PHARMA

DCGI calls for suggestions from industry to reduce compliance burden

Pharma associations are likely to submit their recommendations by early next month

By **Usha Sharma** On **Jan 29, 2021**

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The Drug Controller General of India (DCGI) has asked industry associations to submit their representations highlighting aspects or issues in the Drug and Cosmetics Rule 1945 that can be made redundant to reduce the compliance burden on the industry.

In a recently held webinar, 'Reducing Regulatory Compliance Burden', the DCGI interacted with industry representatives from IDMA, BDMA, FOPE, OPPI, CIPI, HDMA, Laghu Udyog and asked them to highlight regulatory issues faced by the industry.

Some of the associations have already submitted their representation, whereas many of them are likely to submit it by early next month.

The IDMA representative requested that instead of making Schedule M mandatory it should be in the form of guidelines. The IPA representative expressed that the implementation of Schedule M should be done at the earliest.

IDMA suggested making separate rules for excipients and disinfectants and also pointed out that there is a need to properly define APIs and NSQs to avoid misinterpretation.

The association also highlighted issues pertaining to shelf-life of formulations. It said that in the current scenario, shelf-life of formulations is not allowed to go beyond the shelf-life of APIs. It also stressed that bulk drugs which are exported and returned for reasons of non-compliance of physical parameters like moisture, particle size and bulk density should be permitted to be sold in the domestic market. It is not allowed currently.

Similarly, HDMA and IPA requested for QR codes on APIs. BDMA will be preparing a detailed report to submit to the regulatory authority on joint inspection for WHO certification which is taking a long time.

During the session, the association representatives also suggested creating Centre-State Committees wherein industry experts can also join. And these Committees can help in updating the guidelines as is done in the WHO.

Dr Rajesh Gupta, All India Head, Laghu Udyog Bharati Pharma Wing and President of Himachal Drug Manufacturers Association, said, “To ensure ease of doing business modules, we need to amend various sections of D&C Act 1940, which was discussed by all associations like IDMA, FOPE, BDMA, HDMA, CIPI. During the presentation, we demanded that instead of suspension and licences cancellation on *prima-facia,* there should be a consideration for an improvement period and show cause notice for compliance to genuine and valid license manufacturing holders.”

“We have also requested that Section 33 P guidelines should become a Rule and law should protect genuine manufacturers and license holders from spurious allegations,” said Gupta. He said that due to misuse of Section 17(c) and (D), many genuine and v license holders are being prosecuted.

Sudarshan Jain, Secretary-General, Indian Pharmaceutical Alliance, commented, “We are in the process of preparing a representation requested by the DCGI. In the next few days, we will be able to submit our recommendations to the authority.”

Dr Viranchi Shah, National Vice President, IDMA, informed, “This is an excellent and apt initiative of the DCGI, Dr Somani. Removing the redundant provisions under the D&C Act and rules will greatly enable the updation of the law to the needs of the current times. The current law is over 75 years old, formed in an era when India imported most of our pharma needs. Today, the scenario has changed, we are global producers, and therefore the change in Act and Rules is due, in order to fit the current and future needs of the society. This step will also help reduce the burden of compliance and help improve the efficiency of the operations of this industry. This is a path-breaking initiative with a long term vision and IDMA heartily welcomes it.”

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