BULK DRUG MANUFACTURERS ASSOCIATION OF INDIA

BDMAI / CDSCO / 2025

Date: 5.8.2025

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

Dear Sir,

Sub: ONDLS for submitting applications for WHO GMP (CoPPs) – Issues expressed by member companies.

Kindly refer to the meeting the undersigned had with you on 28th July 2025 at the Zonal CDSCO Office on the above subject. We are very thankful for positively responding to some of the issues like foreign directors, Pallets etc., by referring the same to the Technical Team. During the meeting we informed that a meeting of Executives of our member companies who are actually working on this job would be organized to understand their genuine issues.

Accordingly, a meeting was organized on 1st August 2025, where executives from large and medium scale companies attended. The participants expressed several issues, and they also demonstrated the same by executing two applications, one for API and one for Formulations. A list of issues raised in the meeting is enclosed for your kind perusal.

As can be observed from the list of issued raised, some of them can be resolved before the last date given for implementation of the new system for issue of WHO GMP (CoPPs) i.e. 15th August 2025. However, our members apprehend that many of the issues are genuine and cannot be practically resolved before the above date.

Our members have also made the following suggestions, for smooth transition of the process of issuing WHO GMPs from off-line to online:

1. **Historical Data**: As for as Historical data is concerned, applicants may be allowed to upload their entire data of CoPPs through a pre-defined format along with respective WHO GMP certificates issued by the State Licensing Authorities. For this purpose, a format may be designed and made available in the system. Once the applicant uploads the list, SLAs may be allowed to verify and approve in the same system

2. **Registration of Units**: Companies with more than on one manufacturing unit may be allowed to register all their units with single login details, as they do in case of EU Written Confirmations.

3. **Mapping of Technical Staff**: As explained in the attached list of issues, companies with large number of units are severely hit due to mapping of

technical staff. Since the WHO GMPs are issued by the SLAs after due recommendations by CDSCO, where the technical staff data is also verified, it is suggested that for the technical staff mentioned in the already issued WHO GMPs may be given Unique Identification Numbers. For the new technical staff, the present system may be followed.

We sincerely hope the issues / concerns expressed and suggestions given by our member companies are considered favorably. As many of the companies are stuck at various levels and could not process the applications, **we sincerely request you to consider extending the timelines beyond 15th August 2025.**

Thanking you,
Yours sincerely,

BULK DRUG MANUFACTURERS ASSOCIATION ★ Hyderabad

M Roja Rani
Executive Director

BDMAI MEETING WITH INDUSTRY REGULATORY EXECUTIVES ON 1.8.2025 ON NEW ONLINE SYSTEM FOR WHO GMPs

Sl. No.	Description of job	Issues	Remarks
1	Corporate Registration	1. Old Registered Office address is getting picked and there is no option for edit	
		2. Some companies have foreign directors and there is no provision how to enter their details in the absence PAN, Aadhar etc.	
2	Unit Registration	1. Each Unit is to be registered with unique mobile and email id. For those companies with 30-40 units, registering each unit itself is taking lot of time	Units registration is getting delayed due this problem
		2. Applicants are not getting OTPs through emails	
3	Login	Login is taking too much time, particularly in the morning hours	This a common problem expressed by every one
		1. There are too many tiles / tabs with similar nominclature cuasing confusion	Due to multiple issues, it is taking lot of time. It can be avoided if all old data can be
		2. There is no pop-up to describe for the tiles / tabs indicating what it contains	
		3. Too many details to be entered for each product. Like Storage requirement, packing presentation etc., which are not required at the stage of old data mangement	
		4. There is no provision to enter multiple pharmacopeia details. If one product has USP/EP/IP/BP, the applicant has to fill up the application 4 times	
		5. There is a provision to upload Analytical document and there is no clarity which document to be uploaded	
		6. If the product is manufactured for both domestic and export purpose, there is no provision to select both. If Export is selected, SLA mayreject it if export & domestic option is there in the license	

4	Old Licenses Management	7. If the facility has different licenes like Form 25 / 28 , there is no option to select both. If application is completed by selecting one Form,, there is no prosion to select the same license again to complete the other Form	uploaded in a single file along with relevant Licesnes. SLAs can be given an option to verify and approve in the same system
		8. There is a provision to enter the details of packing details. If the description is less than 50 characters, it is not accepting	
		9. Entering Brand Name is mandatory. In case of APIs, there is no brand	
		10. Product Mapping: After completing License details and submitting, the system is picking all junk in place of product details, making it difficult for the applicant to select the product, for which CoPP is required.	
		11. License basic details: There is no clarity on which details (product or facility) to be entered here	
		12. Multiple users are not allowed to enter the data using the same login details. It is very difficult for one signle person to enter the data where some companies have more than 8000 products	
5	Technical Staff data	1. Some employees do not have PAN. In some cases, PAN & Aadhar are not linked	All the participants have expressed same problem
		2. Some employees are refusing to share PAN details, fearing loss of FREE benefits available to their paratents offered by various States & Central governments	
		3. Employees are not allowed to use their mobiles or access their personal emails during working hours and in some cases, do not have access to Laptops / systems to login and complete their details, after working hours.	
		4. Where one person responsible for licensing is entering their details, employees are refusing to share OTP details	
		5.Uploading 10th class certificate is mandatory, who has acquired a Post Graduation certificate also.	
		6. Employees with 15-20 years experieince, finding it difficult to locate their 10th class certificate	

		7. Complete experience details are reuired to be entered, whereas Act requires only 5 years experience	
6	Submission	1. After submitting the application, an error is popping up indicating that your unit is not mapped with any PIN code	
		2. When the issue is escalated to CDAC, the applicant received a reply asking them to contact respective SLA and closed the issue.	
7	SLA approvals	1. It is taking lot of time to get approvals from SLAs - 15 - 25 days	
		2. Most of the times the SLAs are pre-occupied with their regular works	
		3. Sometimes SLAs are also finding it difficult to locate the files that are required to be verified and approved	
		4. In some cases, where the SLAs have approved the licenses, only partial data of products is getting reflected in the approval. Neither the applicant nor the SLAs are able to find the status of remaining products	
8	Application for CoPP	1. Same data which is required for WHO GMP is again asked for CoPP also	
		2. If the applicant has chosen some products in a License and applied for CoPP, he cannot use that license for applying for CoPPs for the rest of the products. They have to wait for the approval of CoPPs applied earlier.	

Note: Above issues are only up to the stage of approval by SLAs as a very few companies have got the SLA approvals and applied for CoPPs.