F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 13/3/2020

NOTICE

Subject: Requirement of CMC documents for approval of additional indication of an already approved drug product – reg.

Under the New Drugs and Clinical Trials Rules, 2019, CDSCO grants permission for import/manufacture of new drugs for sale and distribution.

Concerns have been raised regarding requirement of CMC documents for approval of additional indication of an already approved drug product.

In this regard, it is mentioned that requirements of data and information for permission to import or manufacture of a drug already approved which is now proposed to be clinically tried or marketed with certain new claims are specified in paragraph (3) of Clause 1 of Second Schedule of New Drugs and Clinical Trials Rules, 2019.

As per the said paragraph the CMC data requirements may be omitted depending on whether the drug formulation is already approved and marketed in the country by the applicant in the same dosage form for certain indication. If it is approved and marketed, no further chemical and pharrnaceutical data is as such required to be resubmitted and applicant shall mention so along with reference to his earlier submission of such data etc, in the online application format.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

To,

All Stakeholders.