

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: 15.07.2025

To All State/UTs Drugs Controllers

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

Sir/Madam.

With reference to Circular No. IT/COPP/ONDLS/2025/001 dated 25.06.2025 regarding the "Grant of WHO GMP COPP through ONDLS portal", it was directed that all applications for WHO GMP (COPP) shall be mandatorily submitted through the ONDLS portal from 15.07.2025 onwards, and no physical files will be accepted thereafter.

It has come to the attention that several manufacturers are still in the process of registering and uploading documents onto the ONDLS portal. We have also received representations from various industry associations highlighting challenges in onboarding on ONDLS portal and they need more time to complete the process.

In view of these concerns and to support industry interests, the deadline is hereby extended up to 15.08.2025.

In view of the above, 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. It may be noted that physical files will not be entertained for approval of grant of manufacturing License and WHO-GMP (COPP) from 15.08.2025. Meanwhile CDSCO is organizing multiple knowledge sessions at Zonal/Sub-Zonal levels. Stakeholders may like to attend these sessions for more clarity on the online process, if required.

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. Rajeev Singh Raghuvanshi)

Drugs Controller General (India)

Copy to:

All Zonal and Sub-Zonal offices with direction not to accept the application in hardcopy after the deadline mentioned above.