines in the pharmaceutical field.

1. WHO: World Health Organization
2. IOS: International Organization for Standardization
3. WIPO ICH: International Conference On Harmonization
4. World Intellectual Property Organization
5. WTO: World Trade Organization [9].

WHO: World Health Organization

WHO is a global institution under United Nations control? WHO aims to protect the vulnerable, keep the world secure, and promote health on a global scale? It urges that a billion additional people should have access to universal health care, participate in the monitoring of public health risks, coordinate emergency medical response, and promote their general well-being. It establishes international health standards, offers technical help to nations, and gathers information on problems with global health.

- WHO also serves as a forum for discussions on health issues?
- WHO publish the World health Report to provide assessments of worldwide health topics [10].

[11]

Fig 4: WHO Organisation Chart

- Current Director General Of WHO is Dr. Tedros Adhanom Ghebreyeyesus since 01 July 2017 [12]
- Current Regional Director for South – East Asia of WHO for INDIA is Dr. Poonam Khetrapal. [13]

ICH: International Council on Harmonization

The ICH is an international regulatory body that oversees the design, conduct, safety, and reporting of clinical trials under the Efficacy category. The use of pharmacogenetics and genomics approaches to develop better targeted medications is also covered, as well as innovative forms of medicines derived from biotechnological processes.

Because it brings together regulatory agencies and the pharmaceutical industry to talk about the scientific and technical facets of drug registration, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) is exceptional. Since its founding in 1990, ICH has steadily changed to reflect the increasingly international nature of pharmaceutical development. To ensuring that safe, effective, and high-quality pharmaceuticals are produced and registered in the most resource-effective way possible, ICH's aim is to achieve greater global harmonization. Through the formulation of ICH Guidelines, which are the result of a collaborative effort between regulatory and business professionals, harmonization is achieved. The determination of the ICH regulators to put the final Guidelines into practice is essential to the process' success.

The ICH procedure has changed over time since it was established in 1990. The ICH Guidelines on Safety, Quality, and Efficacy themes underwent significant development during the first ten years of the organization. Additionally, work was done on a number of significant cross-disciplinary subjects, such as the CTD and MedDRA (Medical Dictionary for Regulatory Activities) (Common Technical Document). The requirement to increase communication and information sharing about ICH Guidelines with non-ICH regions became a primary priority as ICH entered the new millennium [14].

ISO: International Organization for Standardization

For nearly every imaginable field, including information technology, fluid dynamics, and nuclear energy, standards are created and distributed by a nonprofit organization called ISO. The 162 members of ISO, which has its headquarters in Geneva, Switzerland and serves as the only representative of each of their respective nations, are each individual entities. The largest standards publisher and developer in the world, ISO, is crucial in serving as a forum for consensus among independent standards makers in order to advance the goal of standardization [15].

Major Regional Regulatory Agencies across World

Every countries have their own Regulatory Agency which is responsible to enforce the rules and regulation and issue guidelines for Drug Development, licensing registration, Manufacturing, Marketing and labelling of pharmaceutical products.

Table 1: Major Regulatory Agencies of Countries

1.	Australia	Therapeutic Goods Administration (TGA)
2.	Brazil	1) Agencia Nacional de Vigiloncia Sanitaria (ANVISA) 2) National Health Surveillance Agency
3.	Canada	Health Canada
4.	China	State Food and Drug Administration
5.	Costa Rica	
6.	Denmark	Danish Medicines Agency
7.	Europe	European Medicines Agency (EMEA)
8.	Germany	Federal Institute of health and Medical Devices
9.	Hong Kong	
10.	India	Central Drug Standard Control Organization (CDSCO)
11.	Italy	Italian Medicines Agency (AIFA)
12.	Ireland	Irish Medicines Board
13.	Japan	Ministry of Health, Labour and Welfare (MHLW)
14.	Malaysia	National Pharmaceutical Control Bureau
15.	New-Zealand	Med safe - Medicines and Medical Devices Safety Authority
16.	Netherland	Medicines Evaluation Board
17.	Nigeria	National Agency for Food and Drug Administration and Control (NAFDAC)
18.	Paraguay	
19.	Pakistan	
20.	Singapore	Centre for Pharmaceutical Administration Health Sciences Authority
21.	South Africa	Medicines Control Council (MCC)
22.	Sri Lanka	Cosmetics, Devices & Drugs regulatory authority of Sri Lanka
23.	Sweden	
24.	Switzerland	Swiss medic, Swiss Agency for Therapeutic Products
25.	Thailand	Thailand Food and Drug Administration
26.	Uganda	Uganda National Council for Science and Technology (UNCST)
27.	Ukraine	Ministry of Health
28.	UK	Medicines and Healthcare Products Regulatory Agency (MHRA)
29.	USA	Food and Drug Administration (FDA)
30.		

Argentina: National Administration on Drugs, Foods, and Medical (ANMAT) DeMAT)

The National Administration of Drugs, Foods, and Medical Devices (ANMAT), also known as Administración Nacional de Medicamentos, Alimentos y Tecnologa Médica (ANMAT), is in charge of supervising and controlling Argentina's pharmaceutical, food and beverage, and healthcare sectors. Along with links to governmental agencies and medical periodicals, the website provides information on rules, press releases, and publications. The only language supported by some website sections is Spanish.

