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# Medical Device Cos Urge Govt not to Punish All for a Quality Lapse

## Want input providers, component suppliers to be held responsible for a faulty device

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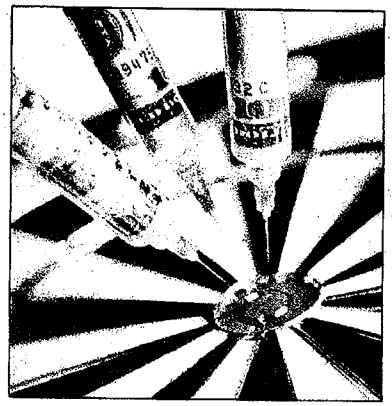
NEW DELHI

The medical devices industry has urged the government not to hold all players in the supply chain responsible in case a quality lapse is detected in a device. Indian and foreign firms operating in the country have separately written to different arms of the government, seeking a change in the Drugs and Cosmetics Bill that they say could lead to booking of even raw material providers and component suppliers in the supply chain in case of a faulty device.

While foreign firms have submitted that brand owners marketing the device should be held responsible for violations, domestic manufacturers have said accountability should be that of the marketing firm as well as primary manufacturer responsible for the final assembly of the product at its plant.



Medical devices made in India remain largely unregulated, barring a few exceptions that have been put under regulation since 2005 but are treated under the definition of drugs. The government plans to bring a new law to correct this by creating an exclusive set of rules for medical devices, a sector that is estimated at about ₹18,700 crore and is growing at a CAGR of about 15%.

While defining the scope of regulation for medical devices, the Drugs and Cosmetics Bill 2013, introduced in the last session of Parliament, describes 'manufacture' of devices as "any process or part of process for making, assembling, altering, ornamenting, finishing, packing, labelling, or adapting any medical device with a view to its sale or stock or export or distribution but does not include assembling or adapting a device already on the market for an individual patient".

AdvaMed, a grouping of top medical devices multinationals, has requested that the government to use the word manufacturer instead of 'manufacture'. "The ultimate legal responsibility for ensuring compliance should lie with the 'manufacturer', which, according to global guidelines, is the legal or natural manufacturer marketing the device. This would exclude cases where the devices are mishandled during transportation, storage or usage," said Gautam Khanna, chair, India Working Group, AdvaMed and country business leader, 3M, a US-headquartered conglomerate.

The domestic firms insist that the definition should also include the primary manufacturer in whose plant premises the device has been assembled finally. "The 'manufacture' of medical devices has been defined on the same lines as for drugs whereas manufacture of a medical device is quite different from drugs," said Rajiv Nath, joint-managing director, Hindustan Syringes and Medical Devices and forum coordinator of AIMED, an industry body of domestic medical devices firm.

Regulatory.