

**AN OVERVIEW OF REGULATORY AFFAIRS IN INDIA****K. Soundharrajan\*, D. Silambarasan, D. Mohan Kumar and R. Venkadesan**Kamalakshi Pandurangan College of Pharmacy, Tiruvannamalai - 606601,  
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Tamilnadu, India.**ABSTRACT**

Pharmaceutical drug regulatory affairs covers different registration parameter of pharmaceutical product. As it is the new profession which was developed from the desired of all over the world to protect the public health by providing good quality of medicine including safety and efficacy in the area of not only pharmacy but also in the area of the veterinary medicine, medical device, insecticides, pesticides, agrochemical, cosmetic and complementary medicine. It also made the interface between the pharmaceutical company and the regulatory agencies. It is also responsible for maintaining the appropriateness and accuracy of the product information. And its main role to act as an

liaison with regulatory agencies, providing expertise and regulatory intelligence in translating regulatory requirement into practical workable plan, advising the company on regulatory aspects and climate that would affect their proposed activities.

**KEYWORD:** Regulatory affairs in India, MHFW, CDSCO, DTAP, DCC.**INTRODUCTION**

Regulatory affairs (RA), also called government affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, agrochemicals (Plant protection products and fertilizers), energy, banking, telecom etc. Regulatory affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, biologics and functional foods).<sup>[1]</sup> As it is heart of all about Collecting, Analyzing and Communicating the Risks and Benefits of healthcare products to regulatory agencies and public all over the world. It is also a science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of regulated products All medicines must meet three criteria: be of good quality, safe and effective. The judgments about medicines quality, safety

and efficacy should be based on solid science. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents.<sup>[2]</sup> Pharma regulatory affairs professionals play an essential role in ensuring all pharmaceutical products comply with regulations governing the industry.<sup>[3]</sup> Those working in Pharma regulatory affairs jobs not only work in the initial application phase for a new or generic drug, but also in the licensing and marketing stages – making sure all operations and products meet required safety and efficacy standards. Professionals must combine knowledge of the business, regulations are being followed and in many cases form the link between pharma companies and regulatory authorities, such as the Food and Drug Agency (FDA) and the European Union.<sup>[4]</sup>



**Fig: Role of ra.**

### **Objective of regulatory affairs**

The main objectives of the regulatory affairs are as given below

- ❖ Regulatory Affairs specialists coordinate and Document internal regulatory processes, as internal audits, inspections, license Renewals or registrations. They may also Compile and prepare materials for Submission to regulatory agencies.
- ❖ The regulatory bodies play a vital role in Between the companies and the government Agencies.
- ❖ Regulatory affairs department plays a vital Role to ensure the safety and efficacy of the Drugs available to the public in the market.
- ❖ Regulatory bodies set guidelines for the Manufacturing, importation, distribution of Drugs and also monitors adverse drug Reactions (ADR's).
- ❖ Regulatory affairs help in the legalization Covering all products with a medicinal claim

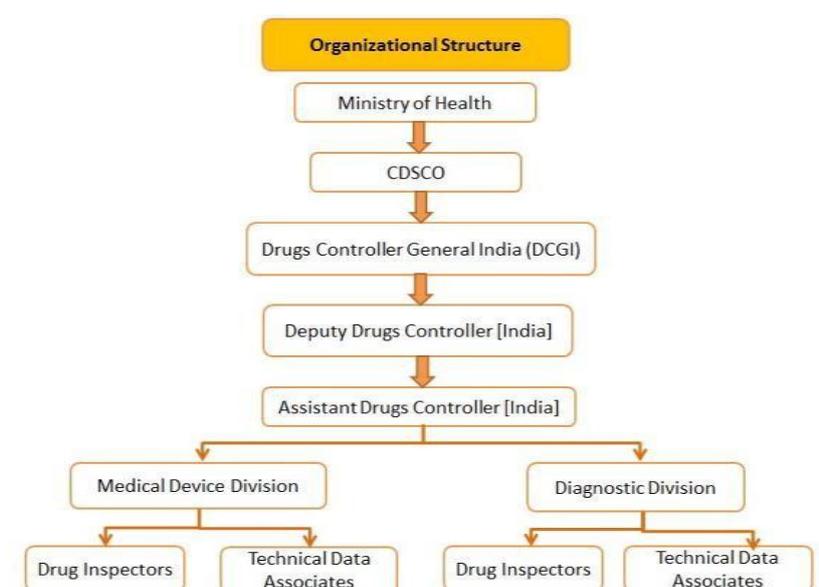
And all relevant pharmaceutical activities, Whether carried out by the public or sector.<sup>[5]</sup>

