PSA Prof. Ajay Kumar Sood chaired the 4th review meeting on progress to improving India's regulatory ecosystem for medical products

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The fourth follow-up meeting of 24th PM-STIAC meeting on ‘Transforming the regulatory ecosystem of the medical products in India’ was chaired by Prof. Ajay Kumar Sood, Principal Scientific Adviser (PSA) to the Government of India on August 19, 2025. The PM-STIAC meeting recommended improving the regulation for medical processes to create a system that ensures transparency, and accountability while promoting innovation in reliable medical products for India and the world.

Dr. Rajeev Raghuvanshi, Drug Controller General of India (DCGI), Central Drugs Standard Control Organisation (CDSCO) updated the progress in priority areas, and informed about the initiatives being undertaken. This included a successful launch of the State Drug regulatory Index on August 12, 2025, where states will be benchmarked based on the performance of state drug regulators through an objective evaluation mechanism. Prof. Sood remarked that such competitive benchmarking would draw all States into the system and significantly raise the overall standard of drug regulation in India.

Dr. Raghuvanshi informed about the release of a comprehensive guidance framework for Subject Expert Committees (SECs) which provides guidelines on application review process. He further informed that the rollout of digital dashboards for tracking and prioritisation has helped reduce processing timelines of applications. For instance, in case of CT-04 applications for Global Clinical Trials for Cell and Gene Therapy (CGTs), the number of days from application submissions to SEC deliberations has decreased significantly, from 226 days in 2022 to 40 days in 2024. Similarly, the approval process for major Post Approval Changes in CGTs has been expedited, with durations of 218 days in 2022 to 98 days in 2024.

Along with the digitisation measures at CDSCO, a digital system with analytics for NSQ (Not of Standard Quality) data, Dual-Use NOC (No Objection Certificate), and digital system of WHO (World Health Organisation) Certificate of Pharmaceutical Product have also been operationalised, creating a harmonised national database and enhancing transparency. Further, in alignment with the global norms, CDSCO has prepared biosimilar guidance which will facilitate enhanced access of biologics in the country.

Prof. Sood emphasised the importance of defining long-term, quantifiable milestones for India's regulatory system, towards international gold standards including periodic internal audits and measurable targets. He stated that the ongoing transformation is expected to enhance patient safety and domestic capabilities while also giving Indian manufacturers a competitive edge in global markets. Acknowledging the progress, the PSA reiterated that these reforms will strengthen trust in India's regulatory framework, boost predictability and global credibility, and facilitate quicker access to safe, affordable medical products through innovation within the country.

The review was also attended by Dr. Parvinder Maini, Scientific Secretary, Office of PSA; Dr. Sindura Ganapathi, PSA Fellow; Dr. Sangeeta Agarwal, Scientist 'F', Office of PSA; Mr. Apoorv Chouhan, Project Manager, One Health PMU from Office of PSA. They were joined by Shri Nikhil Gajraj, Joint Secretary, Department of Health and Family Welfare.

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