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MTaI guides MedTech experts on MDR that could impact packaging

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Medical Technology Association of India (MTaI), an association of research-based medical technology companies who have made significant investments in India in R&D and manufacturing, today organized 'MTaI Medical Packaging Seminar' to educate medical device professionals in the country on new Medical Device Rules introduced in Europe, which could impact exports to that continent.

According to the regulatory experts at the seminar, medical device regulations are changing steadfastly around the world and many of these new guidelines will impact packaging. They stated that these new changes are enabled to develop packaging that will help end-users in ensuring the safe use of sterile medical devices.

Thierry Wagner, Director- Regulatory Affairs, E. I. DuPont de Nemours (Luxembourg) detailed the features and the current implementation issues of EU's new Medical Device Regulations (MDR) adopted in April 2017. He also mentioned new directives and regulations evolving in the Association of Southeast Asian Nations (ASEAN), India, and the Eurasian Economic Union (EAEU). "In light of the current technological advancements, healthcare trends and the need for better patient protection, new state-of-the-art laws have emerged. These new regulations with their advanced features will take a device life-cycle approach, from design to clinical evaluations, certification, distribution including the required post-market clinical follow-up systems," he said.

Chairman & Director General of MTaI, Pavan Choudary said, "Medical Device packaging is vital for product safety, performance, pertinent information disclosure and even sustainability. A small defect can mean a life-threatening event. Packaging is a highly technical and scientific field, which demands professionals to stay abreast of ever-changing regulations, innovations in material and in testing requirements. With this seminar we make our first large scale knowledge sharing contribution to Make in India".

While addressing the audience, Dr V. G. Somani, Joint Drug Controller of India, said, "India has gone on to implement

Medical Device Rules in line with international standards, so as to promote Ease of doing business in India and step towards the goal of Make in India".

Kevin Grum, Global Technical Services Leader, EI Dupont Nemours (USA) said, "Often packaging is an afterthought in the life of a medical device. We are here to change the mindset and deliver the message of how packaging design can add value to the product and even save patient lives."

The seminar was inaugurated by Diwaker Rana, Chairman, Skill Building Committee, MTaI, who said, "Aligning ourselves with PM's overall vision of Ayushman Bharat, MTaI persists in its dedication towards skill-building of healthcare professionals and the manufacturing personnel in the country by providing such state of the art training".

MTaI Medical Packaging Seminar, organized in association with its member company DuPont, is the first of several programmes that MTaI has planned under the aegis of Skill Building Committee. The seminar was focused on Sterile Medical Packaging Regulatory and Standards Review requirements after the new EU MDR, as well as Packaging Engineering and Design, Peel Strength & Microbial Barrier, etc.