Australia: Therapeutic Goods Administration (TGA)

The governing body for the Australian pharmaceutical sector is the Therapeutic Goods Administration (TGA). The TGA supervises and controls a wide range of therapeutic items, such as prescription drugs, vaccinations, and medical equipment. Information on the website is primarily geared toward consumers, healthcare experts, and business manufacturers. It also includes a list of current drug recalls and alerts.

Bulgarian Drug Agency (BDA)

The Ministry of Health of Bulgaria collaborates with the Bulgarian Drug Agency (BDA). It is in charge of ensuring that medications are produced safely in Bulgaria. For the purpose of ensuring the efficacy and security of drug use, the BDA inspects pharmacies, medications, and medical equipment. Regarding medical legislation, technologies, and treatments, their website contains helpful information for people, medical professionals, and businesses.

Czech Republic: State Institute for Drug Control (SUKL)

The safe manufacture of pharmaceuticals in the Czech Republic is governed by the State Institute for Drug Control (SUKL). SUKL is in charge of monitoring the marketing and advertising of pharmaceuticals and medical equipment. Users can search for clinical trials, medications, and pharmacies using the site's numerous databases. On the homepage, there are also articles detailing latest clinical trial findings.

Denmark: Danish Medicines Agency (DKMA)

In Denmark, the pharmaceutical and healthcare sectors are supervised and governed by the Danish Medicines Agency (DKMA). The website provides details on product information, medical devices, pharmacies, and the sale of medications as well as licencing and monitoring. There is also a library with papers on pharmaceutical research and development.

Estonia: Agency of Medicines

The Estonian pharmaceutical and healthcare sectors are supervised and governed by the Agency of Medicines of Estonia. The website provides details about Estonian laws, drug trials, and appropriate medical procedures.

European Medicines Agency (EMA)

By evaluating medications, the European Medicines Agency (EMA) safeguards and advances public health. On the efficacy and safety of medications, the EMA makes recommendations. They use evaluation processes to support the introduction of new medications into the European

Union.

Finland: Finnish Medicines Agency (Fimea)
The Finnish Medicines Agency (Fimea) works to advance public health and safety by policing pharmaceutical, blood, and tissue products and expanding the pharmaceutical industry. The website offers veterinarian knowledge, pharmacy directories, and pharmaceutical databases.

Germany: Federal Institute for Drugs and Medical Devices (BfArM)
The licencing and registration of finished pharmaceutical goods as evidence of their safety and efficacy is the responsibility of the Federal Institute for Drugs and Medical Devices (BfArM). By gathering and analysing laboratory findings, BfArM keeps an eye on the hazards associated with pharmaceuticals. In Germany, the institute also tests and creates secure medical equipment. The BfArM website provides details about the institute, its functions, pharmaceuticals, and medical equipment. There are also a number of research papers available on subjects like neuropsychopharmacology, pharmacogenomics, pharmacoepidemiology, safety of medical devices, and biostatistics.

Greece: National Organization for Medicines
The National Organization for Medicines (EOF) of Greece defends the public's health with regard to pharmaceuticals, medical equipment, dietary supplements, and cosmetics. The EOF assesses novel safe and efficient products, regulates drug manufacture to adhere to good manufacturing practises, and supports medical and pharmaceutical research. Announcements for numerous products and laws are provided on the website. Available only in Greek.

Hong Kong: Department of Health - Drug Office
The Drug Office in Hong Kong is in charge of monitoring the drug market, doing risk analyses, and handling drug-related complaints. The office is also in charge of performing research and development for raising drug standards, licencing producers and sellers, and checking the drugs. The homepage of the website features sections tailored to each of these audiences, including areas for customers, healthcare professionals, and individuals interested in the pharmaceutical industry.

Hungary: National Institute of Pharmacy and Nutrition (OGYÉI)
A licensing and administrative body for pharmaceutical items is the National Institute of Pharmacy and Nutrition (OGYÉI). The OGYÉI also assesses drugs, grants permits, and oversees medical testing. News and details on authorization, supervision, technique, and medications are all included on the website. Only information in Hungarian is accessible in some cases.

Icelandic Medicines Agency (IMA)
The task of evaluating the efficacy and security of pharmaceuticals in Iceland falls under the purview of the Icelandic Medicines Agency (IMA). They conduct inspections to verify that legal criteria are met. Both the public and health professionals can find information on the IMA website. Medical publications on the website.

India: Central Drugs Standard Control Organization (CDSCO)
In India, the Central Drugs Standard Control Organization establishes requirements and controls drug regulations. The group offers advice on medical conditions and treatments. They control clinical research and import standards for pharmaceuticals into India. On the website, you may obtain several legal papers and forms for free in PDF format.

Ireland: Health Products Regulatory Authority (HPRA)
By overseeing the regulation of pharmaceuticals, medical equipment, and healthcare items, the Health Products Regulatory Authority (HPRA) safeguards both human and animal health. They keep an eye on the safety of cosmetics as well. The HPRA website features product lists, descriptions of various medications, discussions of hot legal and medical issues, news, and publications.

Italian Medicines Agency (AIFA)
The Italian Medicines Agency (AIFA), which establishes pharmaceutical policies and ensures their uniform state wide application, promotes good health through the use of medications. In order to increase the efficacy and safety of medications and medical equipment, AIFA supports pharmaceutical research and development. Information on assessments and registration, pricing and reimbursement, medical and scientific data, inspections and certificates are all available on the website.

Japan: National Institute of Health Sciences (NIHS)
The National Institute of Health Sciences (NIHS) carries out research, testing, and studies in an effort to properly evaluate the quality, safety, and effectiveness of pharmaceutical goods, foods, and the myriad chemicals in the living environment. The website offers general NIHS information as well as details on medications, medical equipment, food, and pollutants.