### Why need to regulate

1. All substances are poisons; there is none which is not a poison. The right dose differentiates a
2. Poison and a remedy.
3. To ensure quality, safety and efficacy of drug products in order to assure the continued protection of Public Health.
4. No drug product is completely safe or efficacious in all circumstances, but there is a moral, as well as legal, expectation that appropriate steps are taken to assure optimal quality, safety and efficacy by the Producers concerned Benefit versus Risk.<sup>[6]</sup>

### Drug regulatory agencies in india

India has emerged as one of the leading markets for pharmaceutical products. Increase in the Private healthcare infrastructure, widening rural markets, and inclusion of newer technologies have placed healthcare as an independent sector in India. With privatization of healthcare, the medical devices sector is growing too. In order to regulate the import, manufacture, distribution and sale of drugs and cosmetics, the Drugs and Cosmetics Act, 1940 (“D&C, Act”) was introduced in India in 1940. However, no separate regulation has been enacted for regulating the import, manufacture, distribution or sale of medical devices in India till date by the Government of India. Drugs and Health is in concurrent list of Indian Constitution. It is governed by both Centre and State Governments under the Drugs & Cosmetics Act, 1940.<sup>[7]</sup>



**Fig: Organization of regulatory affairs MAIN bodies.**

- ❖ Ministry of Health & Family Welfare (MHFW)
- ❖ Central Drug Standard Control Organization (CDSCO)
- ❖ Drugs Controller General of India [DCGI]
- ❖ Drug Technical Advisory Board (DTAB)
- ❖ Drug Consultive committee (DCC)
- ❖ Indian Council of Medical Research (ICMR)
- ❖ Indian Pharmaceutical Association (IPA)
- ❖ Central Drug Testing Laboratory (CDTL)
- ❖ Indian Pharmacopoeia Commission (IPC)
- ❖ National Pharmaceutical Pricing Authority (NPPA)

### **Ministry of Health & Family Welfare (MHFW)**

The Ministry of Health and Family Welfare (MHFW) is an Indian government ministry charged with health policy in India. It is also responsible for all government programs relating to family planning in India.

The current minister is **Dr. HARSH VARDAN**

The ministry is composed of two departments:

- 1) Departments of Health and Family Welfare.
- 2) Department of Health Research.

### **Department of health**

- ❖ 13 National health programmes.
- ❖ Medical council of India
- ❖ Food safety and standards authority India
- ❖ Central drugs standard control organisation(CDSCO)

### **Department of welfare**

- ❖ Central drug research institute(CDRI) Lucknow
- ❖ Indian council of medical research(ICMR) New Delhi

### **Department of health research- (DHR)**

Department of Health Research has a scheme to provide advanced training in India and abroad to medical and health research personnel in cutting edge research areas concerning medicine and health to create trained human resource for carrying out research activities.<sup>[8]</sup>

**Central drug standard control organization (CDSCO)**

CDSCO (Central drug standard control organization) National regulatory body for Indian Pharmaceuticals and medical devices. Within CDSCO, DCGI (Drug Controller General of India) regulates pharmaceutical and medical devices under gamut of Ministry of Health and Family Welfare (MHFW).<sup>[9]</sup>

