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The Central Drugs Standard Control Organization (CDSCO) has released new guidelines for manufacturers. The ones who fall under the category of A&B medical devices (low-risk devices). These Manufacturers must be registered under the new scheme by September 2022. Those who fall under category C & D medical devices were directed to do the same by September 2023.

Intending to implement strict measures relating to the testing and licensing of medical devices, the government is planning to set forth SoPs and guidelines to test medical devices.

The current procedure involves the state regulators conducting verification and collecting samples randomly without any proper procedure involving various drugs and pharmaceuticals. The regulator later picks up these samples and transports them to the state registered laboratories. Here, the drug regulator conducts the necessary test to take action accordingly.

The CDSCO conducted a meeting to discuss strengthening the testing infrastructure to enable a smoother transition to licensing for medical devices. The meeting was chaired by the secretary of, the department of pharmaceuticals (DoP). In the meeting, it was proposed that a task force needs to be created. The task force will “prepare a road map for mapping and augmenting the laboratory resources required under medical device regulations. The committee has to submit its report to the DoP within two months.

As of now, there is a monthly minimum sample requirement that a state regulator has to verify. Once the new regulation comes into place, the testing of devices will become compulsory. Therefore the task force’s job is to “identify facilities within government and independent ones available in the country for testing of medical devices”, – an official said.

The Labs which will be selected must be NABL accredited, IIT Labs or National Institute of Pharmaceutical Education and Research (NIPER) labs.

In India, medical devices can be categorised into 5000 products. All the labs cannot test every type of medical device. Hence the labs need to be segregated according to the infrastructure required for testing the products. This segregation of labs according to their needs will be one of the major tasks of the committee.

The new regulation will fill in the loopholes and provide the medical industry with an efficient mechanism for testing medical products.

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