www.pharmaerudition.org

ISSN: 2249-3875

International Journal of Pharmaceutical Erudition

Research for Present and Next Generation

AUG 2020

Vol: 10 Issue:02

(10-16)

ISSN 2249-3875

International Journal of Pharmaceutical Erudition

Review Article

DRUG REGULATORY AFFAIRS

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Drug Regulatory Affairs (DRA) is a vital unit in a pharmaceutical company. It is concern about the healthcare product lifecycle, it provide strategic, tactical and operational direction and support for working within regulations to expedite the development and delivery of safety and efficacy in pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, healthcare products to individuals around the world. Regulatory affairs (RA) professionals are employed in pharmaceutical industry, government, academic research and clinical institutions. As India is growing very rapidly in pharmaceutical sector, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. A regulatory affair is a somewhat new profession which has developed from the desire of governments to defend public health. Substantial documentation and data are required in these types of submissions, resulting in large, complex applications. Today 35 member countries along with 11 candidate countries and 4 international agencies have joined together to create the Pharmaceutical Inspection Cooperation Scheme (PIC/S) to promote a globally accepted GMP.

Keywords: Drug regulatory affairs, Regulatory agencies, FDA, Pharmaceutical Inspection Cooperation Scheme (PIC/S), GMP.

INTRODUCTION

Regulatory affairs in pharmaceutical Industry aim at the protection of Human Health. Regulation promotes various activities so as to ensure. Safely, 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 ageless, which assess their safety and efficacy must first approve them. The concept of regulation in pharmaceutical Industry is not new, mankind has always feel the need for negating the production, Import, storage, distribution sale, and supply of drug.

The negations are applied to all drugs from new, innovative to long established sources, regardless of wheat her they are produced domestically or import by the public or private sector.

Regulatory Agencies should be provided with adequate power so as to meet drug regulatory objectives.

Access to pharmaceutical products (Drug & Biological) requires national drug policies that are part of overall health policy.

The healthcare system counts on drug regulatory affairs (DRA) for good, safe and

effective medicines and for fair rules and control on drug trade, information and use. Regulatory Authorities are continually challenged by the rapid development and sophistication of medicinal products, new technologies, and health care techniques. any strategy to improve anything in the pharmaceutical area in Volvos DRA. Such developments pose a heavy demand on regulatory Affairs control system.

The scope, nature and practice of drug regulation, including priorities, standards, Norms, enforcement strategies, ensures available and the rigor of enforcement vary from country to country.[1]

Basic Function of DRA

The Basic function performed by DRA is more or less the same, which are-

- Licensing of Manufactures, Importers, and distributors, wholesale and retail outlets.
- Marketing Authoriz
- Quality control lab testing and application of Sanctions.
- Provision of drug Information and monitoring of drug promotions and Advertising.
- Adverse drug Reaction (ADR) monitoring.
- Authorization of clinical trials.
- Price control may or may not part of DRA.[2]

Requirements of Good Regulatory

The fundamental requirement for good regulation is clearly state mission and objective and a possibility to assess the Attainment of the same.

(A) Drug Regulatory Body should-

- Base its decisions on scientific evidences and facts.
- Provide efficient and timely services.
- Have a capacity to develop practicable regulatory and enforcement strategies.
- Apply sound management principles.
- Reach its objectives cost-effectively.
- Be Accountable.
- Operate to safe guard against corruption and conflict of interest.

Therefore, the patients should have an easy access to appropriate knowledge and technology about medicines. Regulatory practices also depend largely on the legal, Socio-economic, and political environment of the country.

Therefore, government support, a well-equipped legal frame work and centralized regulation, all are the perquisites of effective regulation.

Aspects of Drug Regulatory Authorities

Most of the drug regulatory Authorities have ministry of health as their supervisory Authority.

As all countries have very good regulatory practices, it can be deciphered that the year of foundation and Experience does not have a significant role to play in the effectiveness of regulatory functions. What-nearly makes drug regulation effective is apropos structure,

Adequate SOPS and guidelines, transparency in operation and efficient and Addition, the whole concept of having a centralized drug regulatory Authority is also very important. Where at most all countries have a single Authority responsible for carrying out the main function of regulating medicines.[3-4]

Regulatory Laws

The main regulatory laws operating in India are the Drugs and Cosmetics Act 1940, Drugs and Cosmetics Rules 1945, Drugs and Magic Remedies (objectionable advertisements) Act 1954, Narcotics and Psychotropic Substances Act 1985, Drugs (Prices control) Order 1995. Various other laws support the regulation of import, manufacture, pricing, distribution and sale of drugs. A Central Drug Laboratory has also been established in Calcutta to monitor the quality of drugs under the supervision of the government analyst. Although the Act and Rules date from some time ago, they are periodically updated and amendments to the existing Act/Rule are issued. [5-8]

The Indian Designs Act, 1911

In general, a design is the outer outlook of an article that a naked eye can see. The definition of a Design as per the act provides that a design means only the features of shape, configuration, pattern, ornament or composition of lines or colors applied to any article whether in two dimensional or three dimensional or both forms, by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye, but does not include any mode or principle of construction or anything which is in substance a mere mechanical device, and does not include any trademark or property mark or artistic work.