Japan: National Institute of Infectious Diseases (NIID)
The National Institute of Infectious Diseases (NIID) is an organisation that conducts basic and applied research on infectious diseases as well as establishes guidelines for testing new antibiotics and vaccines. It is a part of the Ministry of Health, Labor, and Welfare. The NIID website includes details on the organisation as well as current research and news items.

Latvia: State Agency of Medicines of Latvia (SAMLV)
To ensuring that human medicines and medical devices are effective and safe, the State Agency of Medicines of Latvia (SAMLV) executes national and international law. SAMLV ensures that drug makers and distributors are inspected, accredited, and certified while also providing unbiased information on medications. The SAMLV website provides details about pharmaceutical legislation, services offered by the organisation, and latest news articles pertaining to agency operations.

Lithuania: State Medicines Control Agency (SMCA) of Lithuania
The State Medicines Control Agency (SMCA) of Lithuania is responsible for the protection of public health through the evaluation and supervision of medicines for human use. The SMCA supervises manufacturing authorization holders,

wholesale distributors, and pharmacies in Lithuania.

Malaysia: National Pharmaceutical Regulatory Agency (NPRA)
The quality and safety of pharmaceutical products are guaranteed by Malaysia's National Pharmaceutical Regulatory Agency (NPRA). The NPRA website has details on the organisation, press announcements, a newsletter section, and a tool for searching products.

Malta: Medicines Authority
The Medicines Authority's goal is to safeguard the public health in Malta by controlling the production and distribution of pharmaceuticals. The authority offers services for pharmaceutical activity authorization, supervision, and inspection.

Netherlands: Medicines Evaluation Board (MEB)
The efficacy, safety, and quality of pharmaceutical products for both humans and animals are evaluated and protected by the Medicines Evaluation Board (MEB). In the Netherlands, the MEB is the main source of data on fresh pharmaceuticals, fresh uses, and fresh risk data.

New Zealand Medicines and Medical Devices Safety Authority
It is the responsibility of the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) to oversee the control of therapeutic items in that country. Medsafe makes sure that medicines adhere to approved safety and quality requirements. They also educate consumers, industry experts, and health care professionals about medicine. On the website, you can find information on medications, gadgets, dietary supplements, safety, news, events, and publications.

New Zealand: Pharmaceutical Management Agency (PHARMAC)
The safe manufacture of pharmaceuticals and medical devices is the responsibility of New Zealand's Pharmaceutical Management Agency (PHARMAC). PHARMAC informs both the general public and healthcare professionals on pharmaceuticals and medical equipment. Now, PHARMAC is in charge of overseeing hospital pharmaceutical management.

Norwegian Medicines Agency (NoMA)
By ensuring the effectiveness, quality, and safety of medications, the Norwegian Medicines Agency (NoMA) is in charge of maintaining and defending both human and animal health. The NoMA is also in charge of the classification, price, and authorization of medications. Additionally, NoMA offers data on pharmacovigilance, regulatory issues, and clinical trials.

Portugal: National Institute of Pharmacy and Medicines (Infarmed)
The Portuguese Ministry of Health is responsible for overseeing the National Institute of Pharmacy and Medicines (Infarmed). To safeguard the public's health, Infarmed's mission is to track, evaluate, and control all operations involving human pharmaceuticals and healthcare items. The website offers thorough

Romania: National Agency for Medicines and Medical Devices (NAMMD)
Romanian pharmaceuticals intended for human consumption are evaluated for safety by the National Agency of Medicines and Medical Devices (NAMMD). The NAMMD ensures that medical devices used by healthcare networks continue to operate at a high level of performance and safety. Additionally, the agency makes ensuring that patients and medical professionals have access to pertinent information about medications.

Serbia: Medicines and Medical Devices Agency (ALIMS)
The Serbian Agency for Medicines and Medical Devices (ALIMS) grants market authorizations for medical goods and equipment, assesses their quality in accordance with regulations and standards, and informs the general public on the use of drugs and medical equipment. Information about laws, medical supplies, veterinary medications, and pharmacovigilance can be found on the ALIMS website. There are additional news and press releases accessible.

Slovakia: State Institute for Drug Control (SIDC)
The State Institute for Drug Control (SIDC), which is a division of the Slovak Republic's Ministry of Health, is in charge of maintaining the oversight of the efficacy and security of pharmaceuticals. SIDC monitors pharmacies and regulates the advertising of pharmaceuticals.

Slovenia: Ministry of Health
Slovenian healthcare and health insurance issues are handled by the Ministry of Health. The ministry keeps an eye on the country's health policies and the precautions that should be taken in the case of natural disasters. Additionally, it shields the populace from infections and other health issues, particularly those related to environmental harms like garbage or polluted water.

South Korea: Ministry of Food and Drug Safety (MFDS)
The Ministry of Food and Drug Safety (MFDS) of South Korea works primarily in the food and drug industries to protect the country's residents' health and safety. This is accomplished through improving risk management systems, strengthening safety controls, and changing safety rules. The website offers details on the ministry's initiatives, relevant market news, and economic data.

Spain: Medicine and Health Products Agency (AEMPS)
Medicines for human and veterinary use are evaluated and approved by the Spanish Agency for Medicine and Health Products (AEMPS). AEMPS supervises the efficacy and safety of medications, certifies and inspects pharmaceutical facilities, and combats the use of illicit drugs and substandard medical supplies. The website offers information about pharmaceuticals for humans and animals, medical equipment, hygiene and cosmetics, and the pharmaceutical business.

