

Date: 28<sup>th</sup> May 2025

Sri M B R Prasad Director Drugs Control Administration, Government of Andhra Pradesh, Siddhartha Medical College Campus, Gunadala, Vijayawada, -520 008

Dear Sir

Sub: Drug Manufacturing License against Export NOC

Greetings from BDMAI!

We would like to bring to your kind notice that some of our members are expressing some problems in obtaining Drug Manufacturing License for Unapproved / Approved New Drugs, for which Export NoC has been obtained from CDSCO.

As you are kindly aware, CDSCO has issued new guidelines on 7th May 2025 for obtaining Export NoC for Unapproved / Approved New Drugs. As per the new guidelines, Export NoC is issued with a validity period of one (1) year for a specific quantity and for multiple countries. While obtaining NoC, there is no need to submit a Customer Purchase Order. Purchase Order is required to be submitted at Port office at the time of exporting along with reconciliation statement of exported quantity and balance quantity available against the particular NoC.

However, it is understood that after obtaining NoC, when our members are applying for a manufacturing License, Customer Purchase Order is being asked along with the application. You may kindly appreciate that when the validity of Export NoC is for one year and for multiple countries and if manufacturing license is given against one Customer Purchase Order, the very purpose of issuing NoC with one year validity and for multiple countries is defeated.

We also wish to inform that State Drug Control Administration of Telangana is issuing manufacturing license without insisting for Customer Purchase Order.

We, therefore, request you to kindly consider the practical problems, as explained above and issue Drug Manufacturing License for Unapproved / Approved New Drugs against Export NoC, without insisting for Customer Purchase Order.

Thanking you and looking forward to your kind cooperation.

Yours sincerely,

R K A<del>grawal</del> National President