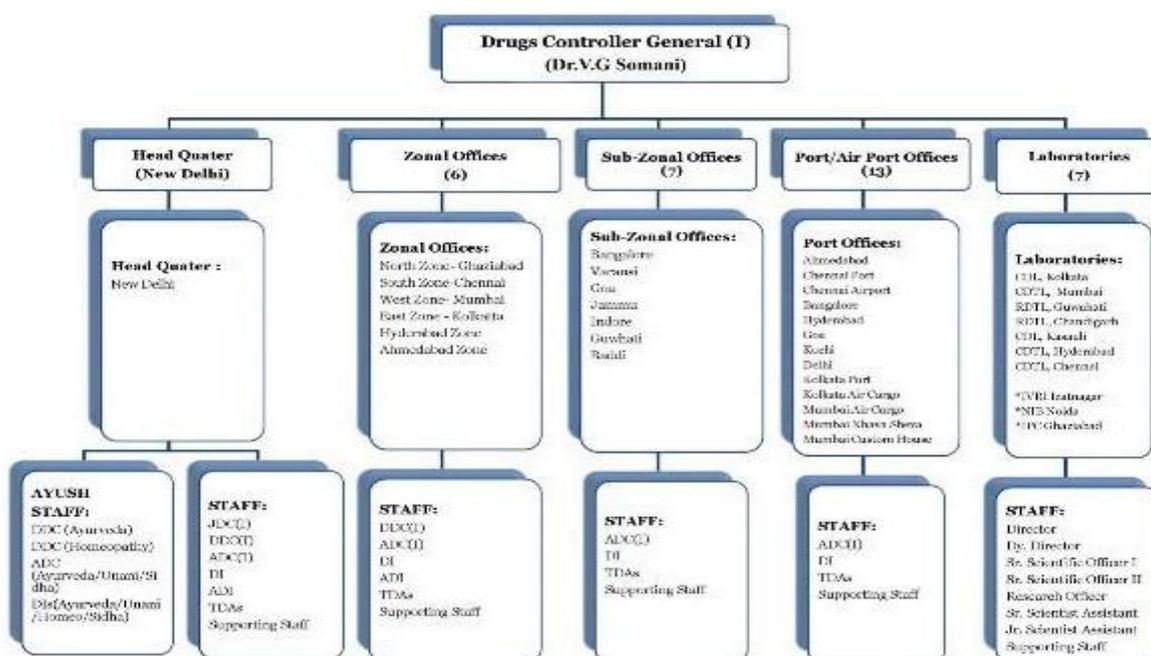
**Head Offices and Zonal office**

The Central Drugs Standard Control Organization (CDSCO) is the Central Drug Authority for discharging functions assigned to the Central Government under the Drugs and Cosmetics Act.

- ❖ CDSCO has six zonal offices,
- ❖ Four sub-zonal offices
- ❖ 13 port offices and
- ❖ Seven laboratories under its control.

**Functions of Cdsco**

1. To protect and promote public health
2. To safeguard and enhance the public health by assuring the safety, efficacy & quality of the drugs, cosmetics, medical device
3. Regulatory control over import, manufacturing, sale & distribution of drugs.



4. Approval of certain drugs & clinical trials
5. Meetings of DCC, DTAB
6. Approval for licenses as Central License Approving Authority
7. Co-ordination with activities of State Drug Control Organization<sup>[10]</sup>

### **Drug controller general of india(DCGI)**

Drugs Controller General of India (DCGI) is the head of the Central Drugs Standard Control Organization, regulatory body for pharmaceuticals and medical devices in India. DCGI is responsible for approval of licences of specified categories of drugs such as blood and blood products, IV fluids, vaccines, and serum in India. Drugs Controller General of India, comes under the Ministry of Health & Family Welfare.<sup>[1]</sup> As a regulatory authority DCGI also sets standards for manufacturing, sales, import, and distribution of drugs in India.

