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Telangana Drugs Control Administration faces resource challenges in regulating pharma & biotech industry

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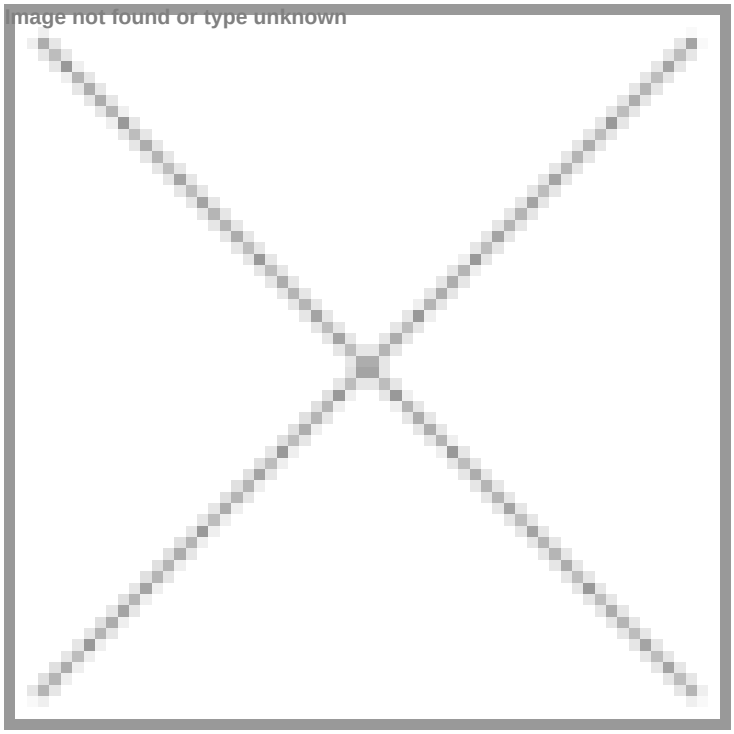

The Telangana Drugs Control Administration (TSDCA) is waging a relentless battle against resource constraints while endeavoring to enforce the Drugs and Cosmetics Act and Pharmacy Act, ensuring that the pharmaceutical and biotechnology industry in the state complies with safety and quality control regulations.

TSDCA operates with a lean team of only 53 officers overseeing a multitude of responsibilities, leaving them grappling with the challenge of meeting inspection deadlines. Their duties encompass the sampling of pharmaceutical products, dispatching them to laboratories for rigorous efficacy and quality assessments, conducting routine inspections, and supervising the adherence to cGMP standards. These tasks extend to monitoring more than 500 pharmaceutical and biotechnology companies, over 35,000 pharmacies, and hundreds of blood banks and hospitals throughout the state, creating a demanding workload for the already stretched resources.

Kamalasan Reddy, IPS, Director General of Drug Control Administration, Telangana, revealed that in his three months since taking office as the full-fledged DG, he has been actively engaging with various stakeholders, including the Bulk Drug Manufacturing Association (BDMA), pharmaceutical and biotechnology industry associations, pharmacy associations, blood bank associations, and other healthcare industry stakeholders. The objective is to identify the challenges and issues within

the sector and develop solutions to address them.

TSDCA shoulders two significant responsibilities: promoting the growth of the pharmaceutical and biotechnology industry by facilitating their establishment in the state, and strictly enforcing the Drugs and Cosmetics Act and Pharmacy Act to ensure that every player in the healthcare and medical technology industry adheres to safety and quality control standards during production.

Despite the staffing crunch with 18 vacancies of drug inspectors yet to be appointed by the state government, TSDCA is making the most of its existing workforce by forming teams and outsourcing additional personnel when necessary to ensure strict implementation of the Drugs and Cosmetics Act.

In response to anticipated changes to Schedule-M by the central government, TSDCA has issued instructions to pharmaceutical and biotech companies with turnovers below Rs 250 crore, requiring them to implement the new Schedule-M regulations within one year. For companies with turnovers exceeding Rs 250 crore, the implementation period is shortened to six months. This move aims to align Indian pharmaceutical and biotech industries with international cGMP standards, which could lead to easier approvals from international regulatory bodies for exporting Indian pharmaceutical and biotech products.

The Director General emphasises that small and medium-scale pharma and biotechnology enterprises should prioritise adherence to cGMP and quality control standards over increasing production capacity. TSDCA employs a two-pronged strategy for inspecting manufacturing units, including joint targeted inspections with the Central Drugs Standard Control Organization (CDSCO) and risk-based surprise inspections. These measures enable TSDCA to uphold the Drugs and Cosmetics Act, ensuring the availability of high-quality medicines for consumers and patients.

The Director General of TSDCA encourages vigilance among citizens and industry stakeholders to combat the proliferation of counterfeit and substandard drugs. While TSDCA and the CDSCO fulfill their roles in implementing drug regulations, the responsibility for creating a better society free from substandard drugs lies with all stakeholders.

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