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Exhaustive analysis needed before notifying more medical devices: MTaI

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Medical Technology Association of India (MTaI) has announced that while the overall decision of the DTAB to bring more devices under regulation is a welcome step its implementation needs exhaustive consideration.

Pavan Choudary, Chairman, MTaI said, “First, an exhaustive analysis of the un-notified part of the device universe is required. Some of these products could be critical & life-saving, but sold in tiny quantities. CDSCO could look at revising downwards the registration fees so that the market stays attractive to these small but vital operators. Also, a game plan should be ready to make up for their likely departure for reasons of viability. To handle the additional workload, CDSCO should assess whether the manpower mandated by DTAB is available to regulate the new devices expeditiously.”

“Medical devices are generically different from drugs and therefore cannot be treated as drugs in the long run. The government should expedite the deliberations on institutionalizing a suitable and exclusive legal framework for medical devices so that areas of quality, adverse events, compensation, prices, healthcare training, Health Technology Assessment, et. al. are comprehensively addressed”, he added.

The association said the decision to bring more devices under regulation is welcome as it would strengthen patient safety, but the government should also prioritize creation of separate law for medical devices.