Indian regulator's revamped approval route looks to clear biosimilar bottleneck

10 August 2026 | News | By Dan Stanton|Editorial Expert - Sartorius

India's drug regulator has cut biologics approval times and set out a route for continuous manufacturing to keep pace with a biosimilar market expected to grow tenfold, a CDSCO official says.

Arvind Kukrety, Deputy Drugs Controller at the Central Drugs Standard Control Organisation (CDSCO), set out the agency's position at Sartorius's Process Intensification (PI) Forum in Hyderabad, India, on 3 June 2026. Kukrety placed India's biosimilar market at $800 million to $1 billion in 2024, projected to reach around $10 billion by 2030, against a global biosimilar market heading toward $75 billion to $80 billion.

CDSCO rewrote its post-approval change rules in 2024, the first revision since 2008. The guidance splits the dossier and post-approval routes, adds a fourth reporting tier for the lowest-risk changes on top of the existing three, and raises documentation to match WHO and Health Canada requirements.

Where the agency has no guidance of its own it accepts ICH standards. Thus, the continuous-manufacturing framework ICH Q13, adopted internationally in 2022, already applies. That framework covers the conversion of an approved batch product to continuous production, extends to biosimilars and other therapeutic proteins, and runs a defined path.

A change to the drug substance process is treated as a notifiable change, carrying a set data package of a process flow diagram, in-process controls, a process performance qualification, certificates of analysis for three batches, and stability data at room temperature and accelerated conditions. Adding a new manufacturing site is a higher-tier supplement needing prior approval. Comparability against the approved product runs through the whole process, with the manufacturer having to show the critical quality attributes are unchanged or justify any that are.

The route is not theoretical, as the Indian drugmaker Enzene – also present at the Sartorius PI Forum – has taken four biosimilars made on a fully connected continuous line onto the Indian market, among them an adalimumab it launched as the first product it commercialized using continuous manufacturing, all cleared by CDSCO.

Kukrety said CDSCO now clears an investigational new drug application in 30 days and a biologics market authorization within 120, though the guidance stops short of committing to fixed timelines. Working with the Kaizen Institute, the agency has stripped redundant steps from its own review and cut turnaround over the past year.. Filing has moved almost entirely online through a set of central and state e-governance portals covering market authorizations, manufacturing and sales licenses, and test licenses, and Kukrety said the agency wants to issue market authorization, registration, and import licenses together rather than in sequence, closing a lag that applicants have long complained about.

The constraint, however, is people. CDSCO runs on about 800 staff at headquarters, with a further 2,000 in central laboratories and up to 3,000 across the states, and Kukrety was blunt that 800 is not enough for a review load running into the thousands a year. The fix rides on Biopharma SHAKTI, the â?¹10,000 crore (about $1.2 billion) program announced in the February 2026 union budget to build out India's biologics and biosimilars base over five years. It funds a dedicated scientific review cadre at CDSCO, and Kukrety put the agency's own reinforcement at 1,500 additional reviewers.

Kukrety framed the overhaul as an open door. “From CDSCO's point of view, we are committed, we are open, and we encourage you to come up with whatever you feel for improvement in our organization or our systems,” he said.