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: 21/2/2020

# NOTICE

**Subject: Sub-acute toxicity study report for injectable products for BA/BE study in human for export - reg.**

CDSCO receives and process application for permission to conduct BA/BE study in human for export.

Concerns have been raised that sub-acute toxicity study report in at least two species for minimum 14 days is required to be submitted for innovator products.

In this regard, it is clarified that sub-acute toxicity data for innovator products are neither required nor asked for conduct of BA/BE study in human for export.

**Yours faithfully,**

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

**To,**

1. **All Stakeholders.**