

File No. X-11026/319/2021-BD  
Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organisation  
(Biological Division)

FDA Bhawan, Kotla Road,  
New Delhi 110002  
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Dated: 28.12.2021

To,  
All State/UTs Drug Controller

**Subject: Vigil on the activities of distribution & sale of suspected spurious Tocilizumab 400mg/20ml Injections in India – reg**

Sir,

CDSCO has received a complaint from M/s Roche Products (India) Private Limited regarding distribution & sale of suspected spurious Tocilizumab Injections in the country. The said firm is holder of import and marketing authorization for Tocilizumab Injection 80mg/4ml, 200mg/10ml and 400mg/20ml (Brand name - "Actemra") in the country and the products are distributed and marketed in the country by M/s Cipla Ltd.

In the complaint, firm has informed that their distribution partner M/s Cipla Ltd., received images of the suspected counterfeit pack from a complainant who had inquired the firm to know whether the product offered for sale to him was genuine or not. Upon preliminary technical investigation performed by M/s Roche, it was revealed that the imprinted batch details do not correspond to any genuine Roche batch in the Roche records and are spurious.

Sale of such spurious products can lead to reduced or no efficacy in the patient and it can cause severe side effects and thereby can cause a serious hazard in the public health. The drug (Tocilizumab which is imported by Roche) is currently being used in COVID-19 management.

In view of above facts and ongoing COVID-19 pandemic situation in the country, you are requested to keep a watch & vigil on the activities of distribution/sale of suspected spurious Tocilizumab Injections in India. Action taken may be informed to this office.

Yours faithfully,



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

Copy to –

- 1) All Zonal/sub-Zonal offices of CDSCO
- 2) Indian Drug/Pharmaceutical Association Forum
- 3) Website of CDSCO