

BDMAI/DCA/13/2025

Date: 12.9.2025

Sri Shahnawaz Qasim IPS
O/o The Director General
Drugs Control Bhavan, Drugs Control Administration
Vengalrao Nagar
Hyderabad

Dear Sir

Sub: Request for off-line issue of WHO GMP (CoPPs)

Greetings from BDMAI!

We would like to bring to your kind attention the concerns of the pharmaceutical industry regarding the recent procedural changes in the issuance of WHO GMP (CoPPs).

As you are aware, the CDSCO issued a notification dated 25th June 2025 mandating that all manufacturers apply for WHO GMP (CoPPs) through the online ONLDS portal, effective from 15th July 2025. Upon representations made by various Industry Associations, the deadline was extended to 15th August 2025.

In line with suggestions made by the Deputy Drugs Controller, Hyderabad Zonal Office (CDSCO), BDMAI organized a meeting with its members to gather first-hand feedback regarding the ONLDS application process. The consolidated list of issues faced by the industry was submitted to the Drugs Controller (India), CDSCO, on 5th August 2025. A copy of this representation is enclosed for your reference. In our submission, we also requested an extension of the implementation timeline, beyond 15th August 2025, until the identified issues are adequately resolved.

It has come to our notice that State Drug Administrations of Maharashtra and Gujarat have suggested modifications to the ONLDS portal and requested customization to accommodate their specific requirements. However, since these changes have not yet been implemented, the respective authorities continue to issue WHO GMP (CoPPs) using their existing offline procedures.

We would like to express our sincere gratitude to the Drug Control Administration of Telangana for acknowledging the industry's challenges and resuming the issuance of CoPPs (for products listed in valid WHO GMPs) through the OLDS platform. However, we understand that applications for new products are being directed exclusively through the ONLDS.

Given the ongoing technical issues with ONLDS, as detailed in our earlier representation, we respectfully request your continued support in issuing WHO GMP (CoPPs) offline—at least until the ONLDS system becomes fully functional and user-friendly. Your kind cooperation will significantly aid exporters in Telangana during this transitional phase.

We would also like to highlight that our members have not encountered any such issues with other online systems such as SUGAM or NSWs. Therefore, we humbly request you to consider recommending to the Drugs Controller (India) that WHO GMP applications be integrated with either of these platforms until ONLDS is streamlined.

We sincerely appreciate your understanding and continued support in addressing this matter, which is critical for the smooth functioning of the pharmaceutical export ecosystem.

Thanking you in anticipation.

Yours sincerely



M. Roja Rani

Executive Director

