

## Review Article

Received on: 14-06-2016  
Accepted on: 02-07-2016  
Published on: 15-08-2016

**Corresponding Author:**

**\* Dr. Jignesh Shah**

Assistant professor  
(Quality Assurance),  
L. J. Institute of Pharmacy,  
Ahemdabad, Gujrat,  
India.

Contact no: +91 8866661571



e-mail: [jss192@gmail.com](mailto:jss192@gmail.com)

## Effect of Recent Amendment in Drug & Cosmetic Act in India

Vishva S. Patel\*, Dr. Jignesh Shah

### ABSTRACT

Globally, every country is the victim of substandard or spurious drugs, which result in life threatening issues, financial loss of consumer and manufacturer and loss in trust on health system. The aim of this enumerative review was to probe the extent on poor quality drugs with their consequences on public health and the preventive measures taken by the Indian pharmaceutical regulatory system. For minimizing spurious drugs or not of standard quality drugs, there is requirement of more strict regulation and legal action against the problem. However, India has taken some preventive steps in the country to fight against the poor quality drugs for protecting and promoting the public health.

**Key-words:** Public health, Clinical trial, Central licensing Authority, Drug controller general of India, labelling, Safety & Current.

*Cite this article as:*

Vishva S. Patel, Jignesh Shah Effect of Recent Amendment in Drug & Cosmetic Act in India, Asian Journal of Pharmaceutical Technology & Innovation, 04 (19); 2016, 45-50. [www.asianpharmtech.com](http://www.asianpharmtech.com)

### **Introduction:**

- Originally the D & C Act was passed in 1940. Then become subsequently Amended as

Follow:

- (1) The Repealing & Amending Act- 1949
- (2) The Adaptation of law order – 1950
- (3) The Drug (Amendment) Act – 1960
- (4) The Drug (Amendment) Act – 1962
- (5) The Drug (Amendment) Act – 1964
- (6) The Drug and Cosmetics (Amendment) Act – 1982
- (7) The Drug and Cosmetics (Amendment) Act – 1995
- (8) The Drug and Cosmetics (Amendment) Act -2007
- (9) The Drug and Cosmetics (Amendment) Act – 2008

### **Objectives:**

- a) This Act regulates the import, manufacture, distribution and sale of drugs and cosmetics.
- b) As Cosmetics contain injurious substance they require control.
- c) Act regulates manufacture and sale of drugs and cosmetics through licensing, so they are manufacture, distribution and sold only by qualified persons.
- d) To regulate and control over import of drugs.
- e) To prevent substandard in Drugs, presumably for maintaining high standards of Medical treatments.
  - The Act also provide the establishment of “Drugs Technical Advisory Board and Ayurvedic, Siddha and Unani Drugs Technical Advisory Board” and Drug Consultative Committee for Allopathic and Ayurvedic.
  - The Drugs and Cosmetics Act, 1940 is a consumer protection law, which is concerned with the standards and quality of drugs and cosmetics and regulates their import, manufacture, sale and distribution in the country.

### **❖ Drug and Cosmetics amendment of 2013:**

- The Drugs and Cosmetics (Amendment) Bill, 2013 was introduced in the Rajya Sabha On the 29th August, 2013 and referred to the Department-Related Parliamentary Standing Committee on Health and Family Welfare on the 09th September, 2013 for examination and report. The bill contains critical drugs and separate regulatory provisions for medical device and expensive provisions for regulating clinical trials.

### **❖ Major changes amendment proposed in 2013 bill:**

#### **❖ Insertion of 3 subchapters:**

1. Chapter 1A- constitution of central drug authority [expanded multi-level authority Chapter].
2. Chapter 1B- clinical Trial [permission & penalties]
3. Chapter 11A-Import, manufacture, sale, distribution, & export of medical devices.
  - (1) Chapter 1A-Constitution of central drug authority is declaration of conflict of interest by members and non-participation in such cases.
    - Vacancies, Defective, Nominations etc. Not be invalidated proceedings.
    - The appointment, salaries, allowances and pensions payable to the DCGI shall be determined by the central Government.
    - Necessary staffing for central drug authority will be created by central government in consultation with the former.
    - Power & functions of central drugs authority have been described.

