Drugs, Medical Devices and Cosmetics Bill, 2023: An attempt at modernizing the regime governing medical products

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Background

The Drugs, Medical Devices and Cosmetics Bill, 2023 (the "**Drugs Bill**") seeks to replace the Drugs and Cosmetics Act, 1940 (the "**Drugs Act**") as the law governing the manufacture, sale and distribution of drugs, medical devices and cosmetics. The Drugs Bill aims to adapt to the changing landscape of medical products, considering a growing global focus towards health and medication, and an advancement in technology. In this update, we have analyzed the key features of the Drugs Bill.

Medical devices treated as a separate category and will require approval prior to sale

The Drugs Act treated medical devices as a subset of "drugs" and the same set of laws governed both types of products. However, due to the increase in sophistication and improvement in technology of medical devices, the need to treat such devices as a distinct category is apparent, and the Drugs Bill regulates such devices differently from drugs.

(i) The Drugs Bill introduces a more comprehensive definition for medical devices to include all types of equipment and software for diagnosis and disease management, including implants, devices for assistance with disabilities, life support systems, disinfection instruments, reagents, conception control devices, in-vitro kits, apparatus and equipment, etc. These devices have been given a risk-based classification.

(ii) The Central Government has proposed to constitute a new "Medical Devices Technical Advisory Board", which will advise the government on the technical aspects of medical devices and will perform functions analogous to those performed by the Drugs Technical Advisory Board. Officials from the Health Ministry, Department of Atomic Energy, Department of Science and Technology, Ministry of Electronics, Defence Research and Development Organization along with experts in the fields of biomedical, biomaterial and polymer technologies will be a part of this board.

(iii) Central and State Medical Device Testing Centres are to be set up along the lines of Central and State Drugs Laboratories to test and evaluate medical devices.

The Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy ("AYUSH") framework has been made more comprehensive

Several key changes have been made to the AYUSH framework to make it more comprehensive.

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(i) The Drugs Act was limited in its scope to Ayurvedic, Siddha and Unani medicine. The Drugs Bill expands the scope to include Sowa-Rigpa and Homeopathy. The Drugs Bill also creates two (2) categories of drugs manufactured under these systems of medicine. The first category, defined as "drugs", pertain to drugs recognized by an official pharmacopoeia or authoritative books, whereas the category of "innovative drug" refers to drugs made using natural substances but not specified in the respective authoritative texts. Separate boards are proposed to be set up to oversee each category of drugs under the AYUSH umbrella.

While bringing in other forms of traditional medicine under the scope of the regulation is a commendable step, creating a separate category for innovative drugs within the traditional medicine framework may create certain complications. As the definition of innovative drugs includes drugs manufactured by using natural substances that are not specified in the respective authoritative texts, these drugs are essentially new formulations. As it is unclear whether these innovative drugs will be as effective as chemical drugs, it may lead to cases of misselling. As such, it may be better to treat them at par with standard drugs in regulating their creation, manufacture and distribution.

(ii) A separate National Medicinal Plant Board will oversee matters related to medicinal plants. A further Scientific Research Board will be set up to support an interdisciplinary approach and to promote the use of modern science and technology in developing innovative AYUSH drugs.

Regulation of e-pharmacies

Acknowledging the need to regulate the mushrooming e-pharmacies in India, the Drugs Bill gives powers to the Central Government to come up with rules to regulate the online sale of drugs. In addition, the Drugs Bill also prohibits the sale, stocking, exhibition or offer for sale, or distribution of any drugs/medicines online without obtaining a license or permission. This is an important step given that unregulated e-pharmacies may lead to the sale of prescription drugs without proper checks and balances. The relevant authority and the process of obtaining such license and permission will be prescribed by the Central Government. E-pharmacies should brace for more regulatory compliance.

Clinical trials and clinical investigations

Although clinical trials (for drugs) and clinical investigations (for medical devices) were regulated under the New Drugs and Clinical Trials Rules, 2019 (the "**NDCT Rules**") and the Medical Devices Rules, 2017 (the "**Devices Rules**"), respectively, they were not regulated by the Drugs Act. The Drugs Bill seeks to cover the aspects unregulated by the Drugs Act and aims to provide a more comprehensive framework than the one currently existing. The Drugs Bill restates requirements under the NDCT Rules and Devices Rules, viz., seeking permission from the Central Licensing Authority prior to conducting trials or investigations, provision of medical management and compensation to participants who face adverse impacts because

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of the trial or investigation, etc.

Penalties

As the penalties prescribed under the Drugs Act, especially the quantum of monetary penalties, have been thought to be insufficient. Therefore, harsher monetary penalties in the form of a fine being the greater of INR1,500,000 (approx. US$18,217) or three times the value of drugs confiscated, and imprisonment extending up to life imprisonment in certain cases (importing or manufacturing sub-standard, adulterated or spurious drugs that are likely to cause death or grievous bodily harm) have been imposed. In case a drug causes an adverse impact on the consumer, the fine amount is to be delivered to such consumer (or heirs in the event of death).

Other miscellaneous changes

Certain other miscellaneous changes are proposed in the Drugs Bill. These include:

(i) The Central Government is empowered to regulate or restrict the import of essential drugs in emergencies arising out of epidemics or natural calamities in public interest.

(ii) Drugs to induce miscarriage is added to the list of drugs whose manufacture is prohibited.

(iii) "Inspectors" under the Drugs Act are designated as "Drugs Control Officers" under the Drugs Bill, and they are authorized to issue "Improvement Notices" if a licensee (who has been granted a license to manufacture a drug or device) fails to comply with any of the provisions of the Drugs Bill. They can also specify measures needed to be taken by the licensee to secure compliance. If compliance is not secured, the license may be cancelled or suspended, either completely or with respect to any specific drug(s) or device(s).

Conclusion

The Drugs Bill represents a crucial stride towards an overhaul of the present drugs and cosmetics regulation system in India, which has not kept up with the myriad changes brought about by technological advancement. The Drugs Bill addresses the pressing need for a comprehensive framework capable of accommodating the advances in modern healthcare. The Drugs Bill also places an emphasis on diversified and compartmentalized regulation and has created independent governing bodies that possess specialized knowledge, which is especially advantageous to the industry.

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