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# â??Regulatory framework to protect IP, innovation and existing governance structures ought to be strengthened"

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**The Ministry of Health and Family welfare was going to implement the Unique Device Identification (UDI) for medical devices from January 1, 2022, but deferred it until further notice. Under Rule 46 of the Medical Devices Rules, UDI would have been mandatory for medical devices approved for manufacturing for sale or distribution or import. Globally, UDI is expected to play a pivotal role in improving patient safety by enabling device identification and tracking and most importantly overcome counterfeiting. Expounding in detail about the counterfeiting menace in India and urging the government to bring into effect the UDI, Nakul Pasricha, President, ASPA (Authentication Solution Providersâ?? Association) converses with BioSpectrum India in an exclusive interaction. ASPA is a Non-Profit organisation that has 69+ member companies providing physical and digital authentication solutions. This industry body of authentication solutions providers encourages its members to adopt best practices, standards, and advanced technology in providing cost-effective, anti-counterfeiting solutions. Edited excerpts:**



**How has the medical device landscape changed in India? What led to this change and how would you perceive its future changes?**

The healthcare sector in India is going through a revolutionary transformation, resulting in a more favourable environment for patient well-being. India is playing a significant role in the global healthcare landscape, the country was already on the brink of this transformation, and COVID-19 accelerated it. A substantial part of this transformation is multi-faceted innovation in medical devices aimed at precision in delivering healthcare to patients. New age innovative and efficient medical devices driven by intelligent technology are a massive support to medical practitioners and nursing staff. With the growing need for healthcare in the country, it has a challenging task in front of them despite putting in its best efforts. There is a shortage of nursing staff in the country; our country currently has 1.7 nurses per 1000 people, while the WHO recommended rate is three nurses per 1000 people. This, coupled with the increasing need for healthcare services; medical devices creates a huge opportunity that can facilitate quick and accurate delivery of healthcare.

**What has made India boost domestic production of medical devices?**

India has been holding an important position in the global healthcare landscape as the pharmacy for the world. This has led to accumulation of meaningful information about this industry. The huge demand and future scope for medical devices in the country and across the world, coupled with the intelligence and insights that the industry has gathered over the years, has motivated Indian manufacturers to participate aggressively. In recent years, the technology-led perspective of the manufacturing industry has enabled the development of excellent products of world-class quality and capable of delivering precision.

**Has the demand for precision medical devices spurred the circulation of substandard and fake MedTech devices?**

Increasing need and widespread popularity of medical devices, especially the growing adoption of precision medical devices, has put pressure on manufacturers and the supply chain. The gap in demand and supply essentially is seen as an opportunity by the illicit manufacturers and sellers. They are further motivated by a relatively immature market and low awareness levels. When customers are unaware of the ease with which spurious, fake or substandard products can be infused into the market, it becomes easier for illicit traders to dupe them. Concerning a new product, customers are relatively less aware of the device and are unaware of how to know if it is an authentic standardised device or not. This gives the illicit manufacturers and sellers a window to cheat them and sell copycat devices. Due to technological advancement, counterfeiters can churn out low-quality precision medical devices and copycat packaging easily and quickly.

**What damages do illicit MedTech devices pose on various facets of the industry, society and ecosystem?**

Fake, spurious or substandard MedTech devices do not go through quality checks and do not match the standards set for those devices. Thus, they undermine and hamper the delivery of good quality and precise healthcare to the patients in need. Their inability to precisely deliver the device's purpose makes it impossible to provide a timely diagnosis or treatment. For instance, a substandard or fake Home Blood Sugar Monitor machine might not display accurate results, and the patient's health would be at risk due to a delay in giving timely treatment. The more crucial the device's purpose, the more significant threat it is to the patient's health.

Apart from the threat of endangering the lives and well-being of patients, illicit products hamper the faith of patients in the medical fraternity and the whole ecosystem. Our medical fraternity, hospitals, pharmaceutical companies, medical device companies, etc., put in a lot of hard work and investment into enabling good quality and timely healthcare to patients. But, the presence of fake and substandard medical devices and drugs can lead to grave tragedies. Additionally, any illicit trade eats into governments' revenues and brands.

