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Review on Drug Regulatory affairs (DRA) and New Drug Approval process in India.

Gaurav Barde[1], Agasti Ware[2], Swaraj Adhane [1], Vikas Ajabe [1].

[1].Department of Quality Assurance Technique, Sanjivani College of Pharmaceutical Education and Research, Kopargaon, Maharashtra, India-423601.

[2].Department of Pharmaceutical chemistry, Sanjivani College of Pharmaceutical Education and Research, Kopargaon, Maharashtra, India-423601.

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KEYWORDS
Drug approval, CDSCO, Regulatory affairs, Regulatory Agencies, Medicines and Healthcare products Regulatory Agency (MHRA).

ABSTRACT:

Introduction: Regulatory affairs is also known as " Government Affairs ". In Current ,Pharmaceutical marketing and industrial area in India is rising rapidly . Therefore need of drug regulatory professionals to increasing the competition globally . Regulatory affairs is profession within pharmaceutical industries including clinical trials, Discovering ,Production ,Manufacture, Marketing and Welfare . Regulatory Affairs is help to company and also government authorities to avoid problems caused by various in proper data or informationRegulation in India can be mapped under – economic regulation , Regulation according public interest and environment regulation . For every country has its regulatory authority that include responsibility of analyzing , Evaluating the research data of new drugs /Medicinal products for safety and efficacy of general health service . In this present study expresses the drug approval process with the National authority in India : central drug standard control organisation (CDSCO).

Conclusions: DRA (Drug Regulatory authority) is a rewarding and approachable field that include legal and scientific both dynamic aspects of new drug development. Regulatory governing bodies (authorities) have been formed globally for confirmation of medicine that are useful for human by making drugs Standard quality safety and effectiveness. In India by CDSCO & DCGI. In that, include legislation that requires drugs to be trailed, manufacturer, tested and developed in according to guidelines given by authority, so that they are safe and patients will be well healthy and protected.

Introduction

1. Regulatory affairs (RA) is a career opportunity for regulating industries including such as pharmaceutical medicinal device , Veterinary medicine Cosmetics and other so on .Regulatory affairs is a bridge between pharmaceutical companies and government authorities for controlling efficacy and safety of medicinal products and also include its registration process so also known as ' government affairs . Regulatory affairs is a profession in the drug development world where one false move can bring years of research data to an unwelcome end .Therefore , an RA Professionals needs to understand all the information and to be hands on both the hardware and the software of the function most of companies ,they are major multinationals pharmaceutical corporations or small Biotechnology companies have specialist departments of regulatory affairs (RA) professionals.
2. For any new pharmaceutical product coming into the market ,it will required about 10-15 years ,spending much time and many money ,but take an current example of covid-19 Disease (Corona virus disease)

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is an infectious disease caused by a newly discovered corona virus (Sars-Cov -2),which has spread rapidly throughout the world. In march 2020,the World Health Organization (WHO) was declared the Covid -19 outbreak a pandemic. The Pandemic has destroyed health system , economic and social progress globally. For in that Emergency condition ,developing of a Corona virus vaccine WHO, ICH guidance Regulatory authorities and the Government of respective countries have taken strong action under the regulation to make vaccine .Developed Corona Virus Vaccine and its authorization is country by country . e.g. covishield , covaxin (CDSCO, india) , covid moderna -19 (USFDA) is an incredible and amazing surprise in the pharmaceutical business market with vaccine created in small time over a year . The Regulatory affairs system has a huge influence on the world. In Product management, clinical trials , and research and development , drug regulatory affairs is a research field. The global market is separated into two categories : Regulated and Semi-controlled markets .

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods) most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals[1-4]. The current Pharmaceutical Industry is well organized, systematic and compliant to international regulatory standards for manufacturing of Chemical and Biological drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics. Stringent GMPs are being followed for blood and its derivative as well as controlled manufacturing for Traditional Herbal Medicines, Cosmetics, Food and Dietary products which was otherwise differently a century before. Each regulatory system had faced certain circumstances which led to current well-defined controlled regulatory framework. This has resulted into systematic manufacturing and marketing of safe, efficacious and qualitative drugs. With the growth of industry, the legislations from each region have become more and more complex and created a need for regulatory professionals [5]. To understand the chronological development of the modern era of pharmaceutical industry and regulatory framework, we will glance through the historical evolution of regulations in USA, Europe and India [6]

3. The regulatory Agencies In Few Of The Countries Are As Follows

Sr.No.	Country	Authority
1	USA	USFDA
2	UK	MHRA
3	Australia	TGA
4	India	CDSCO
5	CANADA	HEATH CANADA
6	South Africa	MCC
7	Brazil	ANVISA
8	European Union	EMEA
9	China	SFDA
10	Nigeria	NAFDAC
11	New Zealand	MEDSAFE
12	Japan	MHLW
13	Zimbabwe	MCAZ
14	Switzerland	SWISSMEDIC
15	Korea	KFDA
16	Sri lanka	MoH

USA- FDA

The United States Food and Drug Administration (FDA or USFDA) is a federal agency of the Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products. The FDA has its headquarters in unincorporated White Oak, Maryland. The agency also has 223 field offices and 13 laboratories located throughout the 50 states, the United States Virgin Islands, and Puerto Rico. In 2008,

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the FDA began to post employees to foreign countries, including China, India, Costa Rica, Chile, Belgium, and the United Kingdom.

