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Government regulations of medical devices: A special case reference to India

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The ideal conditions that will ensure the safety and performance of medical devices require shared responsibility by all stakeholders; manufacturer, vendor, user and the government. Governments can fulfil part of their duties through the implementation of regulations. The critical elements of regulatory attention include; pre-market review, placing on market and post-market surveillance. Global harmonization task force (GHTF) was conceived in 1992 to achieve greater uniformity between national medical device regulatory systems. GHTF was comprised of five founding members: European Union, United States, Canada, Australia and Japan. The organization was replaced by The International Medical Device Regulators Forum (IMDRF) in February 2011. Different subsystems of pre-market review exist globally, based on application of risk management approach by all authorities. Therefore, product approval process for commercialization and end user's usage differs. In the European Union, a notified body plays a vital role, on the other hand US FDA directly manages marketing clearances in the form of 510 (k) or an approval letter (PMA) etc. While in India, CDSCO, New Delhi or the State Licensing Authority approves issuing a manufacturing license. The government of India has introduced a landmark policy i.e. Medical Device Rules, on 31 Jan 2017, that will be effective from 1 Jan 2018. The rules are framed around the guidelines of the Global Harmonization Task force (GHTF) ensure that the Indian norms governing medical devices are on par with those in vogue globally. India regulatory regime is governed by D and C Act 1940 and Rules 1945, and under this act Ministry of Health and Family welfare, central licensing authority and state licensing authority govern the import, manufacture and distribution of medical devices in India. The government of India introduced legislation under the "Make in India" campaign that will make India more lucrative for Medical device development to encourage national, as well as multi-national organizations to manufacture their products in India. The talk will emphasize and focus on why we may consider 2017 as a benchmark year for the Medical device industry from the perspective of India?

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