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EDITORIAL

An Aspiring Nation needs Modern Regulatory Framework for Patient Safety

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The patient-centric approach is the most important aspect of our NMD (National Medical Devices) Policy 2023. The policy aims to build an innovative and globally competitive industry in India, supported by world-class infrastructure in alignment with PM Gati Shakti, Make in India, and Atmanirbhar Bharat programs. The goal is to become a global leader in the manufacturing and innovation of medical devices by increasing our market share in the global market from the current 1.5% to 10 to 12% in the next 25 years.

This is a huge step forward, considering the lack of access to homegrown medical devices at the onset of COVID-19 in 2020, which exposed severe lockdown critical healthcare insecurity. Regretfully India recently slid back by two steps from achieving these global ambitions.

First, by the Ministry of Environment for recently allowing the import of preowned medical equipment, the risk of importing sub-standard products into the country will increase. This will negatively impact the manufacturing and innovation of medical devices in India, slow down investments in the sector, and discourage domestic manufacturers. Also, the industry can in no way compete with abysmally low-priced imports. Other countries like China., Vietnam, Indonesia, Egypt, Peru etc, have strictly banned the imports of such preowned equipment.

Patient Safety may be hugely compromised with exposure to obsoleted technology, absence of calibration, validated performance, and attempts for maintenance by jugaads. This policy needs a review and rollback.

One Step Forward Two Steps Back

2nd step backward. In over 30 years, till 2022, hardly 30 medical device product categories got regulated and incorrectly under the Drugs Act. Most industry avoids regulations. However, many aspiring manufacturers sought regulations but as appropriate regulations. During this monsoon session, MoH & FW recently listed the tabling of a New Bill on Drugs, Cosmetics & Devices to the Parliament to ensure higher Patient Safety. Regretfully a golden opportunity to provide progressive modern regulations benchmarked to latest best international regulations was being squandered away It continues to seek to regulate devices alongside Drugs under the garb of a separate chapter for some provisions instead of using the opportunity to bring in a progressive modern separate law for addressing Patient Safety needs and using the earlier separate visionary Niti Aayog draft Medical Devices (Safety, Effectiveness &Innovation) Bill 2019 or using impactful references of the separate medical devices legislations as in Canada, UK, EU, Brazil, Japan, Saudi Arabia etc.

It's even revised the definition of "manufacturer" that will allow a marketing company to get a manufacturing license and inadvertently proposes legalizing pseudo-manufacturing of low-quality cheaper imports that may affect patient safety. Unfortunately, it discourages investments from manufacturing these in India by treating domestic manufacturers as potential criminals while overseas manufacturers do not need to go through the same rigors to demonstrate conformity.

Engineers and scientists who step forward to design and develop products must fearlessly follow defined, simple regulatory pathways. Manufacturers similarly need to be disciplined and compliant to regulatory conformity requirements and prove conformity by third-party certification or testing to accredited certification bodies and laboratories. The regulators and QCI's NABCB (National Accreditation Board of Certification Bodies) need to jointly supervise the performance of these Certification Bodies and laboratories to ensure a competent staff with relevant expertise is auditing manufacturers and seeking continuous improvement in quality management systems and product performance. India needs to move away from Inspector Raj with inspectors empowered for search and seizure for even licensed manufacturers treating them as criminals with threats of imprisonment for even minor offenses.

A good Law need to be simple, reasonable, and implementable and give direction of intent for a progressive aspiring nation. Medical electronic Devices, which are engineering products like cars, can't be manufactured or regulated like drugs and need to be stored, transported, installed, maintained, and regularly calibrated to ensure patient safety for the product's lifecycle. Users need to be trained and skilled to use medical devices safely and appropriately and have a shared responsibility in their upkeep.

We can't be building world-class expressways and then expect public to drive at a speed limit of 60 km per hour and fine and harass the majority of them for breaking the law. Instead, if strong discipline is inculcated, we need to aim for safer higher speed limits until we have the confidence to trust our drivers like in Germany and even not have an upper-

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speed limit but a minimal speed limit on the expressways. Strong post-market surveillance is needed to monitor the medical devices marketplace to ensure the regulatory system is performing well, and when triggered by an adverse event reporting, regulators seek systemic preventive and corrective actions instead of witch-hunting to ensure patient safety.

The wise Parliamentarians in the Health Committee responded that instead of drafting a combined legislation for Drugs, Medical Devices and Cosmetics, the Ministry should formulate a separate legislation for Medical Devices.

The Committee reiterated its earlier recommendations that the new legislation should set up a new set of regulators at different levels for regulating the Medical Devices industry. Unlike the present structure, the proposed National regulator should license the manufacturing of medical devices like FSSAI, and the state regulators be supervised by the National Regulatory Authority to help harmonize the regulatory process throughout the country.

The Committee believes that the government should not afford regulation of medical devices by pharma experts and are dispensed with by qualified and well-trained Medical Device Officers. Therefore, a separate Regulatory Infrastructure for medical devices with a dedicated workforce instead of adjoining with the CDSCO would serve the purpose better.

The Committee recommends the Ministry to introduce stringent standards and certification processes (particularly for Class C&D products) comparable to global standards. The Ministry, along with compulsory compliance to Quality Management System as per schedule 5 of the MDR, 2017, should also allow cognizance to 3rd party voluntary assurance schemes like Quality Council of India's ICMED 13485.

The Parliament Health Committee rightly felt that since MOH & FW was the key stakeholder in medical devices, the inter-ministry coordination for the promotion of medical devices should be done by MOH & FW only. CDSCO as a regulator needs to enforce regulations and not usurp the job of the Policy Makers.

Time will tell if the Dog wags the tail, or the Tail will continue to wag the Dog.