

CDSCO IT-13011(12)/7/2025

Government of India Directorate General of Health Services Central Drugs Standard Control Organization FDA Bhawan. Kotla Road, New Delhi-110002

Dated

0 7 AUG 2025

То All State/UTs Drugs Controllers

Subject: Grant of WHO GMP COPP through ONDLS Portal reg.

Sir/Madam.

This is to inform all concerned that, as per Circular No. IT/COPP/ONDLS/2025/001 dated 25.06.2025, it was mandated that all applications for WHO-GMP (COPP) must be submitted exclusively through the ONDLS portal starting from 15.07.2025. Accordingly, physical submissions were to be discontinued from that date.

However, considering various representations received from stakeholders and in support of industry interests, the deadline was extended up to 15.08.2025, as communicated vide Circular No. CDSCO IT-13011(12)/7/2025 dated 15.07.2025. It is now re-emphasized that no physical applications/files will be accepted after 15.08.2025 for the grant of WHO-GMP (COPP).

To facilitate a smooth transition, CDSCO has already conducted multiple physical and hybrid awareness and training sessions at Zonal and Sub-Zonal levels from 21.07.2025 onwards, in collaboration with CDAC officials. These sessions were attended by state authorities and Pharma stakeholders to address queries and ensure seamless adoption of the online system.

It is requested that the SLAs ensure proper mapping of the concerned officials along with their respective jurisdictions who are handling these files, and that they may be instructed to approve the list of products after due verification.

In view of the above, as the final deadline is approaching, it is reiterated that no extension beyond 15.08.2025 will be granted for the physical submission of applications for WHO-GMP (COPP) approval. Hence, you are requested to direct the Manufacturing units under your jurisdiction to submit application for the approval of WHO GMP (COPP) through ONDLS portal from 15.08.2025.

Further, CDAC may be contacted at uttamkumar@cdac.in or ondlssupport-noida@cdac.in & CDSCO (it-cell@cdsco.nic.in) for any assistance regarding ONDLS portal. This is for your information and necessary compliance.

Yours faithfully

Dr. Rajecy Singh Raghuvanshi)

Drugs Controller General (India)

Copy to:

- 1. All Zonal and sub zonal office of CDSCO with direction not to accept the application in hardcopy after the deadline mentioned above (15.08.2025).
- 2. All Pharmaceutical association