### **Functions**

- ❖ DCGI lays down the standard and quality of manufacturing, selling, import and distribution of drugs in India.
- ❖ 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 Institutions.
- ❖ Analysis of Cosmetics received as survey samples from CDSCO (central drug standard control organisation)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.<sup>[11]</sup>

### **Drug technical advisory board(DTAP)**

The Drugs Technical Advisory Board advises the Central Government and the State Governments on technical matters arising out of the administration of Drugs & Cosmetics Act and carry out functions assigned to it by this Act.

**Members of DTAB drugs technical advisory board**

1. The Director General of Health Services, *ex officio*, who shall be Chairman;
2. The Drugs Controller, India, *ex officio*;
3. The Director of the Central Drugs Laboratory, Calcutta, *ex officio*;
4. The Director of the Central Research Institute, Kasauli, *ex officio*;
5. The Director of Indian Veterinary Research Institute, Izatnagar, *ex officio*;
6. The President of Medical Council of India, *ex officio*;
7. The President of the Pharmacy Council of India, *ex officio*;
8. The Director of Central Drug Research Institute, Lucknow, *ex officio*;
9. Two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States; one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;
10. One person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;
11. One person to be nominated by the Central Government from the pharmaceutical industry;
12. One pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;
13. One person to be elected by the Central Council of the Indian Medical Association;
14. One person to be elected by the Council of the Indian Pharmaceutical Association;
15. Two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.

**Functions of drugs technical advisory board**

1. Co-ordinate the DTAB meetings under the Chairmanship of Director General of Health Services (DGHS) to advise the Central Government and the State Governments on technical matters arising out of the administration of the Drugs and Cosmetics Act, 1940 and to carry out the other functions assigned to it by this Act.
2. Co-ordinate the DCC meetings under the Chairmanship of Drugs Controller General (India) to advise the Central Government, the State Governments and DTAB on any other matter tending to secure uniformity throughout India in the administration of the Drugs

and Cosmetics Act, 1940.

3. Initiate the amendments in the Drugs and Cosmetics Rules, 1945 as per the recommendations of DTAB and co-ordinate with Ministry of Health & Family Welfare (MOHFW) for draft and final Gazette Notifications.
4. Examination, compilation and consideration of the comments/ suggestions/ objections received with respect to draft Gazette Notifications/ Public Notices/ Circulars etc.
5. Co-ordinate the constitution of sub-committees recommended in DTAB and DCC meetings and further follow-up for their reports.
5. Co-ordinate the stake holders meetings with respect to amendments of Drugs and Cosmetics Rules, as per recommendations from MOHFW whenever required.
6. Prepare minutes of DTAB and DCC meetings and upload on CDSCO website for stakeholders/ public reference.
7. Processing of representations/RTIs/Public Grievances with respect to Drugs and Cosmetics Act and Rules thereunder<sup>[12]</sup>

#### **Drug consultative committee(DCC)**

- 1) The Central Government may constitute an advisory committee to Committee be called "the Drugs Consultative Committee" to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout <sup>28</sup>[India] in the administration of this Act.
- 2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.
- 3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.<sup>[13]</sup>

#### **Recent advancement in drug regulatory affairs**

Recently, the Govt. of India has constituted a few autonomous bodies to gauge the standards of profession of Pharmacy & grade the colleges accordingly so that the students, parents, employers and funding agencies have a valid & reliable rating of the various<sup>[15]</sup> Pharmacy colleges in the country.<sup>[14]</sup>

#### **These are**

- 1) National Board of Accreditation (NBA) under the aegis of All India Council for Technical Education.

- 2) National Assessment and Accreditation Council (NAAC) by the University Grants Commission.

## CONCLUSION

Regulatory Affairs department is constantly evolving and growing and is the one which is least impacted during the acquisition and merger, and also during recession. Regulatory Affairs departments are growing within companies. Due to the changing resources necessary to fulfil the regulatory requirements, some companies also choose to outsource or out task regulatory affairs to external service providers. In today's competitive environment the reduction of the time taken to reach the market is critical to a product and hence the company's success. The proper implementation of regulatory guidelines and laws will improve the economic growth of the company and also improves the safety of the people.

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