Faced with backlogs, medical devices industry suggests third-party audits

PREMIUM

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Domestic medical device makers had requested third-party audits by certified bodies given the lack of competent manpower and expertise at the Drugs Standard Control Organisation

BY PT JYOTHI DATTA

As some medical device makers grapple with the issue of getting a licence for their high-risk products, industry voices have suggested a system of third-party audits by

authorised agencies to facilitate the regulatory process.

Some makers of Class C and D devices have been waiting for over a week to get their registrations and licences. The October 1 deadline, though, has been overrun for multiple reasons, including a reported backlog of applications awaiting regulatory clearance. These medical device makers now hope for a "written (regulatory) reprieve" allowing them to undertake existing business commitments. A similar approach was taken with Class A and B products as well (April 2020), industry-watchers recall.

Ahead of the October deadline, a forum for domestic device-makers had written to the Health Minister on the issue. A system of third-party audits by certified bodies for medical devices was requested, given the limited availability of competent manpower and expertise at the CDSCO (Central Drugs Standard Control Organisation), a letter from Aimed (Association of Indian Medical Device Industry), had said.

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Varsha Rajesh, lawyer with Nishith Desai Associates, says the India Medical Device Regulations were revamped in 2020 and regulators have since been in the process of implementing the licensing regime in a phased manner. Manufacturers and importers of high-risk medical devices (Class C & D) were required to operate with a valid licence from October 1, 2023. "However, the regulator has experienced delays in processing applications and conducting regulatory audits despite manufacturers of devices having applied for licences within stipulated timelines," she said.

There has been no formal notification from the regulator on extension of timelines for obtaining licences. And continuing operations without a valid licence may attract statutory penalties, she added.

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Certified bodies

Industry estimates claim 200-odd manufacturers are awaiting manufacturing licences. And about 500 to 1,000 applications were pending, they said.

In this backdrop, internationally reputed certification bodies -- authorised by the regulatory authorities -- can audit companies without compromising on quality, say some industry voices.

There is no need to have an army of inspectors if the task can be delegated to competent and authorised professionals, says Aimed forum co-ordinator Rajiv Nath, adding that similar practices were followed in developed markets, including the US

and Europe. The risk profile of products are classified and the registration/ licensing process is outlined. Systems are streamlined so multiple countries recognise the other's certification, and the regulator can then focus on where there has been a requirement or there's been a transgression, he added.

Speaking for small entrepreneurs, another medical devices-maker, says the fee for third-party certification services could be steep for start-ups.

A third-party audit system operates in pharmaceuticals -- albeit with exports, to countries like Nigeria. Export requirements are outlined by Nigerian authorities, quality is checked by agencies certified by them (in India), and reports are uploaded and tracked, an industry-hand said.

A medical devices-maker laments, sometimes despite certification, local procurement gets mired in other issues. The solution, he said, was a dedicated dispensation to govern medical devices -- a long-standing ask from the industry.

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