CHANGING INDIAN SCENARIO – DRUGS & COSMETIC LAWS

The Drugs and Cosmetics (Amendment) Bill, 2015

The Union health ministry on 31st December 2014, has released the draft Drugs and Cosmetics (Amendment) Bill, 2015 to amend the Drugs and Cosmetics Act, 1940 for up-gradation and introduction of provisions for clinical trials and regulation of medical devices.

Some of the key amendments, which the Bill proposes in the Drugs and Cosmetics Act, 1940 are as under:-

1. In the long title, the following shall be substituted, namely:
   "An Act to regulate the import, manufacture, distribution and sale of drugs, cosmetics and medical devices, to ensure their safety, efficacy, quality and conduct of clinical trials and for matters connected therewith or incidental thereto".

2. In section 1, of the principal Act, in sub-section (1), for the words "and Cosmetics", the words ", Cosmetics and Medical Devices" shall be substituted.

3. Substitution of words "Drugs Control Officer" for word "Inspector".

4. Substitution of words "the Narcotic Drugs and Psychotropic Substances Act, 1985" for the words ""the Dangerous Drugs Act, 1930".

5. Substitution of new section for section 3 which includes definitions.

6. The Bill proposes to insert a separate chapter on clinical trial, Chapter 4A, according to which "No person, sponsor, clinical research organization or any other organization or investigator, shall conduct any clinical trial in respect of a new drug, investigational new drug, notified category of new medical device and investigational new medical device, new cosmetic, bioavailability or bioequivalence study of any new drug, in human participants except under, and in accordance with, the permission granted by the Central Licencing Authority in such form and manner as may be prescribed".

7. In Chapter II of the principal Act, for the Chapter heading, the Chapter heading "TECHNICAL ADVISORY BOARDS, CENTRAL DRUGS LABORATORIES AND CONSULTATIVE COMMITTEE" shall be substituted.

8. Insertion of new section 5A as per which the Central Government shall, by notification, constitute a Board to be called the Medical Devices Technical Advisory Board to advise the Central Government and State Governments on technical matters pertaining to medical devices, arising out of administration of this Act and to carry out other functions assigned to it by or under this Act.

9. Substitution of following new section for section 7:

   "The Central Government may constitute a consultative committee to be called the Drugs, Cosmetics and Medical Devices Consultative Committee to advise the Central Government, the State Governments, the Drugs Technical Advisory Board and the Medical Device Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act."

10. Insertion of new chapter, Chapter IIA on import, manufacture, sale and distribution of notified category of medical device.

    As per this chapter, "The classification, standards, manufacturing, testing, distribution, labeling, packaging, essential requirements for quality, safety and performance, adverse events, post marketing surveillance, conformity assessment bodies, exemptions, procedure to regulate notified category of medical device, manner and conditions of licence shall be such as may be prescribed".

11. Insertion of Section 9E on adulterated cosmetics.

12. Insertion of new section 39 on removal of difficulty by the provisions made by the Central Government.

13. Insertion of the Third Schedule which includes the categories of drugs for which the central licensing authority is empowered to issue licence and permission.

14. In the Second Schedule, the word "Proprietary" shall be substituted for the words "Patent or Proprietary".

15. Insertion of new section 35A on convicted person liable on cost of storage of any article.

16. Insertion of new section 35B which states that the seized spurious or misbranded or adulterated or not of standard quality drugs, cosmetics and notified category of medical devices shall be destroyed by the Official Authority.

17. Insertion of Section 34AAA on penalty for submission of wrong information or refusal to furnish correct information to the Licensing Authority.

18. Insertion of Section 30A on the recovery of the amount including simple interest as an arrear of land revenue, by the Central Government or the State Government.

19. New Section shall be substituted for Section 25 on the "Report of Government Analyst" in respect of sample of drug, cosmetic or notified category of medical device as evidence.

20. Substitution of new section for section 18 on prohibition of manufacture and sale of drugs and cosmetics.

21. Some other changes shall also be made in other sections of the Drugs and Cosmetics Act, 1940.

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