State Administration for Market Regulation (SAMR)
The State Administration for Market Regulation (SAMR) of China is in charge of anti-monopoly regulations, food safety, trademarks, and patents. The website provides market data, news about current events in politics, and

services including business registration and a directory of small businesses. In addition, recent news is offered.

Sweden: Medical Products Agency (MPA)
The development of pharmaceuticals and medicinal products is governed and regulated by the Medical Products Agency (MPA). The MPA website provides details on medical equipment as well as herbal, homoeopathic, and other types of medication. On the site's home page, recent MPA press releases about recalls or developments in the pharmaceutical business are also displayed.

Switzerland: Swiss Agency for Therapeutic Products (Swissmedic)
The Swiss Agency for Therapeutic Goods (Swissmedic) guarantees the superiority, efficacy, and safety of all therapeutic products that have been granted authorization. Its objectives are to defend both human and animal health as well as Switzerland's status as a hub for business and research. Their website offers information on licencing, authorizations, market surveillance, and legal issues in addition to the most recent news in the Swiss therapeutic business.

United Kingdom: Association of the British Pharmaceutical Industry (ABPI)
The Association of the British Pharmaceutical Industry (ABPI) represents businesses that conduct research and develop treatments for patients that can save their lives. In order to make sure that the UK is at the forefront of aiding patients in disease prevention, ABPI conducts research and develops modern medications. On this website, you can find details about business successes as well as a peek at what lies ahead for medical research

United Kingdom: Medicines & Healthcare Products Regulatory Agency (MHRA)
The government organisation in charge of regulating the safe use of pharmaceuticals and medical equipment is the Medicines & Healthcare products Regulatory Agency (MHRA). The Department of Health's executive arm is the MHRA.

United Kingdom: NHS Prescription Service
A department called NHS Prescription Services determines how much pharmacists should be reimbursed for drugs and medical equipment they dispense to patients using NHS prescription forms. NHS Prescription Services makes financial and pharmacological information available to prescribers and organisations.

United States: Food and Drug Administration (FDA)
The Food and Drug Administration (FDA) is in charge of ensuring the security, safety, and efficacy of biological goods, medical devices, the nation's food supply, cosmetics, and radiation-emitting products in order to safeguard the public's health. The FDA is also in charge of improving public health by hastening developments that make medications safer, more efficient, and more economical [16].

Drug regulatory agencies in India
One of the top markets for pharmaceutical goods is now India. In India, the expansion of the private healthcare infrastructure, the expansion of rural markets, and the use of emerging technology have made healthcare a stand-alone industry. The medical devices industry is expanding as a result of healthcare being privatized.
The Medications and Cosmetics Act, 1940 ("D&C, Act") was introduced in India in 1940 to control the import, manufacturing, distribution, and sale of drugs and cosmetics. However, the Government of India has not yet passed a specific law to govern the importation, production, distribution, or sale of medical devices in India.
The Indian Constitution includes drugs and health in its concurrent list. The Drugs & Cosmetics Act, which is implemented by both the federal and state governments, regulates it [2].

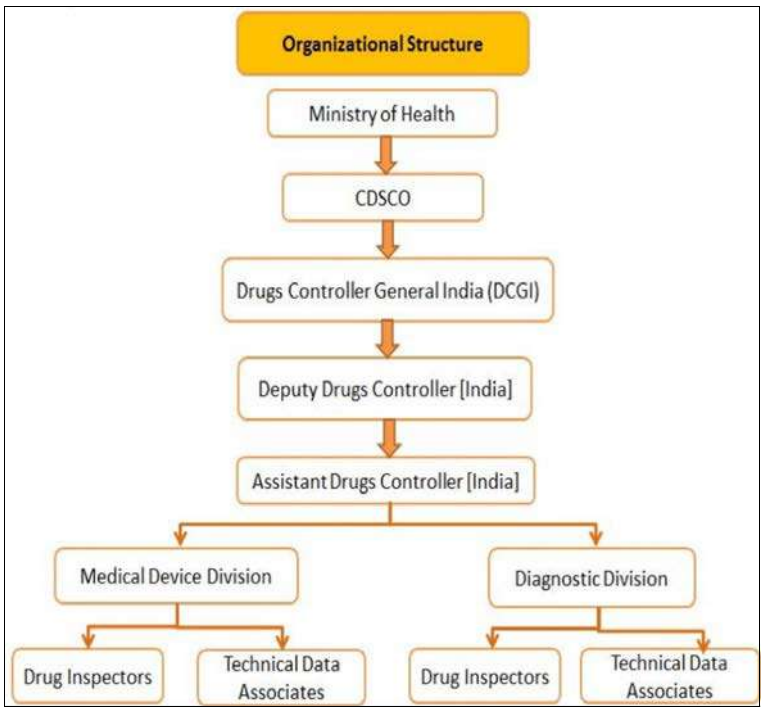

Fig 5: Organization Chart of CDSCO [2]

CDSCO – Central Drug Standards Control Organization

The primary regulatory authority in India now regulating the import, sale, and production of medical devices that have been notified as pharmaceuticals under Section 3(b)(IV) of the D&C Act is the Central Drugs Standard Control Organization ('CDSCO'). The CDSCO offers licenses to drug makers and importers and establishes standards for medications, cosmetics, diagnostics, and gadgets. Additionally, it lays forth regulatory measures, amends Acts and Rules, and governs the standards of imported medications, clinical research in India, and market authorization of novel drugs, among other things.