HEALTH CANADA

The department of the Government of Canada responsible for national health policy. The department itself is also responsible for numerous federal health-related agencies, including the Canadian Food Inspection Agency (CFIA) and the Public Health Agency of Canada (PHAC), among others. These organizations help to ensure compliance with federal law in a variety of healthcare, agricultural, and pharmaceutical activities. This responsibility also involves extensive collaboration with various other federal- and provincial-level organizations in order to ensure the safety of food, health, and pharmaceutical products—including the regulation of health research and pharmaceutical manufacturing/testing facilities.

Medicines and health care products regulatory agency (MHRA)-

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency of the Department of Health and Social Care in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe.

The MHRA has several independent advisory committees which provide the UK Government with information and guidance on the regulation of medicines and medical devices.

There are currently eight such committee

- Advisory Board on the Registration of Homeopathic Products
- Herbal Medicines Advisory Committee
- The Review Panel
- Independent Scientific Advisory Committee for MHRA database research
- Medicines Industry Liaison Group
- Innovation Office
- Blood Consultative Committee
- Devices Expert Advisory Committee

European Medicines Agency (Ema)-

The European Medicines Agency (EMA) is an agency of the European Union (EU) in charge of the evaluation and supervision of medicinal products. Prior to 2004, it was known as the European Agency for the Evaluation of Medicinal Products or European Medicines Evaluation Agency (EMEA)

- The EMA was set up in 1995, with funding from the European Union and the pharmaceutical industry, as well as indirect subsidy from member states, its stated intention to harmonise (but not replace) the work of existing national medicine regulatory bodies. The hope was that this plan would not only reduce the €350 million annual cost drug companies incurred by having to win separate approvals from each member state but also that it would eliminate the protectionist tendencies of sovereign states unwilling to approve new drugs that might compete with those already produced by domestic drug companies.

Objectives

Role of Regulatory Affairs (RA)Department :-

- The Regulatory Affairs (RA) department of the pharmaceutical industry is in responsibility or functioning of obtaining permission for new pharmaceutical medicine or drug that ensuring the approval maintenance process for as desiring firm or for as long.
- Right from the start of a product development, regulatory affairs experts provide technology and strategic guidance to quality control, R &D, production department, among other contributing significantly both financially and scientifically to the advancement of a development initiative & the enterprise.
- Keep in touch with customer practices, guidelines and international legislation.
- Ensure that a company's product comply with the current regulation.
- Keep up to the date with a company's product range.
- Manage review audit reports and compliance, regulatory and customer inspections.
- The Regulatory Affairs professional role is to keep track of the ever changing legislation in all the region in which company wishes to distribute to it's product

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with the advice on the legal and scientific restrains and requirements, and collect also evaluate the scientific data that their research and colleagues are generating.

- Regulation is a binding instruction issued by an agency that tells how to clarify and comply with the law, failures to follow regulation many end up into the "issued warning letter "sections of the FDA website , which is a fair for pharma industry.
- Maintain approved application and the record of registration fees paid against submission of DMF's (Drug Master File) and other documents.
- Regulatory affairs professional help company that avoid problem caused by badly kept records and inappropriate scientific thinking or poor presentation of data.
- A good Regulatory Affairs professional will have 'right first time' approaches and will play a very major and important part in coordinating scientific end with regulatory demand throughout the life of the products, helping to maximize the cost - effective use of the company resources.
- Also in the role to provide physician and other healthcare professionals with accurate and complete information about the safety, quality and effectiveness of the products.

Methods

National regulatory authority :-

India : Central Drug Standard Control Organization (CDSCO).

Drug Controller General Of India (DCGI)

US :- Food and Drug Administration (USFDA)

Europe :- European Directorate for Quality of Medicine (EDQM)

European medicine evolution agency (EMEA)

1)Health Authority (**HA**) **:-** The health authority to prepare drug regulatory guidelines and guidance documents which are conformity and complaint and conformity to existing laws and regulation and also coordinate with global and or regional regulatory body and in consultation with pharmaceutical manufacturer's association issue technical requirements and process for marketing Authorization Approval.

2)Pharmaceutical Industry :- According to regulatory necessity of quality, safety and efficacy of manufacturer develops drugs and applies for market Authorization.

