Licensing delays pushing medical device makers abroad: Parliament panel

Committee says firms relocating to Vietnam, Malaysia

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A large number of medical device-manufacturing units have been forced to move to Vietnam and Malaysia due to delays, inconsistent timelines, and a lack of transparency in licensing processes, according to the Parliamentary Standing Committee on Health and Family Welfare.

"Rather, several medical devices manufacturers are scared to set up a unit in India due to delaying tactics of the CDSCO (Central Drugs Standard Control Organisation)," the panel added in a report presented in the Rajya Sabha this week.

Commenting on the issue, Rajiv Nath, forum coordinator, Association of Indian Medical Device Industry (Aimed), said the industry had conveyed to the Union heath secretary issues related to delays in getting licences.

"These include intervention for streamlining processes, holding training webinars for state regulators along with manufacturers and holding periodic meetings of the Medical Devices Technical Advisory Group (MDTAG), which had been created in 2020 to address regulatory issues but has yet to meet even once," he added. To counter this, the committee has recommended implementing a digitised and trackable licensing system, which must include defined timelines for each stage of the licensing process with automatic notifications to applicants and a publicly accessible database allowing for real-time tracking.

Panel asks CDSCO to shed its image of being a relic of the "licence raj", and calls for establishing an independent industry advisory board

"This will help to identify bottlenecks, promote transparency, reduce discretionary decision-making, and foster a more efficient and predictable regulatory environment," said the panel, chaired by Samajwadi Party (SP) Member Ram Gopal Yadav.

Asking the CDSCO to shed its image of being a relic of the "licence raj", the committee recommended establishing an independent industry advisory board comprising representatives of manufacturers (including startups), importers, health care providers, and experts.

The board would provide regular feedback to the CDSCO on regulatory challenges and potential improvement, participate in developing guidelines and policies, and serve as a platform for resolving disputes.

Terming the frequently delayed queries raised by the CDSCO a major obstacle for applicants, particularly startups, the committee recommended overhauling the query process. This would include establishing a single-query policy where all questions would be consolidated and raised at once rather than in multiple rounds and implementing a system of conditional approvals within 45 days, based on self-declaration and submitting documents, especially for products with international certifications. To counter challenges on capacity and expertise, the panel recommended accelerating the recruitment of qualified drugs inspectors and other key persons in the medical-device vertical.

The panel asked for exploring lateral entries of professionals from device manufacturers.