National Medical Devices Policy, 2023 – A job half done

As evident from its name, the Drugs, Medical Devices and Cosmetics Bill, 2022 seeks to regulate both drugs and medical devices.

Written by **Guest**

May 10, 2023 17:02 IST

Five medical colleges to be inaugurated in Andhra Pradesh in Aug, says health minister.

By Shantanu Jindel and Shivani Singh

The Ministry of Chemical and Fertilizers, Department of Pharmaceuticals released the National Medical Devices Policy, 2023 on 2 nd May 2023 (“Policy”). 1 This Policy has been released in the backdrop of the approach paper on Draft National Medical Devices Policy, 2022 2 and National Health Policy, 2017 3 . While the Policy is clearly a step in

released the Policy), has now managed to draw attention of the regulators due to the role played by it in the battle against COVID-19 pandemic.

The Policy recognises the role of medical devices on two fronts: (a) having robust capabilities to innovate and produce medical devices will be crucial to meet the health and wellness goals of the country; and (b) medical devices industry is poised for significant growth, and can play a key role in creating employment and attracting foreign investment.

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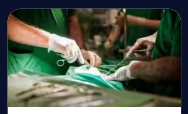

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Challenges

Firstly, while the various limbs of the roadmap identified in the Policy requires government to spend or attract funds from the industry participants on all fronts, 'regulatory streamlining' can be achieved with little expense. Once the regulations governing medical devices industry (including those regulating manufacturing, sale, storage, import, export, etc.) are streamlined and assurance is given to the stakeholders that the changes to the regime will be infrequent, greater interest will be garnered from the industry participants. While the industry stakeholders have been demanding for a separate regulatory regime for regulation of medical devices, the government appears to be keen on regulating drugs and medical devices under the same umbrella legislation. As evident from its name, the Drugs, Medical Devices and Cosmetics Bill, 2022 seeks to regulate both drugs and medical devices.

Secondly, frequently the path to self sufficiency (on most fronts) is an easier one as compared to the path to R&D and innovation. For example, while the country has lagged behind in the development of new drugs, it is fairly self sufficient as far as the most basic generic medicines are concerned. As a result, the medicines to treat ailments which impact the larger population are available at more affordable rates as compared to some of the more developed economies. Given the nature of the industry, the expense that needs to be incurred in R&D is significant – and once that cost gets built in the price of the device, the affordability by the masses may be questionable. While the importance of R&D and innovation cannot be disregarded in the long run, a more immediate need would be to be

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Thirdly, the Policy sets the ambitious goal of formulation and adoption of Indian standards for medical devices. Rather than focusing on developing indigenous rules, Indian standard setting bodies (such as the Bureau of Indian Standards) should focus on streamlining the sectoral standards with the existing internationally acceptable norms on standardization for medical devices. This will lead to two-fold benefits: (a) ease of doing business for foreign entities; and (b) increase competitiveness of domestic manufacturers. If India is looking to be a global player in this industry, then global quality standards will need to be met.

Long road ahead

Considering that the government has recognised medical devices to be having a multiplier effect in the cost of healthcare, it must focus on increasing affordability and accessibility to medical devices as well as removing/ reducing entry barriers for industry participants. This can be achieved by: (a) reducing compliance burden (such as through implementation of the 'Single Window Clearance System'); and (b) focusing on increasing domestic and foreign investment into manufacturing of medical devices such as by offering financial incentives). Often when policies aim to achieve too much too soon, the focus is shifted away from priorities. In this case, health benefits of a well-developed medical devices industry are more important than the economic benefits and access is more important than innovation.

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First published on: 10-05-2023 at 17:02 IST

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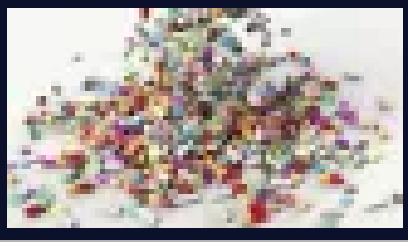

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