The Design Law in India is governed by the Designs Act, 2000. The old Design Act, 1911 was amended in 2000 to incorporate the amendments which were rendered necessary because of the tremendous progress made by India in the field of Science and Technology. The said Act was amended with a view to provide more protection to registered designs and to promote design activity in order to promote design element in an article of production. The Rules were last amended in the year 2008.

The Indian Intellectual Property Office (IPO) is the primary office, which comprises of the Trade Marks Registry, The Patent Office, and The Designs Office in India. The Designs Office has its head office at Kolkata and the other Branches of the Patent Office only function to accept design applications but all technical examination is conducted at the Kolkata Office.

Ever since the production of useful articles, design or rather industrial design as a form of human endeavor and as a part of industrial manufacture engaged the attention of human

society. From the dawn of civilization through the middle ages until the recent times man has been taking care to provide ornamentation to his products. The manufacturer of an article – who himself was its designer in early times always took care to see that his product was, in addition to being efficient, attractive to the eyes of the consumer. The elements which make the product attractive to the eyes are called design. The design of an article also makes it attractive in the market. As such, good design is encouraged and if good design is to be encouraged, the maker of design ought to be protected from those who would take advantage of the fruit of his labor. As such, the necessity for a law for protecting the interests of the makers of new and original designs in the same way as protecting the interests of new and useful inventions.[9-13]

Registration of Designs

Proprietor of new or original design should file his application in the prescribed form in the prescribed manner and accompanied by the prescribed fee, to the controller of designs.

Essential requirements for the registration of designs under the Act are as follows

- The design should be new or original and not published in India at the date of application for registration.
- The design should be relate to features of shape, configuration, pattern or ornamentation only of an article.
- The design should be applied to any article by an industrial process.
- The features of design in the finished article should appear to and judged solely by the eye.
- Any mode or principle of construction or operation or anything which is in substance a mere mechanical device would not be register able as a design.
- The design should not include any trademarks, stamps, labels, tokens, cards etc.
- Once designs registered, the controller shall grant a certificate of registration to the proprietor of the design.

A register of design is containing names and address of the proprietors of registered designs, notification of assignments and of transmission of registered designs etc. is kept at the patent office.

Registered proprietor of a design has copyright in the design for 5 years from

the date of registration. This period may be extended to a second and

third term of 5 year search at a time. Thus a design may be protected

or a maximum period of 15 years.[14-17]

Cancellation of Registration

A cancellation action may be filed by any person interested for cancellation of registration of the design on the following grounds.

- Design has been previously registered in

India.

- It has been published in India or in any other country prior to the date of registration.
- The design is not new or original design.
- The design is not registrable under this Act.
- It is not a design as defined under the Act.

The cancellation is to be filed before the Designs Office and the decision is appealable before the High Court. The Controller may also refer a cancellation petition to the High Court for decision.[18-20]

Piracy of Registered Design

(1)During the existence of copyright in any design it shall not be lawful for any person.

(a)For the purpose of sale to apply or cause to be applied to any article in any class of goods in which the design is registered the design or any fraudulent or obvious imitation thereof, except with the license or written consent of the registered proprietor, or to do anything with a view to enable the design to be so applied.

(b)To import for the purposes of sale, without the consent of the registered proprietor, any article belonging to the class in which the design has been registered, and having applied to it the design or any fraudulent or obvious imitation thereof.[21-23]

(c) Knowing that the design or any fraudulent or obvious imitation thereof has been applied to any article in any class of goods in which the design is registered without the consent of the registered proprietor, to publish or expose or cause to be published or exposed for sale that article.

(2)If any person acts in contravention of this section, he shall be liable for every contravention.

(a)To pay to the registered proprietor of the design a sum not exceeding five hundred rupees recoverable as a contract debt.

(b) If the proprietor elects to bring a suit for the recovery of damages for any such contravention; and for an injunction against the repetition thereof, to pay such damages as may be awarded and to be restrained by injunction accordingly.

(3)When the court makes a decree in a suit under sub-section, it shall send a copy of the decree to the Controller, who shall cause an entry thereof to be made in the Register of Designs.[23]

Offences of Penalties

Contravention of a copyright in a designs an offence and for every such offence the person liable may have to pay to the registered propriety or a sum not exceeding Rs. 500 subject to maximum of Rs. 1000.[24]

CONCLUSION

Many in the Regulatory Affairs Profession believe the New Approach to regulation will eventually be adopted for all healthcare products as it represents the best model for delivering new healthcare advances to market

in a reasonable time with acceptable safety. 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 fulfill 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's and hence the company's success. The proper conduct of its Regulatory Affairs activities is therefore of considerable economic importance for the company.

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