An Overview of Drug Regulatory System in India

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***Abstract*: Pharmaceutical drug regulatory affairs encompass a variety of pharmaceutical product registration parameters. As a new profession, it arose from the desire of people all over the world to protect public health by providing high-quality medicine, including safety and efficacy, in areas such as veterinary medicine, medical devices, insecticides, pesticides, agrochemicals, cosmetics, and complementary medicine. It also served as a link between the pharmaceutical industry and regulatory bodies. It's also in charge of making sure the product information is up to date and accurate. Its primary responsibility is to function as a liaison with regulatory bodies, offering experience and regulatory intelligence in translating regulatory requirements into a practical, workable strategy, and advising the company on regulatory elements and climate that may affect their intended actions.**

Index Terms: Regulatory affair, Safety, Efficacy, Quality, Central Drugs Standard Control Organization (CDSCO), DTAB, and Drugs Consultative Committee (DCC)

1. INTRODUCTION:

The availability of effective pharmaceuticals to address sickness and diseases afflicting humans is critical to the effectiveness of health-care delivery systems. As a result, the availability of safe, effective, and high-quality medications, as well as their prudent use, is a top national priority. The creation of specific legislation to regulate the import, production, sale, distribution, and promotion of medications and pharmaceuticals has resulted from these societal concerns.

Drug regulatory measures are dynamic in nature, evolving in response to advances in science and technology in the fields of drug discovery, manufacturing techniques, various sources of substances used as medicines, and the expansion of knowledge about the pharmacokinetics and pharmacodynamic of drug molecules, as well as their long-term safety. Along with its scientific and technological component, it includes special rules to control commercial drug transactions in order to protect customers' interests.

As a result, the drug regulatory system is a social and public health measure enacted by the government to ensure that all medical products meet current safety, efficacy, and quality standards and are manufactured and distributed in such a way that their quality is maintained until they reach patients and their commercial promotion is accurate. Consumers have a right to anticipate that the drug administration will not only protect public health by keeping dangerous pharmaceuticals off the market, but will also make safer and more effective new drugs more readily available.

The infrastructure, which consists of trained and competent personnel and drug testing facilities, enforces the law enactments governing drug regulatory criteria. Special compendiums called as pharmacopoeias are produced to ensure uniform standards for drug molecules and to monitor their quality. Pharmacopoeias give precise specifications concerning particular drug compounds, their formulations, and numerous dosage forms.

2. CHALLENGE TO REGULATORY AFFAIRS PROFEESION

Regulatory affairs include complete dynamics:

- Multi –dimensional
- Knowledge in science and technology
- Prolific communication skill
- Deal with people with diverse background, skills, culture, and personalities
- Deal with conflicting loyalties, motivations, social and ethical's, responsibilities

Case in point: submission of a dossier.

During submission of a dossier a regulatory affair would be: Guided by various regulatory guidance.

- Receiving input from various departments within the firm about process capabilities and product attribute specification.
- Receiving advice from peers about easy way to get approvals.
- Receiving motivation from the management through incentives for achieving speedy approvals.

The essential concepts upon which the Indian drug regulating legislation is based are as follows:
1. Identifying the products that must be regulated.
2. Defining the regulatory scope
3. Establish broad safety, effectiveness, and quality standards for products to be controlled
4. Establish quality specifications for each product.
5. Establish production requirements that would ensure product adherence to quality objectives in general.
6. Regulate manufacturing through establishment licensing and supervision by qualified regulatory staff
7. Specify storage and distribution requirements to ensure that a drug's quality and safety are maintained until it is used.
8. Impose penalties in the form of administrative and judicial action for activities that violate defined rules.
9. Provide for appropriate procedures and personnel for enforcement of the legislative intent as well as its review and updation.

3. ENFORCEMENT

The federal and state governments administer quality, safety, and efficacy aspects of drug and cosmetic importation, manufacture, distribution, and sale, as well as various diagnostics and equipment. Control over the manufacture and sale of medications is generally exercised by state governments and union territories through Drug Controlled Organizations, whereas importation of drugs and market authorization of any new drug in the country is governed by the federal government.

4. DRUG REGULATION BY CENTRAL GOVERNMENT

Central functions are exercised by **Central Drugs Standards Control Organization (CDSCO)** in the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India and are headed by Drugs Control General of India. CDSCO has six zonal offices, four sub-zonal offices, thirteen port offices and seven central laboratories in the country. Functions undertaken by Central Government through CDSCO under Drugs and Cosmetics Act are as under:

- Laying down standards of drugs, cosmetics, diagnostics and devices.
- Laying down regulatory measures through amendment to Act and Rules.
- To regulate market authorization of new drugs and clinical trials.
- To regulate import of drugs.
- Publication of Indian Pharmacopoeia.
- Prohibiting manufacture and sale of harmful and therapeutically inadequate drug products
- License approving authority for various categories of drugs.
- Monitor Adverse Drug Reaction (ADRs).
- Guidance to state on technical matters to achieve uniformity of enforcement.