The Drug Controller General of India (DCGI), which is part of the CDSCO and has its headquarters in New Delhi, is in charge of overseeing the regulation of pharmaceuticals and medical devices in India. The Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee provide advice to the DCGI (DCC). The Central Licensing Approval Authority is responsible for medical device licensing and classification (CLAA). Additionally, the CLAA is in charge of establishing and implementing safety standards, designating notified bodies to supervise conformity assessment, carrying out post-market surveillance, and issuing alerts and recalls in the event of unfavourable incidents.

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The CDSCO sets safety, effectiveness, and quality requirements for drugs and medical equipment. The Indian Pharmacopeia, a catalogue of regulated drugs and devices, is published and updated by it. The CDSCO appoints notified bodies to carry out conformity assessment procedures, including testing, for all drug and device applications in order to make sure that their standards are being followed. The CDSCO is further divided into a number of zonal offices that conduct inspections prior to and after licence issuance, post-market monitoring, and recalls if required.

The CDSCO performs regulatory duties in addition to providing technical advice, training regulatory analysts and officials, and monitoring adverse incidents. The CDSCO collaborates with the World Health Organization to advance global regulatory parity and good manufacturing practises (GMP) [2, 18, 19].

Dr. Venugopal G Somani is the Drugs Controller General of India (DCGI) since July 2019.

Dr. Naresh Sharma is Deputy Drugs Controller (India) at CDSCO, Ministry of Health and Family Welfare

Organisation of CDSCO

CDSCO is an Indian national pharmaceutical regulatory body which have a several no of designation and their responsibilities and working criteria. CDSCO organisation can be shown as –

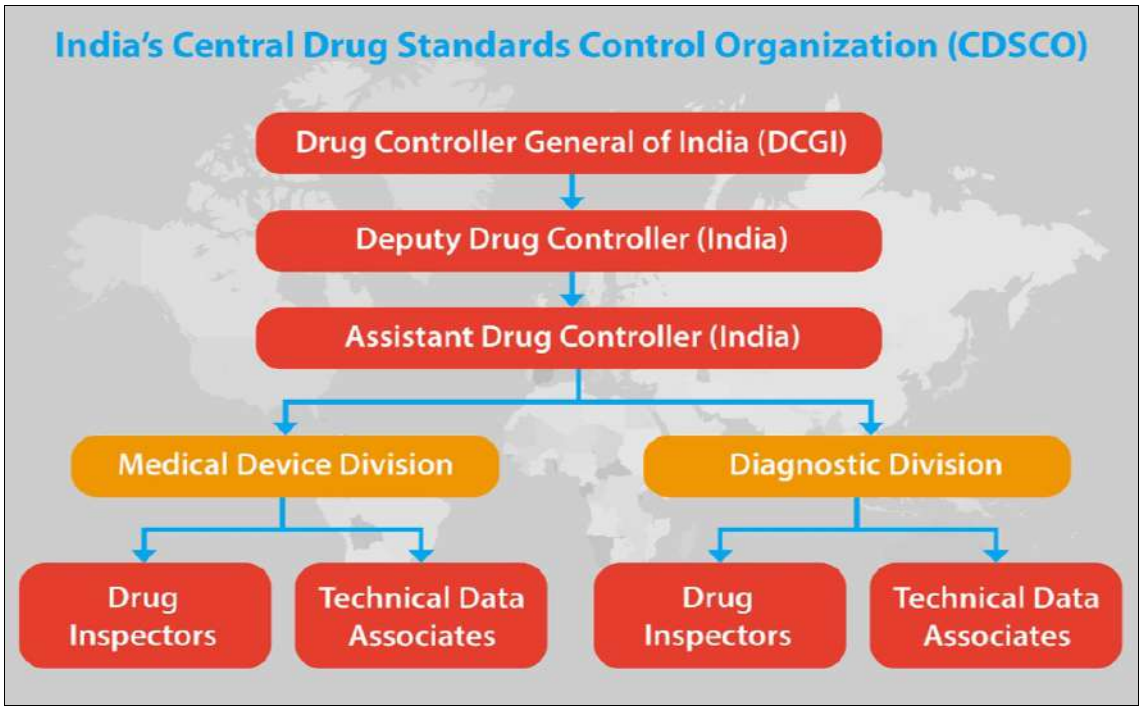

Fig 6: Organization Chart of CDSCO [20]

