



BULK DRUG MANUFACTURES ASSOCIATION (INDIA)

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New Guidelines for obtaining NoC for Export of Unapproved/Approved New Drugs

We wish to inform that CDSCO has issued a Public Notice dated 7th March 2025 giving guidelines and user manual for obtaining **No Objection Certificate** for Export of Unapproved/Approved new Drugs. Copy of the Public Notice is enclosed for information of members.

As per the new guidelines, NoC can be obtained for export of any Unapproved/Approved New Drugs through online systems provided in SUGAM portal of CDSCO and validity of the NoC would be for one year.

While appreciating the efforts of CDSCO in providing an online facility to obtain NoC for export of Unapproved/Approved New drugs, which is valid for one year, some of the members expressed concerns about some of the provisions in the guidelines.

We request the members to kindly go through the guidelines and inform us if you have any concerns about any provisions of the guidelines, so that BDMAI can make a representation to CDSCO.

Please send your views/concerns to ed@bdmai.org; info@bdmai.org before 14th March 2025.

With regards

M Roja Rani
Executive Director