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REVIEW ARTICLE

An Overview On Drug Regulatory Agencies: Europe And India

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ABSTRACT

Regulatory affairs in pharmaceutical industry aim at the protection of human health. People and government spent money on drugs because of the role they can play in saving lives, restoring health, preventing diseases and stopping epidemics. But, in order to do so, drug must be safe, effective and of good quality. Since the purpose of drug is to diagnose, prevent or treat diseases or ailments in humans, they are products intimately linked with the advances in research and regulation. The pharmaceutical industry, while pursuing an international market, is obliged to comply with national regulations. So, in this review article, an overview of few drug regulatory agencies of two countries: Europe and India is covered.

Key Words: Drug regulatory agency, EDQM, EMEA, ICMR.

INTRODUCTION

Regulation promotes various activities to ensure safety, efficacy and quality of drugs. It also ensures the appropriateness and accuracy of product information. Before new medicines reach the prescription pad, the appropriate regulatory agencies, which assess their safety and efficacy, must first approve them. The production, import, storage, distribution, sale and supply of drugs must be regulated to ensure that they meet prescribed standards. The regulations are applied to all drugs from new, innovative to long established products. It also applies to drugs from different sources, regardless of whether they are produced domestically or imported by the public or private sector. Since a long time, many countries are trying to strengthen the regulatory processes at the national and international levels. To achieve this, guidelines and adequate norms and standards have been developed continuously. Unfortunately only few developed countries enjoy a well-operated drug regulatory system. Most of the countries have a week system while in some countries the system is totally lacking. Market circulation of substandard drugs is always a threat to the population. Regulatory agencies should be provided with adequate power so as to meet the drug regulatory objectives. The role, responsibilities and duties of the parties involved in drug regulation have to be defined clearly.

The scope, nature and practice of drug regulation, including priorities, standards, norms, enforcement strategies, resources available and the rigor of enforcement vary from country to country. However, the goals are generally the same: promotion and protection of public health by ensuring the safety, efficacy and quality of drugs and the appropriateness and accuracy of product information. But an effective drug regulatory body is one that demonstrates results in accordance with the objectives and targets set for it. 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 should be transparent.

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DRUG REGULATORY AGENCIES

Different organizations are working in different countries as drug regulatory agency at the national and international level. In this review article, an attempt has been made to get an overview of some of the drug regulatory agencies of EUROPE and INDIA.

EUROPE:

- European Directorate for the Quality of Medicines and Healthcare (EDQM).
- European Medicines Agency (EMEA).
- Heads of Medicines Agency (HMA).
- EU Legislation- Eudralex.

INDIA:

- Indian Council of Medical Research (ICMR).
- Central Drug Standard Control Organization (CDSCO).
- Government of India Directory of Health Organizations.
- Ministry of Health and Family Welfare.

HISTORY

- **EUROPE:**

1. EDQM:

It is established in 1996. But the base of EDQM is established in 1964 with the convection on the elaboration of European pharmacopoeia signed by 8 member states.

With time going, it involves:

- Harmonization and co-ordination of standardization, regulation and quality control of medicines (1991-1992).
- Blood transfusion and organ transplantation activities (2006)
- Pharmaceuticals and pharmaceutical care (2008)

At present, in 2011, ISO 9001:2008 certificate was extended to:

- The market surveillance of finished medicinal products.
- Issuance of guidelines for the release of human immunological and blood derivative medicinal products.

2. EMEA:

It is established in 1995 at London. It was formed to co-ordinate the processing of European Union (EU) license application.

It is a part of EU commission and co-ordinates scientific resources of the member state for evaluation, supervision and pharmacovigillance of medicinal products for both human and veterinary throughout the EU.

- **INDIA:**

ICMR:

It was created in 1911 as IRFA (Indian Research Fund Association) and redesigned as ICMR in 1949 at Delhi.

It is the one of the oldest medical research bodies in the world and funded by the government of India through the Ministry of Health and Family Welfare.

RESPONSIBILITIES

- **EUROPE:**

1. EDQM:

It is responsible for:

- Organizing the activities related to the procedure for the certification of suitability of European pharmacopoeia monographs.
- Organizes general market surveillance studies on products marketed throughout Europe.
- Testing a number of biological products.
- Setting the standards for the quality and safety of organs and substances of human origins, blood and blood derivatives.

2. EMEA:

It is responsible for:

- Protection and promotion of public and animal health.
- Scientific evaluation of application for European marketing authorization.
- Approval of medicines for human and animal use.
- Human medicines intended for treatment of:
  - HIV/AIDS
  - Cancer
  - Diabetes
  - Neurodegenerative diseases
  - Autoimmune disease
  - Viral diseases.

- **INDIA:**

1. ICMR:

The council promotes biomedical research in the country through Intramural as well as Extramural research.

Intramural research:

It is carried out through the council's 30 permanent research institutes.

These institutes pursue specific area of research such as tuberculosis, leprosy, cholera, viral diseases including AIDS, malaria, kala-azar, vector control, nutrition, food and drug

toxicology, reproduction, immunohaematology, oncology and medical statistics.

Extramural research:

It is promoted by ICMR by establishing centers for Advanced Research in different research areas around existing expertise and infrastructure in selected departments of Medical Colleges, Universities and other non ICMR Research Institutes.

The ICMR funds task force studies. Open ended research is conducted on the basis of application for grants-in-aid. The ICMR encourages human resource development in biomedical research. For retired medical scientists and teachers, the council offers the position of Emeritus Scientist to enable them to continue or take up research on specific biomedical topics.

CONCLUSION

Any drug regulatory body is an important participant in advancing the development of science, and hence has an important role to play. The pharmaceutical industry is now perhaps the most highly regulated of all industries demanding a high level of information to be submitted to governments before a pharmaceutical product is brought to the market place. Regulatory authorities can be said to be the function responsible for obtaining and maintaining licenses to market medicinal products in as many countries as is necessary. According to the present laws all organizations involved in the development and marketing of medicinal products are legally required to have some form of regulatory support.

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