(2) Chapter 1B-In The starting of Act clinical trial should perform take permission of central drug authority but now a day also take permission of drug controller general of India & central licensing authority. Such as:

1. No person shall initiate or conduct any clinical trial in respect of a new drug or IND or Medical device or device IND or BE study of any drug in human subjects without permission by central licensing Authority.
2. No person shall initiate or conduct any clinical trial without an ethics committee approval
3. No person shall initiate or conduct any clinical trial before it is registered with the central drug Authority

❖ **PRINCIPAL, POWER & FUNCTIONS OF CENTRAL DRUG AUTHORITY.**

- a) Issue, renew, suspend or cancel licenses or export & import manufacture drugs Cosmetics or medical devices or clinical trial.
- b) Collect the fees or charge for issues or renewal of licenses, certificate, approval & Permissions issued by the central licensing Authority.
- c) Discharge any other functions as may be assigned to him by the central drug Authority.

❖ **Other responsibilities:**

- DCGI shall have administrative control over the officers & employees of central drug Authority.
- Accounts & Audit will be maintained by the central drug authority.

❖ **Recent amendments in Schedule Y**

a) Introduction of Rule 122DAB (also called as the Drug and Cosmetics Act (First Amendment) and Appendix XII:

- This rule provides directives about compensation for injury and death during the clinical trials.
- It states that a subject is entitled to compensation if injury or death is due to: Adverse effect of investigational product. (IP).
- Failure of IP to provide intended therapeutic effect. Use of placebo in a placebo-controlled trial.
- For injury to a child in-utero because of the participation of parent in a clinical trial. Any clinical trial procedures involved in the study.

b) Introduction of Rule 122DAC (Second Amendment):

- This rule specifies various conditions for conduct and inspection of clinical trials. It specifies the prerequisites required for a clinical trial to be considered as adequate, in order for the licensing.
  - In January, 2003, the Central Government constituted an Expert Committee under the Chairmanship of Dr. R.A. Mashelker, Director General of the Council of Industrial Research (CSIR) to undertake comprehensive examination of drug regulatory issues, including the hazard of spurious drugs and to suggest measures to improve the drug Administration in the country.
  - The Committee noted that the problems in the drug regulatory system in the country are primarily due to inadequate or weak drug control infrastructure at the state and central level and therefore, recommended centralized licensing of manufacture of drugs.
  - The Committee further recommended for a strong, well equipped, empowered, independent and professionally managed Central Drugs Standard Control Organization (CDSCO) which may be given the status of Central Drug Administration reporting directly to the central Government.
  - The said Bill was referred to the Department-related Parliamentary Standing Committee on Health and Family Welfare for examination and Report.
- The provisions relating to regulation of clinical trials and exports in the Bill also needed to be made more comprehensive and therefore, the Central government decided to withdraw the Bill of 2007 and introduce a new Bill, namely, the Drugs and Cosmetics (Amendment) Bill, 2013.
- The new Bill contains more comprehensive provisions for regulating clinical trials and exports and a revised composition of the Central Drugs Authority.

- Almost all the recommendations of the Parliamentary Standing Committee on the 2007 Bill have been accepted and incorporated in the new Bill. In accordance with the Government's decision, So 2007 Bill has been withdrawn and the new Bill, namely Drugs & Cosmetic (Amendment) Bill, 2013 has been introduced in its place on 29.8.2013. The Drugs & Cosmetics (Amendment) Bill, 2013 contains more comprehensive provisions than the 2007 Bill.

**The salient features of the Bill are as follows:**

(i) New / amended definition of many terms such as drugs, medical device, new drugs, investigational new drugs, investigational medical device, clinical trials, Ethics Committee, Investigator, Protocol, Sponsor, BE and BA studies, etc.

(ii) Creation of Central Drugs Authority (CDA) with revised structure and composition, as follows:

(a) Secretary to the government of India, Ministry of Health and Family Welfare, department of Health and Family Welfare--Chairperson, ex officio;

(b) Secretary to the government of India, ministry of health and family Welfare, department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy-- Member, ex officio;

(c) Secretary to the Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals-- Member, ex officio;

(d) Secretary, Department of Health Research & Director General, Indian Council of Medical Research, Ministry of Health and Family Welfare -- Member, ex officio;

-The Government of India has also published a draft amendment to Drugs and Cosmetics Act, and Rules (D&C Act and Rules) on 24th October 2013. In This creates regulatory provisions of defining phytopharmaceuticals (botanical-based drugs) and a schedule providing requirements of scientific data on quality, safety, and efficacy to evaluate and marketing authorization for a plant-based lead as a drug on similar lines to synthetic, chemical moieties [4]