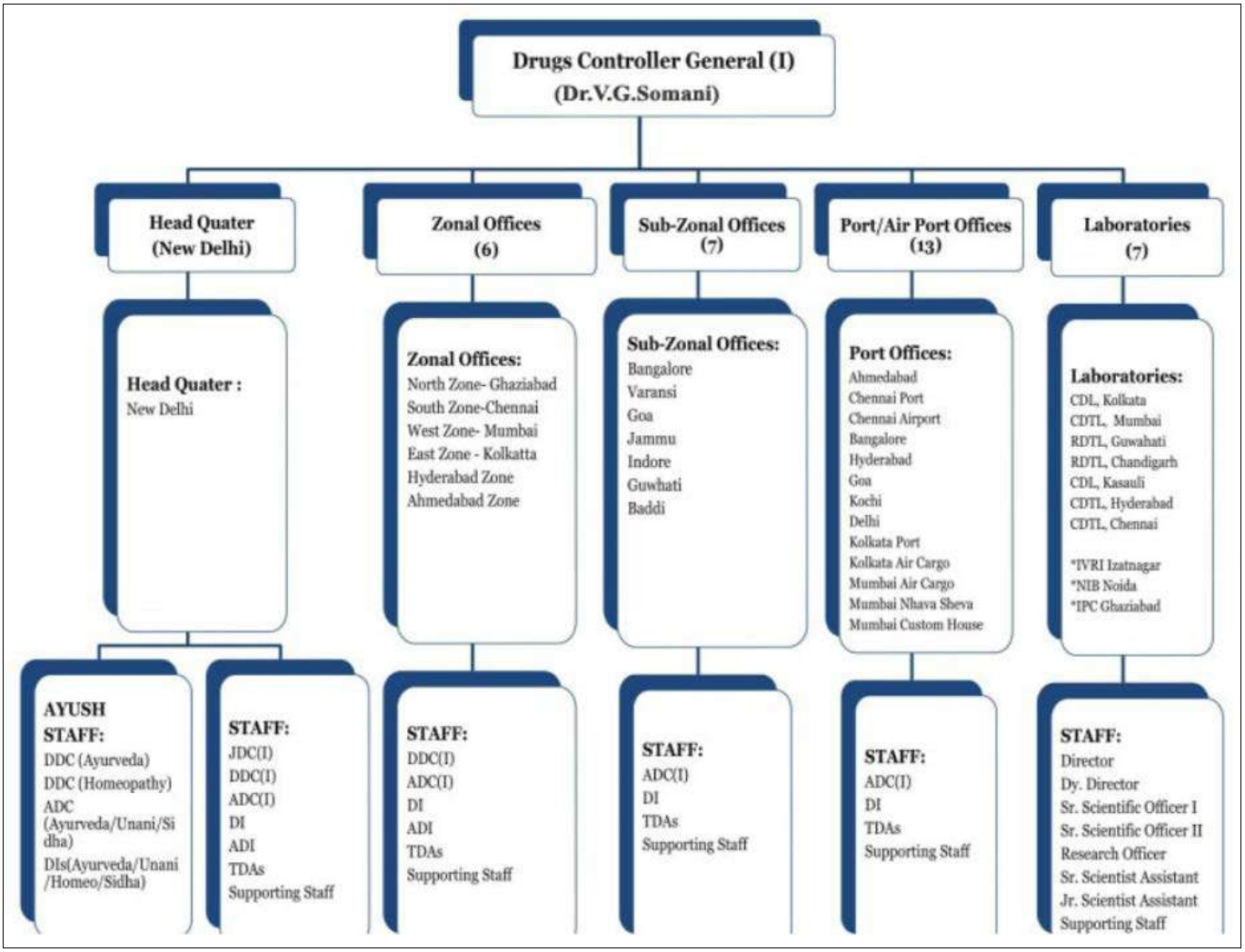

Fig 7: Zonal Organization of CDSCO [21]

CDSCO's Approval Process for New Drug Product

CDSCO – the Indian regulatory agency has a pattern and process for approval of any new drug by manufacturer or for import any new drug.