Headquarter: **FDA Bhawan, Kotla Road, New Delhi**
Zonal Offices:

- ➢ Ghaziabad (North Zone)
- ➢ Kolkata (East Zone)
- ➢ Mumbai (West Zone)
- ➢ Chennai (South Zone)
- ➢ Ahmadabad (Zonal Office)
- ➢ Hyderabad (Zonal Office)

Sub- zonal:

- ✓ Bangalore (Karnataka)
- ✓ Varanasi (UP)
- ✓ Goa
- ✓ Jammu and Kashmir
- ✓ Indore (MP)
- ✓ Guwahati
- ✓ Baddi (Himachal Pradesh)

Central drug Testing Laboratories:

- ❖ Central Drugs Testing Laboratory, Mumbai, Maharashtra
- ❖ Central Drugs Testing Laboratory, Kolkata, West Bengal
- ❖ Central Drugs Testing Laboratory, Chennai, Tamil Nadu
- ❖ Central Drugs Testing Laboratory, Hyderabad, Andhra Pradesh
- ❖ Central Drugs Testing Laboratory, Central Research Institute, Kasauli, Himachal Pradesh
- ❖ Regional Drugs Testing Laboratory, Guwahati, Assam
- ❖ Regional Drugs Testing Laboratory, Chandigarh
- ❖ National Institute of Biological, Noida (U.P.)

5. DRUG REGULATION BY STATE GOVERNMENT

State Drug Control Organizations are responsible for enforcing the laws of the Medications and Cosmetics Act and Rules promulgated by the federal government, as well as giving licenses to drug production and distribution businesses and monitoring the quality of drugs on the market. As a result, states bear primary responsibility for enforcing the law governing the quality and safety of pharmaceuticals. Pre- and post-licensing inspections, recalls of sub-standard drugs, quality monitoring of drugs and cosmetics by collecting samples and having them tested by notified laboratories, conducting investigations, and prosecuting offenders are the main activities carried out by the state drug administration. On a daily basis, around 1,000 drug inspectors are on the job.

6. IMPORTANT STATUTORY BODIES

Drugs and Cosmetics Act has laid down provisions for forming one statutory board and a committee for advising the government on different matters of drug regulation and uniformity of enforcement in the country.

The Drugs Technical Advisory Board (DTAB):

It has technical experts that advises Central and State governments on all technical matters arising out of the enforcement of the drug regulation. DTAB is constituted under Section 5 of the Act with the Director General of Health Services as its Chairman. Amendment to drugs and Cosmetics Act and Rules are made after consulting this board.

Drugs Consultative Committee (DCC):

It has Central and State Drug Controls officials as its members. The main function of DCC is to ensure that the drug control measures are enforced uniformly in all states in India and to evolve progressive measures relevant to contemporary needs.

7. IMPORT OF DRUGS

After an extensive amendment in the Drugs and Cosmetics Rules, all overseas manufacturing establishments and every drug product imported in the country now requires import registration by paying a fees of 1500$ and 1000 $, respectively. Following that, such registered products are allowed to be imported under the terms of a special license given by the CDSCO office. CDSCO port officers inspect the documentation that come with the pharmaceuticals, and random samples are taken to ensure their purity. Import registration is not required for cosmetics at the moment.

8. NEW DRUG

Rule 122E of the Drugs and Cosmetics Rules provides specific definition of ‘new drug’ as applicable in India. This includes new molecules as well as drugs used abroad but to be introduced for the first time in country. New indication or new dosage form of an already approved drug is also considered as a new drug. Even fixed dose combinations of drugs already in use are considered as new drugs. Market authorization of new drugs in the country is responsibility of CDSCO under the Directorate General of Health Services, Government of India.

Applicants for approval of new compounds discovered and developed in the country would be needed to give data on pre-clinical animal toxicity, phase I, phase II, and phase III clinical trials, the overall benefits-risk profile, and so on, depending on their classification. A medicine that has previously been licensed and is in use in another developed country, on the other hand, may require a 'bridging' clinical trial in India to ensure its safety in the Indian population before being approved for sale. New medication product evaluation is multidisciplinary, and drug safety benchmarks have gotten more stringent over the world. Even after a thorough review of a new drug prior to its clearance for the market, there have been a number of cases where such drugs have had to be withdrawn after a short period of time as new data regarding the drug's risk emerges via post-market monitoring studies.

CONCLUSION

Drug regulation in India is a complicated process overseen by many ministries, notably the Ministry of Health and Family Welfare, and governed by law, namely the Drugs and Cosmetics Act of 1940. At both the federal and state levels, the law establishes a web of regulatory entities to oversee the process. The Drugs and Cosmetics Act of 1940 established the Central Drugs Standard Control Organization (CDSCO), within which the Drugs Controller General of India (DCGI) serves as the primary regulatory authority, acting on the advice of the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC). CDSCO is organized into zone offices that are located around the country and have specific responsibilities in drug control, including as inspections, recalls, and market surveillance. CDSCO also has a role in overseeing the functioning of state authorities involved in drug regulation.

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