India to prepare detailed guidelines, SoPs for testing medical devices

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The government is preparing detailed guidelines and SoPs for laboratories testing medical devices. These measures are being taken to strengthen the testing infrastructure for licensing medical devices.

As of now, state regulators randomly take samples and conduct verification without any compulsory regulations in place on the lines of drugs and pharmaceuticals. The state drug regulator picks the sample with its batch number and conducts verification in its own laboratories. All the states have developed labs so that they are able to take action as and when required.

A task force has been set up for the exercise to map the existing labs available for such certification and testing.

“A meeting was held last month on the measures to be taken towards strengthening testing infrastructure to enable smoother transition to licensing for medical devices under the chairmanship of secretary, department of pharmaceuticals (DoP). A task force has been constituted to 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," said an official in the know of the matter requesting anonymity.

“There’s a minimum mandatory requirement for the state regulator that every month how many such samples they have to pick and verify. Once the medical devices regulation comes into place, testing of medical devices will become compulsory. So now, this task force is to identify facilities within government and independent ones available in the country for testing of medical devices," said the official.

These labs could be NABL accredited labs, IIT Labs or National Institute of Pharmaceutical Education and Research (NIPER) labs.

In India, medical devices are a category of almost 5,000 products. Different categories of medical devices may require different kinds of testing infrastructure.

“The committee will also tell us which category of product which lab may be able to test. We have brought in multiple stakeholders from Central Drugs Standard Control Organisation (CDSCO), industry, DoP, NIPER to do this exercise and give its report," said the official.

According to the CDSCO, from October 1, 2021, manufacturers of category A & B medical devices (low risk devices) were told to come under a compulsory registration scheme up to September, 2022 and manufacturers of category C & D medical devices (high risk medical devices) were directed to do so up to September 2023. After the compulsory registration period, these classes will respectively move to the licencing regime. “The purpose is to prepare the industry for a smooth transition regulatory regime. The testing has been mandated by the CDSCO as per the norms; besides, random samples are also being done. This exercise will create an enabling environment and fill the existing gaps.

Queries mailed to the department of pharmaceutical spokesperson were unanswered at press time.