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**Issues Pertaining to Issuance of WHO GMP/CoPPs through ONDLS Portal**

1 message

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11 June 2026 at 13:12

To: "Dr. A. Ramkishan" &lt;hyderabad@cdsco.nic.in&gt;

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**BULK DRUG MANUFACTURERS ASSOCIATION OF INDIA**

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BDMAI/CDSCO/2026

11th June 2026

Shri K Narendran  
Dy. Drugs Controller (I)  
O/o CDSCO Zonal Office  
Hyderabad

Dear Sir,

**Sub: Issues Pertaining to Issuance of WHO GMP/CoPPs through ONDLS Portal**

Greetings from Bulk Drug Manufacturers Association of India (BDMAI)!

At the outset, on behalf of the bulk drug industry, we would like to express our sincere gratitude for the continued support and guidance extended by your good office to the pharmaceutical industry. We also take this opportunity to place on record our appreciation for your valuable efforts in organizing a series of interactive meetings with the industry during the initial implementation of the ONDLS portal for issuance of WHO GMP /CoPPs, as well as the subsequent review meetings conducted from time to time.

We wish to bring to your kind notice that, despite the best efforts and support extended by your office, the industry continues to face several challenges while obtaining WHO GMP / CoPPs through the ONDLS portal. During a recent interaction with our member companies, numerous issues were brought to our attention, some of which are enclosed herewith for your kind reference.

It may kindly be noted that tickets have been raised for most of the issues listed. While a few issues have been resolved, a large number of them remain pending. It is also observed that, in several instances, identical issues have been resolved for certain companies and remain unresolved for other companies. Such delays are adversely affecting export commitments and regulatory submissions of the industry.

In view of the above, we sincerely request your good office to kindly consider the following:

**a) Organizing a One-Day Workshop at Hyderabad:**

A dedicated workshop may kindly be organized involving officials from C-DAC, CDSCO Headquarters, Drug Control Administration, Telangana, and representatives from the pharmaceutical industry. During

the workshop, live filing of applications may be undertaken and issues encountered in the process can be discussed and resolved on the spot. Such an exercise would greatly help in identifying systemic issues and improving the efficiency of the portal. BDMAI shall be pleased to extend all possible support and coordination for organizing the workshop.

**b) Establishment of a Physical Help Desk:**

A dedicated physical Help Desk of C-DAC may kindly be facilitated at your office to address day-to-day operational issues faced by the industry. Such a mechanism would enable immediate resolution of technical and procedural difficulties without the need for raising multiple tickets and waiting for online responses, thereby significantly reducing delays in issuance of WHO GMP Certificates and CoPPs.

We are confident that the above measures would go a long way in resolving the practical difficulties being faced by the industry and in ensuring smooth and timely processing of applications through the ONDLS portal.

We shall be grateful for your kind consideration of the above requests and look forward to your favourable response.

Thanking you,

Yours sincerely,

M Roja Rani  
Executive Director



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# Issues Faced in ONDLS Portal for WHO GMP Applications

## 1. Product Details Module Issues

Initially, it was advised by ministry that all products should be included in the ONDLS Portal for authorization by State Licensing Authorities. However, this approach created several operational difficulties:

- Even after submission and approval, many products are not reflected properly in the portal.
- State officers are unable to easily review products due to the extremely large number of products handled for each manufacturing site.
- Subsequently, the Ministry advised manufacturers to submit only those products required for WHO GMP applications first and obtain authorization from the State Licensing Authority.
- Later, another circular clarified that approval was not mandatory for application processing, while simultaneously making approval compulsory for WHO GMP Approval

Further, the portal interface is not user-friendly:

- The tiles and workflow in the portal are unclear and difficult to understand.
- There is no proper sequential flow for product entry and submission.
- Users are required to switch between multiple tiles for product entry, submission, and product history updates.
- Product history must first be entered and registered before becoming eligible to apply for WHO GMP, making the process lengthy and confusing.

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## 2. WHO GMP Filing Issues

After submission of product details, applicants are required to file the WHO GMP application through the portal. However, several technical and procedural issues are being faced:

- Even after approval from the Central Authority, approvals from the State Licensing Authority are delayed due to portal-related issues.
- The portal is updated frequently, sometimes on a daily basis, without proper notifications or communication regarding the changes made.
- Applicants are unable to submit additional products WHO GMP application while one application is already under process (“in transit”).
- Even after approval of one WHO GMP application, there is no option available to submit another WHO GMP application for additional products.
- At present, only the COPP option is visible after approval.

There is also a major lack of clarity regarding the scope of WHO GMP approval:

- Earlier, under the old procedure, WHO GMP approvals were product-specific.
  - Under the current portal system, it is unclear whether approval is being granted for the manufacturing site or for individual products.
  - Since many ROW markets specifically require product-wise WHO GMP approval, the present system is creating serious compliance and export difficulties.
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### **3. Site and Approval-Related Issues**

Several issues are also being faced at the site and approval stage:

- Product details are not properly visible in the portal.
- Brand names entered by the firm are not visible in the approval section.
- Approved details cannot be properly viewed or verified.
- There are no clear amendment, correction, or modification options available after approval.
- Multiple technical issues continue to affect the approval workflow and usability of the portal.

#### **COPP Certificate and Preview Issues**

- The preview format of the COPP Certificate is being modified frequently without prior intimation.
- After entering the COPP product details, the “View Product Preview” option is displayed; however, the document is not opening.
- After completion of the COPP checklist, the product preview becomes visible. However, the checklist itself requires attachment of the COPP application form/document.
- Since the process directly moves to Challan payment and final submission after checklist completion, there is no clarity regarding:
  - how the preview/application document should be attached, and
  - at which stage the attachment is required to be uploaded. as per the state DI Requirements

#### **Challan and Payment-Related Issues**

- We are facing difficulties in Offline Challan payment processing for applications submitted through the ONDLS Portal.
- In the existing ODLS system, there was a dedicated online payment facility through which applicants could make payments directly online.
- However, in the ONDLS Portal, there is currently no provision available for online payment, causing delays and operational difficulties.
- There is also no clarity regarding the calculation methodology of fees/payment for COPP applications.
- Applicants are unable to understand:

- the basis of fee calculation,
  - whether fees are calculated product-wise or country-wise,
  - and how challan amounts are determined for multiple products and multiple countries.
- Due to the lack of clear payment guidelines and absence of online payment options, applicants are facing repeated issues during challan generation and submission of applications.