Tutorials, Training sessions & Promotions push: CDSCO in full charge for CoPP online play

Discontinuing the earlier practice of physical submission to obtain CoPP certificate, drug regulators have laid out a comprehensive plan for a seamless transition of business with video tutorials, industry training sessions boosted with social media push to streamline approval process while improving transparency and accountability of actions.

New Delhi: From video tutorials, industry training sessions to promotions on social media, Indian drug regulators are in full swing to facilitate the onboarding of drug manufacturers onto the ONDLS portal ahead of the August 15 deadline of mandated online submissions for obtaining WHO GMP (CoPP) certificate.

In an ongoing effort to digitise various regulatory procedures—submissions, review, approvals—the Drugs Controller General of India (DCGI), last month issued a directive, discontinuing the practice of physical applications for WHO GMP Certificate of Pharmaceutical Product (COPP) and mandated the digital route, effective from August 15 as of now.

With the announcement, officials at the Central Drugs Standard Control Organisation (CDSCO) are mustering all hands and means to facilitate the onboarding of manufacturing units onto the Online National Drugs Licensing System (ONDLS), in order to ensure a smooth transition and prevent commercial disruptions.

Beginning with, is the extension of the onboarding phase deadline by one month (July 15 to August 15), in response to multiple representations from industry lobbies concerning export disruptions and urging additional period, noting that “several manufacturers are still in the process of registering and uploading documents onto the ONDLS portal.”

This was followed by the release of "user manuals" in video format on the CDSCO official YouTube channel, providing step-by-step guidance to apply for the WHO Good Manufacturing Practice (GMP) and CoPP certificates.

Most recently is the announcement of a month-long training schedule—-from July 21 to August 13—to conduct knowledge sessions for manufacturing firms with designated trainers “to provide more clarity on the online process.”

As per the notified schedule, the CDSCO will conduct forenoon and afternoon sessions on select dates at its zonal offices (North East, West, and South) and sub-zonal offices located in Hyderabad, Bengaluru, Baddi, Ahmedabad, Dehradun, Indore, Vizag, Goa, Guwahati, and Jammu.

Giving a modern booster dose is the CDSCO officials, who from their personal social media space are attempting to amplify the updates and expand engagement.

An instance of this, is a recent post by Dr Ranga Chandrashekhar, Joint Drug Controller (India) who on a professional platform shared the video tutorial produced by the body.

Sharing the tutorial the senior regulator posted, "CDSCO has made step wise video guidance for submission of WHO GMP/CoPP. You may follow the YouTube link for the videos."

While participating at a panel discussion at the World Health Summit Regional Meet 2025 in New Delhi, the DCGI Dr Rajeev Raghuvanshi stated, digitization of regulatory procedures has helped to build trust and improve transparency and with its continuous efforts the CDSCO has digitised 99 per cent of its regulatory and administrative procedures.

Earlier this month, another senior regulator Dr Annam Visala, Joint Drugs Controller (India) in her keynote address at the ETPharma Tech Innovate conclave noted that, the central regulator is working on upgrading the SUGAM portal (another online platform of CDSCO) and will soon launch Version 2.0, which will be at par with leading international regulatory platforms.

"CDSCO has digitised 99 per cent of its processes and in the second stage of digital maturity, it plans to introduce new protocols and launch Version 2.0 of the SUGAM portal to enhance ease of doing business and support faster drug approvals," she stated.

According to the World Health Organisation (WHO), a Certificate of Pharmaceutical Product (COPP), is a document issued by a country's regulatory authority to certify that a pharmaceutical product is manufactured in compliance with Good Manufacturing Practices (GMP).

It establishes that the product is approved in the exporting country and can be evaluated for approval by the importing country NRA (National Regulatory Authority).

As per a CDSCO note "COPP certificate is issued under the WHO GMP Certification Scheme for the purpose of international commerce i.e. for registration of products in foreign countries."

Until now, manufacturing units in India were required to submit physical applications at their respective zonal and sub zonal offices, but as the industry joins the digital wave harmonising domestic regulatory practices with international benchmarks stands as an imperative step.

However, surrounded with apprehensions, the digitisation of the approval process suggests merely the incipient phase of a comprehensive overhaul.

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