

BULK DRUG MANUFACTURERS ASSOCIATION INDIA

C-25, Industrial Estate, Sanath Nagar, Hyderabad 500 018

info@bdmai.org; ed@bdmai.org; www.bdmai.org

Dr. Rajeev Singh Raghuvanshi

Drugs Controller General (India)

O/o Central Drugs Standards Control Organization

New Delhi

Dear Sir,

Sub: Request for Support and Transitional Measures for New Online WHO-GMP CoPP Application System

We refer to the circular dated 25th June 2025 informing the industry about the launch of the new portal developed by CDAC for submission of applications for the grant of WHO-GMP CoPPs.

While the industry appreciates CDSCO's continued efforts in streamlining regulatory procedures through digital platforms, there is growing concern that the implementation of such a critical regulatory process via an online system, without adequate guidance and support, may adversely affect product registrations and international supply commitments. There is apprehension that Indian exporters could lose valuable business opportunities in global markets due to potential challenges in navigating the new system. The industry is already facing lot of issues with respect the online system (NSW) for obtaining Test Licenses etc.

In light of the above, we respectfully request that the following measures be considered to facilitate a smooth transition:

1. **User Manual:** Kindly provide a detailed user manual or step-by-step guidance document for the new portal to assist applicants in understanding and navigating the system.
2. **Stakeholder Engagement:** Organize zonal-level stakeholder meetings or webinars, including a live demonstration of the portal, to address user queries and concerns.
3. **Parallel Offline System:** Continue accepting offline applications for WHO-GMP CoPPs alongside the new online system for a limited period, until the latter is fully stabilized and users are well-versed in its operation.

We sincerely hope that these requests will be considered favorably and necessary action will be taken at the earliest, given that the new system is scheduled for implementation from **15th July 2025**.

Thank you for your continued support and understanding.

Thanking you,

Yours sincerely,

R K Agrawal

National President

Copy to:

Shri A Narendran

Dy. Drugs Controller India (India)

CDSCO Zonal Office

Hyderabad