Process of approval of new drug product is given below –

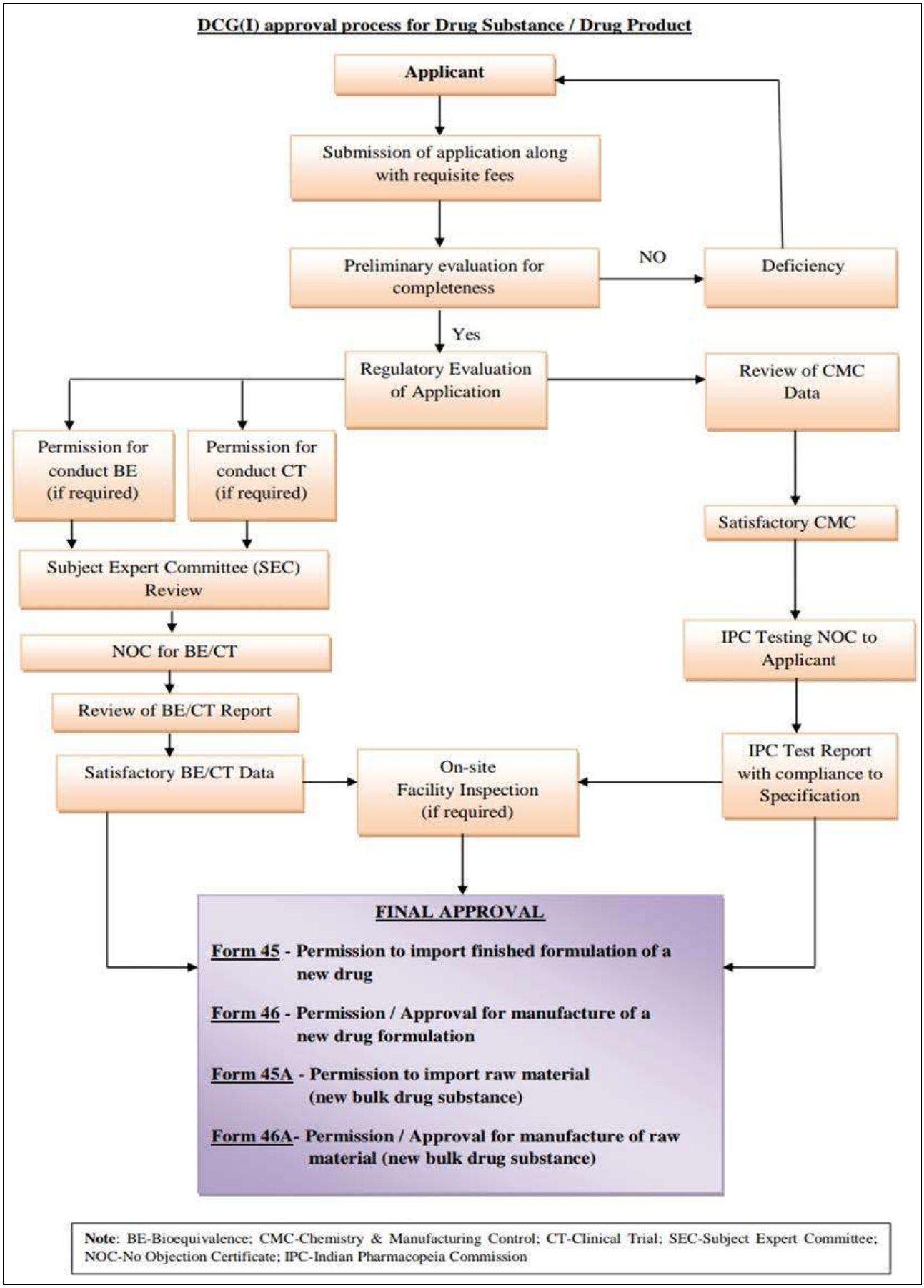

Fig 8: Approval Process for Drug Product by CDSCO [22]

Requirements for Common Submission Format For Registration and Import of Bulk Drug and Finished Formulation in India

1. Coverin letter
2. Authorization letter
3. Form 40

4. TR6 Challan (Fees)
5. Power Of Attorney (Form no 10)
6. Wholesale License
7. Schedule D (1)
8. Schedule D (2)
9. Free Sale Certificate
10. GMP Certificate of WHO or COPP
11. Manufacturing License
12. Establishment License
13. Inspection / Audit Report
14. Undertaking [23].

Some Format for Application Requirements

1. Audit Report – During Inspection an Audit report given by Inspection team which contains basic information about manufacturing site and APIs used during manufacturing –

a. For Bulk Drugs (API)

Name of site intermediates are manufactured	Name of site where API is manufactured	Name of site where API is tested	Name of site where API is packed	Name of dispatch site of API

b. For Finished Formulations (FF)

Name of API source	Name of site where formulation is made	Name of site of Primary Packing	Name of site of Secondary packing	Name of site of testing and Release	Name of dispatch site of FF

FORM 40 – application for registration of import or manufacturing of drug.

FORM 40

(See rule 24-A)

Application for issue of Registration Certificate for import of drugs into India under the Drugs and Cosmetics Rules 1945

I/We*_____
_____ (Name and full address) hereby apply for the grant of Registration Certificate for the manufacturer, M/s. _____(full address with telephone, fax and E-mail address of the foreign manufacturer) for his premises, and manufactured drugs meant for import into India.

1. Names of drugs for registration.
   1 * * *

2. I/We enclose herewith the information and undertakings specified in Schedule D (I) and Schedule D (II) duly signed by the manufacturer for grant of Registration Certificate for the premises stated below.

3. A fee of_____for registration of premises, the particulars of which are given below, of the manufacturer has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Finesll under the Drugs and Cosmetics Rules, 1945-Central *vide* Challan No._____ dated_____(attached in original).

4. A fee of_____for registration of the drugs for import as specified at Serial No. 2 above has been credited to the Government under the Head of Account "0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines" under the Drugs and Cosmetics Rules, 1945-Central vide Challan No._____, dated _____. (attached in original).

5. Particulars of premises to be registered where manufacture is carried on:
Address (es) _____
Telephone No._____ Fax_____ _
E-mail_____
I/We* undertake to comply with all terms and conditions required to obtain Registration Certificate and to keep it valid during its validity period.
Place: _____
Date: _____

*Signature*_____
*Name*_____
*Designation*_____
Seal/ Stamp of manufacturer or his authorised Agent in India.

(**Note**: In case the applicant is an authorized agent of the manufacturer in India, the Power of Attorney is to be enclosed).
**Delete whichever is not applicable.*

Form 41 – Registration Certificate for Import of Drug or Manufacturing of Drug

Form 41 (See rule 27-A)
Registration Certificate

Registration Certificate to be issued for import of drugs into India under Drugs and Cosmetics Rules, 1945.

Registration Certificate No._____ Date _____

M/s _____(Name and full Address of registered office) _____ _____having factory premises at_____ (full address) has been registered under rule 27-A as a manufacturer and is hereby issued this Registration Certificate.

2. Name (s) of drugs, which may be imported under this Registration Certificate.
   (1)
   (2)
   (3)
3. This Registration Certificate shall be in force from _____ to _____unless it is sooner suspended or cancelled under the rules.
4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/s (name and full address) _____ who will be responsible for the business activities of the manufacturer, in India in all respects.
5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the Act and the rules, from time to time.

Place _____
Date: _____

Licensing Authority

Seal/Stamp

TR6 Challan – TR6 Challan is to pay the Registration Fees

TR6 Challan

T.R. - 6. Civil
(See Rule 92)
Challan No.