- In India, it is known that though the new draft regulation was not present, Guggulu tablets (for treatment of hypercholesterolemia), Gingko-biloba tablets (to treat temporary loss of memory), and Silymarin capsules (to treat liver disorders)[2] have been approved and marked as drugs by the Central Drugs Standards Control Organization (Drug Controller General of India).
- There is a need for development of science-based drugs from botanicals especially from the basket of traditional knowledge (namely Ayurveda), which has a long history of safety and use documented in the authoritative books. The authors are not the first people to have felt this need for separate and appropriate regulatory provision for botanicals as drugs. In fact US Food and Drug Administration (FDA) has published a document titled "Guidance to Industry for Botanical Drugs" in June 2004.[3]
- It is also known that US FDA has issued a marketing authorization to a topical cream containing standardized green tea extract as a US botanical for treating genital warts after evaluating the respective Investigational New Drug application scientifically.

-At this juncture it is important to recognize the following:

1. Phytopharmaceuticals can be from a botanical (medicinal plant) from any part of the globe.

2. Phytopharmaceutical's proposal above is in line with regulations in USA, China, and other countries involving scientific evaluation and data generation. It does not simply depend on traditional knowledge alone.

3. Phytopharmaceutical as proposed above permits development as a drug under chapter IV of D & C Rules, adopting the drug development technologies involving modern techniques of solvent extraction, fractionation, potentiating steps, add-back techniques, modern extraction techniques (like CO<sub>2</sub> based extraction), freeze-drying, formulation developments, and many other techniques.

## SUMMARY:

- In the last few years, the Indian pharmaceutical field has seen an immense growth both in terms of domestic and international stratum and recognized itself as one of the largest in terms of volume. The emerging market of medical devices is one of the biggest Contributions behind the growth in this overall pharmaceutical field in India.
- The Bill proposes changes in the regulation of the import, export, manufacture, distribution and sale of drugs, cosmetics and medical devices and to ensure safety, efficacy, quality and conduct of clinical trials.
- The definition of drugs is changed to include new drugs that are:
  - (i) Not in significant use in India and are not recognized as effective and safe by the Drugs Controller General of India (DCGI).
  - (ii) Approved by the DCGI for certain claims but are being marketed with modified/new claims.
- Under the Act, medical devices were covered under the definition of drugs. The Bill changes this by adding a definition of medical devices to include any instrument, implant, material or other article, including the software, intended to be used specially for human beings or animals for the specific purposes of diagnosis, prevention, treatment of any disease or, injury, modification of the body's anatomy and sustaining life
- Clinical trials are defined in relation to drugs, cosmetics and medical, and involve their systematic study with the objective of determining their safety, efficacy, performance or tolerance. Anyone initiating a clinical trial has to register with the Central Drug Authority (CDA) and get approval from an Ethics Committee registered with it.
- The Bill creates provisions for the medical treatment and compensation in case of injury or death of a person during participation in a clinical trial.
- The DCGI also has the sole power to issue license for the manufacture, sale, and export of 17 categories of drugs.
- The Bill constitutes the Medical Devices Technical Advisory Board and the Drugs Technical Advisory Board to advise the central and state governments.
- In order to ensure standard quality of drugs, cosmetics, and medical devices, the Bill specifies conditions under which they will be considered misbranded, adulterated, and spurious and specifies penalties and offences for the same.
- In the last amendment the Government establishes rules and regulations regarding "Clinical trial" subjects as per chapter 1B.

There are many beneficial impacts of the above amendments such as

- 1) Any person voluntarily takes part in research activity without the fear of his death & its consequences such as financial condition.
- 2) More and more clinical trial on the subject gives the society in near future.
  - Chapter 1A amendment also gives some advantages like uniformity regarding rules and regulations of quality assurance of all medicines of central level drug authority.
  - Chapter 11A amendments enhances the use of medicinal device and thus give the force of replacement treatment for the Indian patient.

## CONCLUSION:

- As India is approaching towards globalization in the recent developments in the Pharmaceutical sector occurring worldwide, India portrays to be a prospective hub for many big foreign Pharmaceutical Companies for drug innovation, based on its Comparatively low cost and skill base, this opportunity for the betterment of the country.
- Even aware that in our Country there is existence of "right" to lead a safe and healthy life.
- The present study highlights the impact of the new regulation on clinical trial registered for approval of DCGI.

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