Exhaustive analysis needed before notifying more medical devices: MTaI

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New Delhi: Medical Technology Association of India (MTaI) in its statement on 15th April, said that while the overall decision of the DTAB to bring more devices under regulation is a welcome step but its implementation needs exhaustive consideration.

“First, an exhaustive analysis of the un-notified part of the device universe is required. Some of these products could be critical and 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”, said Mr Pavan Choudary, Chairman, MTaI.

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 the creation of

separate law for medical devices. “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,” Mr Choudary said.