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Figure :1 Regulatory Affairs Department

- **Preclinical Research :-** pharmacology and toxicology studies.
- **Clinical trails :-** paper writing, Evidence gathering and mathematical interpretation.
- **Manufacturing :-** includes extensive safeguards are in place to ensure that goods are efficient and clean.
- **Quality Control :-** Analyzing materials for purity, potency, safety and quality.

  Quality Assurance :- includes activities such as defeat audits, complains, auditing and record processing.

India: Approval process of New Drug

The Drug and Cosmetic Act 1940 and rule 1945 was passed by Indian government at Parliament to export, import and production of medicinal products. National regulatory Authority of India is Central Drug Standard Control Organization (CDSCO).

CDSCO is Indian government evaluatory agency that for applicant of new drug product for safety and product efficacy. CDSCO give review and analytical report to DCGI (Drug Controller General Of India).

DCGI is a provide license and authority of Licensing of India that approves and give permits a new drug product manufacturing and production and also marketing in India.

To start the marketing business in India with import or developing a new drug or new medicine in industry, it must require fill out FORM 44 and transfer the data that needed under Schedule Y of Drug and Cosmetics Act 1940 and rules 1945.(Rule 122A , 122B , and 122D with appendix I, IA, and VI) .

Following are some provisions of the Drug and Cosmetics Rule 1945 –

- In Rule 122A involve a request for a new drug approval
- In Rule 122B involve application of import permission of new drug or new medication
- In Rule 122D Fixed Dosage Combination permission to import and export
- In Rule 122DA involve request to approval to perform clinical trials for IND (Investigational New Drug)
- In Rule 122 involving majorly DAB that include compensation of injuries /death during clinical trials.

CDSCO : Central Drug Standard Control Organization

It under Directorate General of Health Services , Ministry of Health and Family Welfare ,Government of India .

It is National Regulatory Authority (NRA) of India .

CDSCO Headquarter located at FDA Bhawan ,Kotla Road, New Delhi. It has 6 Zonal offices, 4 sub Zonal offices, 13 port office and 7 Laboratories allover in India.

Role of CDSCO :-

1. For approval of new drug.
2. Processing and conducting the clinical trials.
3. Licensing and import registration.
4. Also approving license for blood banks, r-DNA Vaccine, LVPs vaccine, and some medicinal device and products.
5. New drug testing.

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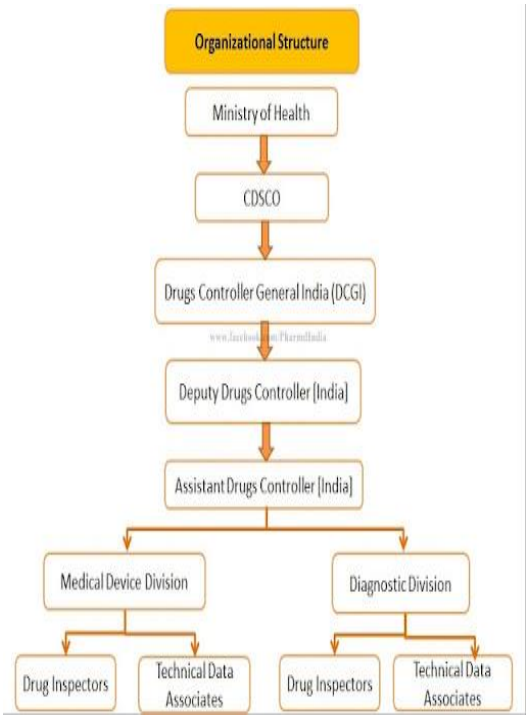
6. Drug and cosmetics banning.
7. Market surveillance through inspectorate center and state Authority.



- **Some Regulatory Agencies In The Countries-**

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Drug Approval Process in India :

It is given in three phase

First phase :-

1) Applicant is filling the application of IND (Investigational New Drug) with their informational studies to CDSCO headquarters.
2) All the information is examined by new drug division.
3) Then detailed review by IND committee.
4) With proper information of CDSCO – Recommendation to DCGI (Drug Controller General Of India).
5) Then IND application is approved .

Second phase :-

1) Application is given one copy of IND information to ethical committee with application.
2) Then ethical committee report the application of IND.
3) This process taken within 12 Weeks .

Third phase :-

1) In 1st phase, IND application is approved and in 2nd phase, ethical committee report is positive then 3rd phase is started.
2) In 3rd phase, clinical trials is started.
3) Then again give application for new drug registration to CDSCO.
4) Then finally review by DCGI .
5) If Review is positive or complete then **LICENSE IS GRANTED** .
6) If Review is not complete then refused to grant license .

Requirement of Drug Approval Process in India :-

- Registration process of New drug approval is one time .
- Approval timeline is 2-18 months.
- Approval presentation format - paper .
- Process validation is required.
- Batch size is Pilot scale batch.

Results

1. The Regulatory Affairs (RA) department of the pharmaceutical industry is in responsibility or functioning of obtaining permission for new pharmaceutical medicine or drug that ensuring the approval maintenance process for as desiring firm or for as long.
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