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Government proposes amendment to Medical Devices Rules, 2017

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Draft amendments aimed at reducing time limit for issuance of licenses

The Ministry of Health and Family Welfare, Government of India, has published a draft gazette notification proposing amendments to the Medical Devices Rules, 2017. It aims to simplify and expedite the licensing process of medical devices while ensuring full compliance with the prescribed standards related to quality, safety and performance.

The proposed amendments are aimed at rationalising the timelines for licensing of medical devices of various risk categories. The objective of this initiative is to promote ease of doing business, improve regulatory efficiency and ensure timely availability of high-quality medical devices in the country.

Under the Medical Devices Rules, 2017, medical devices have been classified into four categories — Class A, Class B, Class C and Class D — based on risk. These include the highest-risk medical devices in Class D. These rules prescribe statutory timelines for disposal of applications received for grant of licenses of each category of medical devices. The proposed amendments seek to reduce these timelines so that regulatory approvals can be granted more expeditiously without compromising on the established standards of quality, safety and performance.

The time limit for licensing of Class B medical devices, including low to medium risk devices such as blood pressure monitors, hypodermic needles and pulse oximeters, has been proposed to be reduced from 140 days to 115 days.

Similarly, the time limit for licensing of Class C and Class D medical devices, including high-risk devices such as heart stents, hip and knee implants and implants related to other orthopaedic diseases, is proposed to be reduced from 105 days to 90 days.

The amendments to the proposed draft also prescribe clear timelines for each stage of the licensing process. This includes scrutiny of applications, audit by notified bodies, verification of compliance and process for issuance of licenses. This is expected to bring in greater transparency, predictability and efficiency in the regulatory regime. This will benefit the medical devices industry as well as the patients as they will have faster access to quality medical devices.

The draft notification has been placed in the public domain inviting suggestions and comments from all stakeholders.