



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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Health ministry to table medical devices Bill in Monsoon Session

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<http://www.financialexpress.com/news/Health-ministry-to-table-medical-devices-Bill-in-Monsoon-Session/632707/#>

New Delhi The health ministry would soon produce an exclusive Bill on medical devices in Parliament. “The Bill, which will be finalised after receiving the concurrence of states, is likely to be introduced in Parliament during the monsoon session,” minister of state for health Dinesh Trivedi said at Ficci on Friday. Currently, medical devices are treated synonymous with drugs. With only 14 notified devices regulated under the Drug and Cosmetic Acts, thousands others remain unregulated in the country. An attempt of the DCGI to increase the number of devices to 19 from 10 met with stiff resistance from the industry. The industry has a long-standing demand of creating separate guidelines and definition for medical devices.

The Bill has to have the assent of states, considering that health as a subject falls under the concurrent list. Drug Controller General of India Surinder Singh said that the proposed law to regulate medical devices would be specific to India and cater to the country’s socio-economic conditions. “The role of the government would be to enforce the law and facilitate the growth of the indigenous industry,” he added. FE had reported in November that the DCGI is targeting June to notify a separate bill for medical devices.

This comes after the Prime Minister's Office backed the health ministry to prepare the Bill over the department of science and technology. The health ministry was asked to consult and study the draft document prepared by the department of S&T and incorporate relevant inputs from the same in its own version of the draft Bill.

The PMO was concerned that two Bills—Draft Medical Device Regulation Bill proposing creation of Medical Devices Regulatory Authority and a Bill seeking amendments in the Drugs and Cosmetics Act to set up a Central Drugs Authority to regulate the medical devices industry and the pharma industry—are working in parallel towards the same goal. This was creating confusion in the international spheres as to which body would get the final authority to regulate the medical devices industry.