Please indicate whether	Civil
	Defence
	Railways
	Posts & Telegraphs

Chelan of cash paid into Treasury/sub- Treasury
Bank of Baroda,K.G Nagar, New Delhi

To be filled by the remitter			To be filled by the department officer or the Treasury		
By whom Tendered	Name (or designation) And address of the person on whose by half money is paid	Full particulars of the remittance and /of authority(if any)	Head of Account	Accounts officers by Whom adjustable	Order to the Bank
Name Signature		Total	104-Fees & Fines		Date Correct, receive and grant receipt (Signature and full Designation of the Officer Ordering the money to be paid in)
(in words) Rupees					To be used only in the case of remittance to the Bank through Departmental Officer or the Treasury officer.

Received payment (in words) Rupees

Treasurer Accountant Date Treasury Officer

Agent or Manager

Note: 1. In the case of payment at the treasury, receipts for sums less then Rs 50,000. 00 do notrequire the signature of the Treasure office but only of the accountant and the Treasurer. Receipt for cash and cheques paid for service postage stamps should be given in form T.R.5.

2. Particulars on money tendered should be given below.

[23]

Functions of CDSCO

1CDSCO is responsible for Approval for new Drugs and drug products. CDSCO also overseas about the approval of license to manufacture of new drug, clinical trails, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of state drug control organizations and expert advice with a view of bring uniformity in the enforcement of Drugs and Cosmetics Act.

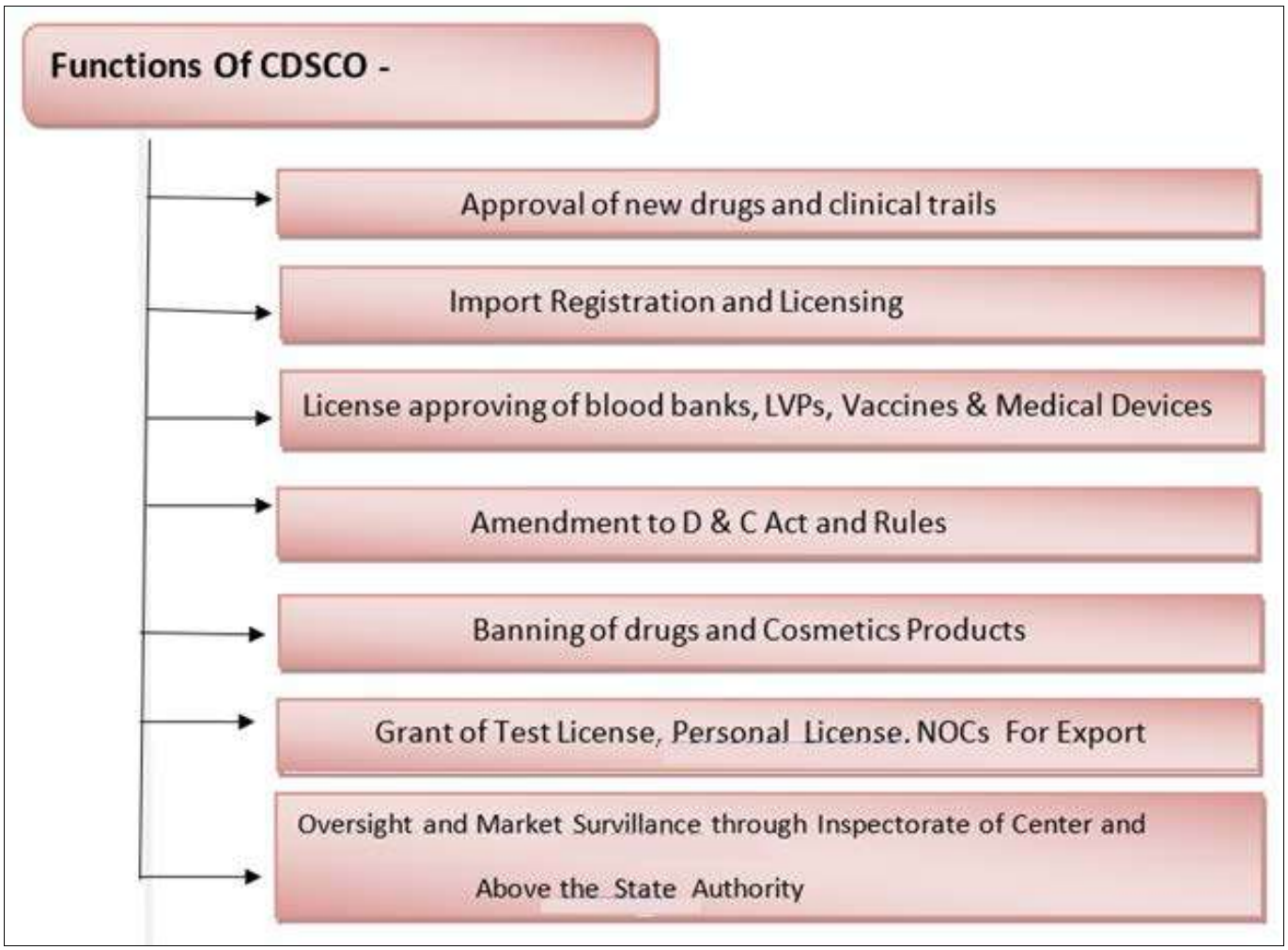

Fig 8: Function of CDSCO [24]

Conclusion

Regulatory agencies and organizations around the world need to ensure the safety, quality and efficacy of medicines and medical devices, harmonization of legal procedures related to drug development, monitoring and ensuring compliance with statutory obligations. However the need of the hour is-

- More centralized procedures in drug regulation
- Harmonization of regulatory norms
- Strengthening the regulatory authorities

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