New Drugs, Medical Devices and Cosmetics Draft Bill, 2022

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'First published on LEXOLOGY' By: Madhu Rewari and Vaishali Sharma The Union Health Ministry has released a draft of **The Drugs, Medical Devices and Cosmetics Bill, 2022**. Once implemented, the current Drugs and Cosmetics Act, 1940 (*hereinafter referred as "D&C Act"),* of the pre independence era, will be repealed. D&C Act presently governs the manufacture, distribution, and import as well as efficacy, safety, and compliance of the medicines and cosmetics sold in India with state quality standards. With changing times technology plays a major role in drug discovery, development, clinical trials along with the rise of e-pharmacy portals, updating the current laws is the need of the hour. The draft Bill intends to address such growing concerns. The major provisions of the Bill are as below:

- **New definitions:** For greater clarity, efficient operation, and effective implementation, the draft Bill adds a number of new definitions or provisions in Chapter I, including medical device, drug, new drugs, over-the-counter (OTC) drugs, cosmetics, adulterated cosmetics, bioequivalence study, bioavailability study, clinical trial, clinical investigation, controlling authority, manufacture amongst others.
- **Medical devices to be treated separately and distinct from Drugs**: Currently, all medical devices are covered as 'Drug' and regulated as per Drugs & Cosmetics Act and Medical Devices Rules 2020. The draft Bill now intends to repeal the current laws and proposes a new definition for medical devices placing them outside the purview of 'Drugs'. Also, Chapter II of the draft Bill has a recommendation for constitution of a Medical Devices Technical Advisory Board (MDTAB), separate from Drug Technical Advisory Board (DTAB), including specialists from various associations to recommend the Central Government in technical matters.

Under the new draft Bill, provisions to name or build medical device testing facilities for the purpose of evaluating and testing medical devices for regulators and business have also been included.

- **Constitution of the Drugs, Medical Devices and Cosmetics Consultative Committee**: To advise the Central Government, the State Governments, the Drugs Technical Advisory Board and the Medical Devices Technical Advisory Board on any matter and to secure uniformity in the country in the administration of this Act and the rules made thereunder. The Drugs Controller General, India (DCGI) shall be the Chairperson of the said Committee.
- Chapter III deals with standards being laid down for import of drugs and cosmetics. Chapter IV deals with manufacture, sale and distribution of drugs and cosmetics and clinical trial of drugs. Whereas Chapter VI deals with standardising import, manufacture, sale and distribution and clinical investigation of medical devices.

- Chapter V of the draft Bill features a distinct chapter for Ayurvedic, Unani, and Siddha drugs and cosmetics that are currently covered by the D& C Act. In addition, such Chapter intends to regulate Sowa Rigpa and homoeopathy for the first-time including standardising its import, manufacture, sale, distribution and clinical trial of such products.

The Central Drug Regulatory authority for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs and cosmetics appointed by the Central Government shall regulate the manufacture and sale of such drugs and cosmetics. The Central regulatory authority shall also develop such infrastructure, at State level as prescribed by the Central Government to effectively enforce the provisions in this Act for the quality assurance of such drugs and cosmetics.

- **E-pharmacy:** For the first time, a law to regulate highly unregulated and ever-growing space of e-pharmacies is planned to be introduced. The draft Bill now seeks to control e-pharmacies and hence it has been clearly specified that no person shall himself or by any other person on his behalf sell, or stock or exhibit or offer for sale, or distribute, any drug by online mode (e-pharmacy) except under and in accordance with a licence or permission issued in such manner as may be prescribed. However, the draft Bill does not mention the procedure and guidelines with respect to issuance of licenses of the e-pharmacies yet which may be laid down post consultation with the Central Government.
- **New provisions with respect to clinical trials introduced**:
- Currently Drugs and Clinical Trial Rules, 2019 are the only regulation in this regard. Now a separate Chapter has been included in the draft Bill for clinical trials and investigation. The draft Bill prohibits clinical trials or clinical investigations of drugs and medical devices without permission from the central licensing authority.
- The Central Government has been authorised to create measures for the Central Licensing Authority to forgo the necessity of performing clinical trials for the production or import of new drugs or experimental new medications in the nation in the interest of public health or during drug emergency period.
- The draft Bill lays the onus of providing medical management for any injury arising due to the trial on the investigators.
- The draft Bill makes provisions for compensation to participants or their legal heirs for injury or death suffered in clinical trials and investigations for drugs and medical devices.
- There is a new provision for imprisonment, and fine amounting to double the compensation amount if the compensation is not paid. This is seen as a welcome change as monetary compensation of few lakhs was not a deterrent for big companies conducting trials as of date whereas imprisonment might act as one.

It is relevant to note here that the Draft Bill completely misses on provisions for recalling of drugs, cosmetics or medical devices if found to be in violation of the provisions of law. However, the draft Bill provides a mechanism towards regulating online sale or distribution of medical devices, which will be a welcome move for the industry. Though, how such sale or distribution is tackled including tackling issues regarding sale of counterfeits, spurious, misbranded products, along with the intermediary liability issues that are inherent to the e-pharmacy industry, is yet to be seen. The wait is to witness the final law that comes into force and the impact and effectiveness with which it may empower the authorities to enforce drug, cosmetics and medical devices regulation in the country.
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