

Bill Summary

The Drugs and Cosmetics (Amendment) Bill, 2013

- The Drugs and Cosmetics (Amendment) Bill, 2013 was introduced in the Rajya Sabha on August 29, 2013. The Bill amends the Drugs and Cosmetics Act, 1940 and changes the name of the Act to the Drugs, Cosmetics and Medical Devices Act, 1940.
- 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 recognised 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; (iii) a fixed dose combination of two or more drugs, which are individually approved but are being combined for the first time in a fixed/changed ratio; and (iv) all vaccines, Recombinant Deoxyribonucleic Acid derived products, Living Modified Organisms, stem cells, gene therapeutic products etc. which are intended to be used as drugs.
- 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 or alleviation 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 or due to it.
- The Central Government shall establish a CDA to subsume the existing Central Drugs Standards Control Organisation. The CDA will be composed of representatives from the Ministries of Health and Family Welfare, Law, Commerce and Industry, Science and Technology, Chemicals and Fertilisers, DCGI, Indian Council of Medical Research, Directorate General of Health Services, and other experts nominated by the central government, including those from state licensing authorities.
- The CDA shall among others, specify guidelines, structures and requirements for the effective functioning of the central and state licensing authorities; review, suspend or cancel any licence or permission issued by them; and decide on disputes between two or more state licensing authorities relating to the provisions of the Act and rules and regulations made under it
- The DCGI is the central licensing authority that has the power to issue, renew, suspend or cancel licences for import, export or manufacture of drugs, cosmetics or medical devices or permission for conducting clinical trials. The DCGI also has the sole power to issue licenses 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 and the CDA on technical matters pertaining to medical devices, and drugs.
- 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.

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