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Japan to revise medical device approval procedures

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Singapore: In order to speed up the approval process for medical devices, Japan is planning to introduce some changes in the accreditation procedures. News reports emerging from Japan stated that the Health, Labor and Welfare Ministry of Japan will propose a bill that will allow some Class III medical devices to be eligible for the new accreditation procedures.

Another proposal is to replace the permit system for production of medical devices with a registration system. The proposal also admits to the need of a more speedy approval for regenerative medical products made from induced pluripotent stem cells.

The Class III devices, which will be pushed for quicker approvals, will include kidney dialysis machines and generic dental implant products among others. The bill proposes that companies hoping to market such Class III devices will be able to get approvals through private accreditation organizations. This proposal is a departure from the Pharmaceutical Affairs Law of the country that makes it mandatory for all Class III and IV devices to be approved by the Pharmaceutical and Medical Devices Agency, which is an independent body under the health ministry.

The regulatory change is being proposed with the view that this would reduce time-frames for the approval of generic medical devices, while also reducing the burden on the Pharmaceutical and Medical Devices Agency.