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NITI Aayog plans to bring all medical devices under one regulatory regime

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Sohini Das | December 19, 2019

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Government think-tank NITI Aayog has proposed to bring all medical devices under one regulatory regime in a phased manner and have a separate Medical Devices Administration (MDA) with four divisions.

In a stakeholders' meeting in New Delhi on Wednesday, the NITI Aayog discussed the key features of the draft Medical Devices Bill. The new regime aims to bring in ease of doing business, as the NITI Aayog has proposed to do away with the need to have manufacturing licences to register a medical device or get a certificate of compliance.

The government also moots to have a National Register of Medical Devices. These devices are presently governed by the Drugs and Cosmetics Act, 1940. Experts expect the proposed bill to be notified within the next six months.

The Medical Devices Authority would be a parallel vertical to the Central Drugs Standard Control Organization (CDSCO) and would be under the Directorate General of Health Services (DGHS), the NITI Aayog proposed.

The CDSCO, it is learnt, has already requested the health ministry to sanction the creation of 700 permanent posts for the separate vertical.

“There can also be a separate statutory body on the lines of the Food Safety and Standards Authority of India (FSSAI) for the regulation of medical devices. A final decision on the same has not been taken. However, the government has decided that medical devices would now be regulated by a separate body,” said an official who was a part of the meeting. The official said the industry was divided in its opinion. “While some wanted an autonomous statutory body on the lines of the FSSAI, others preferred medical devices regulation to remain under the CDSCO.”

Meanwhile, the NITI Aayog has proposed in the draft Bill to have four separate divisions under the new Medical Devices Administration — health and safety division, conformity assessment division, enforcement division, and the laboratories and medical devices testing division.

The health and safety division would grant permission for clinical investigation on human subjects, specify and evaluate the clinical evidence, collect and analyse results of the post-market surveillance.

The conformity assessment division would issue, reject, recognise, and validate conformity assessment certificates, and also conduct audits of manufacturing sites. The enforcement division would inspect, investigate, carry out searches and seizures. The laboratories division would specify procedures for the analysis or testing of medical device.

The draft Bill has also proposed several penalties in case of non-adherence to the new Act. Existing medical devices will have a window of 12-36 months (depending on the device class) from the date the new Act comes into force for registration.