

MTal welcomes govt's plan to regulate critical care medical devices

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Medical Technology Association of India (MTal), which represents leading research-based medical technology companies with significant manufacturing investments in India, has welcomed government's plans to regulate manufacture, import and sale of critical medical devices such as pacemakers, CT scanners, X-ray machines, etc in the country.

"The association believes such a decision will ensure that only high quality products will be used in the healthcare of the patients and will discourage the production and usage of sub-standard products. This has to be quickly and elaborately communicated to all the manufacturers and importers to ensure timely compliance."

"Currently many departments of the government impinge on the medical electronic device sector. This creates problem of jurisdiction as well as inter-departmental delay in decision making. For e.g. X-Ray machine suppliers need to comply with the regulations as per the Ministry of Health and Family Welfare (MoHFW), as well as the Atomic Energy Regulatory Board (AERB) at several steps, ranging from importing to operating by users. We believe implementation of these new regulations to the aforementioned medical devices, will not only erase overlapping, but will also result in less red-tape thereby helping in ease of doing business in the country." MTal added.

It was reported in certain sections of media that on May 16th, a proposal by The Drugs Technical Advisory Board was approved to include implantable medical devices and high-end medical equipment under the purview of the Drugs and Cosmetics Act, 1940.