**How do illicit manufacturers and sellers get into the ecosystem and supply chain?**

Authentication solutions are implemented on some products, which can easily determine their authenticity. But due to a lack of awareness about this and low participation in the authentication process, illicit products are not identified and reported correctly to enable corrective action.

Low awareness among consumers, medical fraternity, nurses and pharmacists about the widespread presence of substandard and fake products allows them to cheat them into buying these. During a global crisis, a vulnerable supply chain also presents itself as an opportunity for these criminals. The pandemic was one such eye-opener in this regard. Through the duration of the pandemic, a disturbing number of incidents surfaced, which were related to substandard and falsified medicines and medical products in India and globally. There was an alarming spike of 47 per cent in the incidents reported of falsified and substandard medical products during 2020-2021. It was also observed that these were mainly related to COVID-19 products such as vaccines, antibiotics, test kits, sanitizers and face masks (Ref: ASPA's Report to the Nation). These incidents were observed in 23 out of 29 Indian States and Union Territories of the country.

**Is there a proper regulatory framework that protects authentic MedTech devices and innovations?**

MedTech space is changing rapidly, which calls for the regulatory framework to adapt and become more inclusive to cover innovations and new technologies. Medical devices continue to be regulated as drugs under the Drugs and Cosmetics Act 1940. Efforts have undoubtedly been made to bring medical devices under proper regulation by amending the Drugs and Cosmetics Rule from time to time. And it was only in January 2017 that the Medical Devices Rules were framed for the first time. A step in the right direction, but more improvements are required. International norms have been revised since then, and in some cases, Bureau of Indian Standards norms are not in conformity with Indian Standards Organisation or International Electrotechnical Commission requirements.

The Ministry of Health and Family welfare was implementing Unique Device Identification (UDI) for medical devices from January 1, 2022, but this has been delayed till further notice. Under Rule 46 of the Medical Devices Rules, UDI would have been mandatory for medical devices approved for manufacturing for sale or distribution or import. Globally, UDI is expected to play a pivotal role in improving patient safety by enabling device identification and tracking. Such positive initiatives, in our opinion, should not be delayed and should be implemented as soon as possible. The regulatory framework for protecting innovation and intellectual property and existing governance structures needs to be strengthened to stay attune to the new age changes.

**How can the country, industry and brands prepare themselves to fight the problem of fake and substandard MedTech devices?**

The solution starts from acknowledging and understanding the problem and its magnitude. We need to stay one step ahead of the criminals to make their task difficult and unrewarding. Government can guide the whole ecosystem towards a more

nurturing environment for authentic products. They can take the lead by making it mandatory to use authentication and traceability solutions to secure the supply chain.

The MedTech brands that invest heavily into producing world-class devices should take on the responsibility of protecting the product by implementing physical and digital solutions. From tamper-proof packaging such as one-time break plastic sleeves to digitally enabled labels that easily give information about the origin and journey of the product to QR Codes that can be scanned through intelligent devices. It is a misconception that implementing authentication solutions or building track and trace systems is a considerable cost. There are cost-effective tech-enabled solutions which are highly effective. Together with industry, governments, authorities, and brands are responsible for undertaking awareness campaigns that would engage the medical fraternity, nurses, pharmacists, and consumers into actively being careful of buying a fake device. Their participation in the authentication system can be a game-changer.

**How practicable is it to implement a robust track and trace infrastructure to secure the supply chain and avoid pilferage?**

It is possible to implement a robust track and trace system that records, and provides information on-demand about an authentic product in the ecosystem. Getting this information is as easy as scanning a QR Code or barcode or sending an SMS from a mobile phone. Every product has a unique identification that makes its location known in a few seconds when attached to the track and trace system. The track and trace system, due to its design, has proved very effective in identifying pilferage spots in the supply chain by showcasing inconsistencies. This helps in identifying the defaulters and the culprits in the system.

**Anusha Ashwin**