BDMAI BULK DRUG MANUFACTURERS ASSOCIATION OF INDIA

6th June 2025

GOVERNMENT OF INDIA 317 MH&FW, DGHS 06/06/25 CDSCO ZONAL OFFICE HYDERABAD

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)
O/o Central Drugs Standards Control Organization
New Delhi

Dear Sir,

Greetings from BDMAI!

Sub: Representation on various issue raised by the Industry

We take this opportunity to extend our sincere thanks for appreciating the genuine problems faced by the industry and providing solutions to many of the issues raised by the industry subsequent to the guidelines issued on 7th March 2025.

We are also thankful to the DDC, Zonal Office, Hyderabad, for organizing an interactive meeting with the stakeholders on 23rd May 2025 and providing clarifications on the issues raised by the stakeholders. Based on the discussions during the meeting, we bring the following points to your notice:

a)Destruction of APIs with less than 60% shelf-life:

Many of the members expressed that destruction of unapproved / approved New Drugs API's with shelf-life less than 60% should be last option as the API may be treated differently than finished formulation and can follow retest procedure.
Other possibilities such as refining or rework procedures may be explored.

b) Aligning validity of export NoC with the validity Manufacturing License:

As per revised guidelines, validity of export NoC is for one year from the date of issue. You may kindly appreciate that after obtaining export NoC, the manufacturer has to obtain drug manufacturing license, manufacture the product, which takes a considerable time. After sending the sample, the customer takes a minimum 6 months time for evaluation and by the time the manufacturer gets the order, the validity of NoC expires. In view of these practical problems, we suggest that the validity of NoC may be aligned with the validity of Drug Manufacturing License, which is for 5 (five) years. This would rationalise the work on both sides.

c) Exemption from export NoC for established unapproved / New Drugs:

We also would like to bring the following long pending issues, which has been represented many times on earlier occasions:

There are some APIs which are being treated as New Drugs even though they have been manufactured by Indian companies for more than 30 years for export purpose. As these APIs are not approved for sale in India, but are listed in other major Pharmacopeia like USP / EP / JP etc., they should not be treated as New Drugs and thus the manufacturer is not required to obtain export NoC every time. Drug Manufacturing License for such product is

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also not given for the 2nd unit of the company, though the company has a valid license for its another unit.

This issue has been brought to the notice of CDSCO many times & we sincerely request you to look into the genuine problem. We suggest that export NoC to be exempted for those APIs, which are being exported and / or supplied to Export market for more than 5 (five) years.

d) Drug Pellets:

As you are kindly aware, the manufacturing of drug pellets is a highly specialized segment within the pharmaceutical industry, requiring specific infrastructure, technology, and expertise. Fortunately, India has developed significant capabilities in this area and is now recognized as one of the leading countries involved in drug pellet manufacturing.

Although the Drug pellet segment in India's pharmaceutical industry is well-established, it currently lacks exclusive regulatory guidelines. At present, pellets are treated as semi-finished formulations, and manufacturing licenses are issued for each drug, strength wise. However, for a same dose capsule pellets, different formulators ask pellet manufacturers to supply pellets of different strengths to suite their diligent mix, capsule size etc. Pellet manufacturers are forced to seek license for each strength, though they are very close and no much difference in strength. This means that even a very minor variation such as a 0.5% or even less change in active ingredient strength, separate license is required, despite the fact that such a change will not have any impact on the final dose of marketed capsule.
In today's dynamic and highly competitive market environment, the ability to respond quickly to customer is very essential. For example, if a manufacturer holds a license to produce Omeprazole pellets at 10% strength and receives an order for 10.5%, they must apply for a new license. This process can cause delays, potentially resulting in the loss of business to competitors and other countries who already possess the required license in required strength.

To address this practical and pressing issue, it is proposed that a simplified, scientifically acceptable manufacturing license for pellets be issued based on strength ranges—such as 1–10%, 11–20%, etc., based on market experience for individual drugs. This approach would allow manufacturers to produce any strength 'within the approved range' under a single license, enabling faster response to market demands without compromising on regulatory compliance.

We shall be highly thankful if the above suggestions are considered favourably.

Thanking you,
Yours sincerely,

R K Agrawal
National President

Copy to:

Dy. Drug Controller (India), O/s Zonal Office, CDSCO, Hyderabad

- With a request to send your recommendations to the above suggestions, which are based on the discussions with stakeholders in the meeting held on 23.5.2025 at your office.