THE DRUGS AND COSMETICS ACT, 1940(Amended in 1995)

The Drugs and Cosmetics Act is mainly aimed to regulate the import, manufacture, distribution and sale of Drugs and Cosmetics, presumably for maintaining high standards of medical treatment. Substandard medicines / drugs may cause severe damage to lives of people.

All Medicines (Ayurvedic, Siddha, and Unani) for internal or external use of human being or animals and all substances (other than food) intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparation applied on human body or to destroy insects.

The Central or State government have power to make rules and appoint inspector to control or inspect any drug or cosmetic for its standardisation and safety which can be tested in the Central or State Drug laboratory. The Government can prohibit manufacturing, importing or selling of any drug or cosmetic. Violation of law by any person or corporate manager or owner is liable for punishment for a term which may extend to 3-10 years and shall also be liable to fine which could be five hundred or ten thousand rupee or with both.

Drugs and Cosmetic Rules 1995 contains the list of drugs for which license is required by manufacturer, importers, and exporters. Recently 'in vitro' blood groups, sera and in vitro diagnostic devices for HIV, HBsAg, and HCV are also included in schedule CI. All imported drugs in indigenous manufacturers have to register to control over the quality of imported as well as locally manufacturing kits.

Reference

Drugs and Cosmetic Rules 1995 vide Gazette Notification - GSR No. 86 (E) A 6/2/02.

The Gazette of India. The Drugs and Cosmetics Act 1940. No. 23 of 1940.