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Launching a Drug or Medical Device in India: From Clinical Trial to Sale [PODCAST}

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Series Introduction: Dr. Milind Antani, Darren Punnen and Shreya Shenolikar of Nishith Desai Associates have analysed the key regulations applicable to the Indian pharma, medical device and health-tech industry in a multi-part podcast series. The series starts off with the basics of pharmaceutical and medical device regulation and subsequently delves deeper into the regulation of various aspects of the industry. Each episode begins with an overview of applicable regulation, how the regulation applies to the industry and ends by providing some practical inputs on how stakeholders should approach this space.

Episode Introduction: In this episode, Shreya Shenolikar provides a comprehensive overview of how drugs and medical devices are regulated across the supply chain covering drug development, clinical trials, manufacture, import and sale. The Drugs and Cosmetics Act, 1940 (D&C Act) is India's principal drug and medical device regulatory legislation. There are different rules framed under the D&C Act that specifically regulate each stage from drug discovery to sale. The rules stipulates the procedure to be followed for conducting clinical trials and obtaining marketing approval. The rules also require manufacturers, importers and sellers of drugs and medical devices to obtain permission to engage in the activities of manufacture, import and sale respectively. The podcast charts the entire process of bring a drug to the market starting from the manner in which drug discovery is regulated to the conduct of clinical trials/clinical investigations, manufacture and import of drugs and concluding with the sale of the drug. The stages covered include:

· Drug/medical device development.

· The process for conducting clinical trials of drugs and clinical investigation of medical devices.

· The process for obtaining a marketing authorisation for drugs and medical devices.

· The process for manufacture of drugs and medical devices.

· The process for import of drugs and medical devices.

· Sale of drugs and medical devices at a wholesale level.

Sale of drugs and medical devices at a retail level.

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