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Centre readies to regulate Medical Device alongside Drugs; industry expresses dismay

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No committee was formed to review the different tenets of the Bill: AIMED



Consumer Patient groups, Healthcare Providers have joined manufacturers associations in expressing profound dismay as the Centre reportedly prepares to table the New Drugs, Cosmetics & Medical Device Bill, 2023 in Parliament without adequately addressing their concerns.

The proposed legislation, aimed at regulating the medical device sector, had earlier garnered widespread apprehension from industry stakeholders who feel that their input has been overlooked.

Despite recent consultations, industry leaders argue that key issues such as regulatory complexities, the potential impact on innovation, and the need for a conducive business environment have yet to be adequately assured by redressal in the bill.

The lack of alignment with industry expectations has raised fears of stifling growth and hindering technological advancements in the medical device sector and continued import dependence as it is easier to import high end medical devices than to get regulatory approval for domestic manufacturers.

As the Bill is reported to move forward, there is a palpable sense of frustration among industry leaders who were hopeful for a more collaborative and responsive approach from the government.

Association of Indian Medical Device Industry (AIMED) Forum Coordinator Rajiv Nath, while expressing his disappointment, said, "NITI Aayog had drafted an excellent Medical Devices (Safety, Effectiveness and Innovation) Bill, 2019 but in vain and we keep going in circles. Who gains from putting Indian manufacturers at a disadvantage over imports and by Drug pharmacists weighed biased regulatory controls? Even the impactful recent progressive legislations in countries like Canada, UK, EU, Brazil, Malaysia, Singapore and Saudi Arabia were not studied. Who blocked that progressive visionary Bill?”

Discussing the potential impact of the Bill, which appears to favour foreign players, Dr Giridhar Gyani, Direcor General of the Association of Healthcare Providers India (AHPI), said, "In the national interest, it is crucial for us to highlight that if the Bill is passed as is, the healthcare providers sector, heavily reliant on medical devices and advocating for increased availability of affordable, high-quality, made-in-India medical devices, may once again face challenges in management of supply chain, leading to crisis and country wide lockdown similar to the onset of Covid. Domestic manufacturers might lose their capacity to swiftly address domestic demand, especially in the event of a pandemic”

K L Sharma, former Joint Secretary in the Ministry of Health & Family Welfare, GoI (2014-17), who coordinated the creation of Medical Devices Rules, 2017 stated, "Treating medical devices at par with drugs for regulatory purposes is fraught with danger for various reasons including the fact that such an arrangement puts unnecessary burden on medical device manufacturers in terms of compliances and leaves out more vital aspects that are crucial for ensuring the safety and effectiveness of medical devices."

Gaurav Agarwal, Managing Director, Innvolution Healthcare that produces cardiac imaging equipment said “If food can have FSSAI we need a separate regulatory framework too if we aspire to be global leaders. “

Interestingly the Parliamentarians in the Health Committee had initially responded specifically that instead of drafting a combined legislation for Drugs, Medical Devices and Cosmetics, the Ministry should formulate a separate legislation for Medical Devices.

The Committee had reiterated its earlier recommendations that the new legislation should set up a new set of regulators at different levels for regulating the Medical Devices industry. Unlike the present structure, the proposed National regulator should license the manufacturing of medical devices like FSSAI, and the state regulators be supervised by the National Regulatory Authority to help harmonise the regulatory process throughout the country.