Union Ministry of Health and Family Welfare Proposes Amendments to Medical Devices Rules, 2017 to Promote Ease of Doing Business

Proposed amendments seek to simplify regulatory requirements, standardize testing fees and facilitate faster market access for eligible medical devices

Loan Licensing requirements removed for outsourced sterilization activities

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The Government has introduced key regulatory reforms in the medical device sector with a view to promoting Ease of Doing Business (EoDB), simplifying regulatory processes, enhancing transparency and facilitating timely access to advanced medical technologies in the country.

Towards this objective, the Medical Devices Rules, 2017 have recently been amended to simplify the regulatory framework governing outsourced sterilization of medical devices and to expand the list of recognized stringent regulatory jurisdictions for waiver of clinical investigation requirements.

The amendment to Rule 44 of the Medical Devices Rules, 2017 has been finalized after extensive stakeholder consultations with the objective of simplifying regulatory compliance for medical device manufacturers availing outsourced sterilization facilities.

Under the amended provisions, manufacturers outsourcing product sterilization to another facility holding a valid licence under the Medical Devices Rules, 2017 will no longer be required to obtain a separate loan licence for the outsourced sterilization activity.

The amendment eliminates the requirement for a separate loan licensing process in such cases, thereby reducing duplication, administrative burden, compliance costs and associated timelines, particularly for manufacturers that do not have in-house sterilization facilities.

The amended provision also provides a six-month transition period for implementation of the new labelling requirement. This will allow manufacturers adequate time to make necessary changes to their labelling, packaging and related processes before the provision comes into effect.

The reform seeks to strike a balance between regulatory oversight and ease of doing business by simplifying the licensing framework while retaining an essential traceability mechanism for outsourced sterilization.

The measure is expected to provide greater operational flexibility to manufacturers, facilitate faster and more efficient manufacturing processes, and support the growth and competitiveness of India's medical device industry.

Additionally, Rule 63 of the Medical Devices Rules, 2017 has been amended to include the European Union (EU) among the recognized stringent regulatory jurisdictions for waiver of clinical investigation requirements for medical devices without predicate devices.

The provision currently recognizes the United States of America, United Kingdom, Australia, Canada and Japan. With the inclusion of the European Union, eligible medical devices that have already been approved in the EU will be able to benefit from the waiver provisions, facilitating faster patient access to advanced medical technologies in India.

The amendment is also expected to reduce the regulatory burden and associated timelines for importers and manufacturers while strengthening international regulatory convergence in the medical device sector.

These reforms are expected to simplify regulatory processes, reduce costs, enhance transparency and predictability, and facilitate the timely availability of advanced and innovative medical devices in India.

The measures represent an important step towards strengthening the medical device regulatory ecosystem and promoting greater Ease of Doing Business, while continuing to maintain robust standards of quality, safety and performance of medical devices.

The Official Gazette notification may be accessed through this link: https://egazette.gov.in/WriteReadData/2026/275637.pdf

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