Published on *The National Law Review* https://natlawreview.com

Regulating the Prices of Drugs and Medical Devices in India: A Legal and Policy Perspective

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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: Drug prices in India are heavily regulated since the early 1970s with the regulation changing every few years to remain relevant. Presently, drugs are considered to be essential commodities and are regulated under the umbrella legislation applicable to such commodities i.e. the Essential Commodities Act, 1955. The pricing mechanisms are more specifically laid down under the the Drugs (Price Control) Order, 2013 (DPCO) which is administered by a drug pricing authority. The authority sets ceiling prices for certain essential drugs and medical devices while the prices of other drugs and medical devices are indirectly regulated.

Therefore, understanding the drug and medical device pricing mechanism is crucial for stakeholders wishing to launch a drug or medical device in India. In this podcast, Darren Punnen takes us through how prices for drugs and medical devices are controlled in India, its various mechanisms, and who gets covered. More specifically, Darren deals with:

- The types of drugs and medical devices for which prices are fixed in India.
- How the decision on which drugs are considered to be ‘essential’ is made.
- The manner in which the prices are fixed.
- The effect of price revisions on existing stock in the market.
- The methods followed for determining the price fixed.
- Compliances required to be undertaken by drug and medical device companies under the

DPCO.

- Trends in enforcement of applicable regulation.

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National Law Review, Volume X, Number 357