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Health ministry proposes new draft guidelines for Drugs, Medical Devices and Cosmetics Bill, 2022

01 August 2022 | News

Calls for suggestions, comments and objections from various stakeholders

The Union Health Ministry is in the process to revise the outdated Drugs and Cosmetics Act of 1940 with an updated one where the focus will be more on laying down strict regulatory guidelines to keep pace with changing needs and technology. The ministry has called for suggestions, comments and objections from various stakeholders.

The bill proposes new definitions for clinical trials, over-the-counter drugs, manufacturers, medical devices, new drugs, bioavailability studies, investigational new drugs and imported spurious drugs, among others. It seeks to bring in regulations for online pharmacies and medical devices and penalties such as imprisonment and compensation in case of injury or death during clinical trials for drugs.
The draft also proposes that no clinical trial can be carried out without permission, medical management and compensation for injury or death, the draft proposes. The bill further mentions that no person shall himself or by any other person on his behalf sell, stock or exhibit or offer for sale or distribute any drug by online mode (e-pharmacy) except under and following a licence or permission issued in such manner as may be prescribed.

The Centre has proposed a separate Drugs Technical Advisory Board (DTAB) and Medical Devices Technical Advisory Board (MDTAB). Other than officials from the health ministry, the board will also include people from the department of atomic energy, department of science and technology, Ministry of Electronics, DRDO, and experts in the field of biomedical technology, biomaterials, and polymer technology. The draft proposes to allow the Centre to waive the requirement of conducting a clinical investigation for the manufacture or import of a new medical device in the public interest.

It proposes medical device testing centres on the lines of drug laboratories in states and at the central level and states that medical management and compensation have to be provided to persons who are injured while participating in such trials. And, in case of death, the legal heir of the participant should be awarded compensation.

The Bill proposes that the Central government must come up with rules to regulate the online sale of drugs and for online

pharmacies to operate “following a licence or permission issued”. The Bill also includes a chapter on Ayurveda, Siddha, Sowa-Rigpa, Unani and Homeopathy, and their respective Drug Technical Advisory Boards.