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UNION CABINET APPROVES NATIONAL MEDICAL DEVICES POLICY 2023

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Introduction

In a major boost to the medical devices company sector, the Union Cabinet, chaired by Hon'ble Prime Minister Narendra Modi, has approved the National Medical Devices Policy 2023 (NMDP) on 27 April 2023 and the final policy has been notified on 03 May 2023 in e-Gazette of India. This is in furtherance to the 'approach paper to National Medical Device Policy, 2022' published for stakeholder consultation by the Department of Pharmaceuticals (DoP) on 10 May 2022.

Medical devices / MedTech sector in India comprises of: (a) electronic equipment, (b) implants, (c) consumables and disposables, (d) surgical instruments, and (e) in-vitro diagnostic reagents, and is termed as a sunrise sector for its tremendous potential of growth and capacity to become self-reliant with minimal dependence on imports. India is a key player in the global generic medicines and vaccines markets, but the MedTech sector is yet to realise its full potential.

In the recent past, the DoP implemented the Production Linked Incentive Scheme (PLI Scheme) for MedTech companies whereby around 14 projects were commissioned for production of high-end medical devices. With various government departments having undertaken significant steps to encourage accelerated growth in this sector and permission of 100% foreign direct investment (FDI) in the sector under automatic route since January 2015, it was felt that a comprehensive umbrella approach may have been missing. Accordingly, the NMDP has been adopted to fill this precise missing block in terms of a centralised drive towards structured focus areas, some of which are discussed below, briefly.

Salient Features of the NMDP

A. Vision: The NMDP envisions achieving 10 to 12% of the global market share in MedTech sector over the next 25 years to become global leader and a globally competitive industry in India with a patient centric approach.

B. Policy Interventions:

1. Regulatory Streamlining – NMDP proposes to: (a) set up a single window clearance system on portal of Central Drugs Standard Control Organisation , in alignment with the National Single Window System for filing applications for medical device manufacturing license, import license and clinical investigation approval; (b) expand applicability of Indian standards by the Bureau of Indian Standards (BIS) and such other similar standards setting bodies for medical

devices; (c) incorporate framework for coherent pricing regulation for incremental number of medical devices under the Drugs Prices Control Order, 2013 (DPCO); and (d) implement an institutional arrangement for aligning industry practice with code of ethics prescribed by the National Medical Commission to strive towards ethical marketing of medical devices.

Comment:

Under the Medical Devices Rules, 2017 (MDR), MedTech companies are required to procure a wide range of regulatory approvals which creates substantive regulatory burden and compliance challenges leading to delayed timelines. The single window clearance system is expected to reduce such timelines of procuring licenses and aims to integrate all key stakeholders involved in the medical devices licensing framework. Applicability of established standards such as BIS will result in better quality compliance and standardisation. However, timelines for ensuring standard compliance will be a key factor in assessing efficiency. A coherent pricing framework applicable to wider scope of medical devices under the ambit of DPCO will be able to make the medical devices sector much more affordable to the general public. The implementation of an institutional arrangement applicable to ethical marketing by medical device companies, perhaps in the nature of the draft Uniform Code of Medical Devices Marketing Practices, has been long awaited and is expected to be instrumental in comprehensive regulation of unethical advertisement practices in India.

2. Infrastructure Development – The NMDP recommends bolstering state governments' efforts to set up large medical device parks (*as also provided for under the MDR*) and mid-sized medical devices clusters with common infrastructure facilities in proximity to economic zones. Further, while testing and certification facilities for medical devices are available in some governmental bodies, the NMDP envisages setting up of additional medical device testing laboratories to bolster testing and certification efficacy.

   Comment:

   The "Promotion of Medical Device Parks" scheme notified by DoP dated 21 July 2020 provides for common medical device testing laboratories to be set up at one place to reduce manufacturing costs of MedTech companies significantly, as these laboratories carry out test or evaluation of the medical devices on behalf of manufacturers. Establishing more medical device parks, medical devices clusters with accredited laboratories are expected to result in significant reduction of manufacturing costs, facilitation of manufacturing of high-end medical devices, increased competitiveness, better availability and affordability of reliable medical devices in the domestic market.

3. Measures to attract investments in MedTech sector – The NMDP envisages to encourage private investment and external resources funding in the sector through measures such as: (a) inviting venture capital funds for screening of start-ups to incubate; and (b) engage, leverage and systematically build upon the 'Startup India' initiatives by Department for Promotion of Industry and Internal Trade to actively support startups in the MedTech sector.

   Comment:

   India has been witnessing strong inflows of FDI in the MedTech sector after 100% FDI was permitted under automatic route for manufacturing medical devices. The focus points set out herein are expected to promote indigenous manufacturing of medical devices and build competitiveness and competence amongst start-

ups in the sector. Clarity on effectiveness of such promotional activities will invariably depend on the execution of the above propositions.

Conclusion

There has been a pressing need in the Indian medical devices / MedTech sector for a consolidated and comprehensive approach to drive accelerated growth, as most schemes and policies till date, including the PLI Scheme introduced by the DoP and establishment of medical devices parks in some Indian states, have been scattered in their approach. The NMDP is a welcome move, however it's impact may only be assessed once meaningful steps, including regulatory and statutory actions, are introduced, and quantitative outcome metrics for assessment of its success are published in public domain. We look forward to seeing Indian MedTech sector gaining the stride of the generic drugs and vaccines sector once the measures under the NMDP are fully implemented.

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