

For better patient care

The new Drugs Bill must be passed at the earliest

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The Drugs, Medical Devices and Cosmetics Bill 2023, aims to oversee and control the import, production, distribution and sale of drugs, medical devices and cosmetics. Its primary objectives include guaranteeing standards in quality, safety, efficacy, and performance. Moreover, it focuses on regulating clinical trials for new drugs, investigations into experimental medical devices, and evaluation of the clinical performance of new in-vitro medical devices.

This encompasses a broad spectrum of drug products including Ayurveda, Unani, Siddha, Sowa-Rigpa, and homeopathic products in its oversight of drugs, medical devices, and cosmetics. The draft Bill seeks to replace the 83-year-old Drugs and Cosmetics Act of 1940, with a transformative step to accommodate the new requirements within the regulated space and adaptation of new technology.

The various provisions prioritising patient safety makes this Bill a compelling one that needs to be passed at the earliest opportunity.

QUALITY CULTURE

For the pharma industry quality is fundamental, and this proposed Bill encourages innovation and R&D, strengthens quality management systems, and propels the pharma industry to the next level. There are several salient features of the Bill. Among them, the Centre will regulate the import of drugs, cosmetics, medical devices, and the clinical trials of new drugs and clinical investigation of new medical devices. Sales and distribution will be regulated by the States. It has provisions for regulation or restriction of the import of drugs in public interest.

It also provides for emergency approval and accelerated approval and use of new drugs and investigational medical devices, and the creation of certain quasi-judicial authorities to adjudicate certain procedural and minor offences. There are also separate verticals for the regulation of the pharma and medical devices industries.

The Bill signifies a pivotal step in revamping India's current drugs and cosmetics regulatory framework. It aims to meet the growing demands of modern healthcare by providing a comprehensive structure that aligns with these advancements.



FOCUS. On modern healthcare

Moreover, the Bill prioritises segmented and diversified regulation, establishing specialised governing bodies equipped with focused expertise, offering substantial advantage to the industry. The much-awaited Bill should be immediately passed in Parliament as this has an impact on patient welfare.

The Bill brings forth a distinct classification for medical devices, encompassing a wide range of diagnostic tools and associated software. The expanded definition will cover implants, devices aiding those with disabilities, life support systems, disinfection instruments, as well as reagents or kits. Previously, under the 1940 Act, medical devices were regulated as drugs, which was a pain point for the medical devices industry.

It also provides for the regulation of Good Manufacturing Practices and Good Distribution Practices to promote the quality of medical products at the supply chain level. The Bill also has a framework for clinical trials while protecting the rights, safety, and well-being of participants, and ensuring compensation in case of injury and death.

It provides for the promotion of global clinical trials, and early access opportunity to the latest drugs for use by the public. It also has recall provisions to withdraw drugs from the market in certain conditions for patient safety. It also seeks to regulate the online sale of medicines to rationalise such sales and ensure patient safety. The pharma and medical devices sectors are set to benefit immensely from the government's scheme from the Promotion of Research and Innovation in Pharma-MedTech sector, which has an allocation of ₹5,000 crore. The Draft New Drugs, Cosmetics and Medical Devices Bill will further facilitate taking the industry to the next level.