F. No. 12-38/2017-DC (Pt-Misc-SND)
Directorate General of Health Services
Ministry of Health and Family Welfare
Central Drugs Standard Control Organisation
Office of DCG(I)

Date : 10 NOV 2017

NOTICE ON OSIMERTINIB DRUG APPROVAL IN INDIA

In pursuance to the Import and Market permission granted to M/s. Astra Zeneca Pharma India Limited, Bangalore., for Osimertinib Film coated Tablets 40mg/80mg (as Osimertinib Mesylate), "For the treatment of patient with metastatic epidermal growth factor receptor (EGFR) T790 M mutation-positive non-small cell lung cancer (NSCLC), as detected by an appropriate test, whose disease has progressed on or after EGFR TKI therapy", on 29/05/2017. The drug alert issued vide F. No. 12-38/2017-DC (Pt-Misc-SND) dated 13/10/2017 shall stand withdrawn.

However, all the State Drugs Controllers, CDSCO zonal or sub-zonal offices and port officers were requested to have vigil on the illegal manufacture/import, sale or distribution of Osimertinib mesylate tablets as per the provisions of Drugs and Cosmetics Act and Rules there under.

(Dr. G. N. Singh)
Drugs Controller General (India)

To

1. All State/UT Drugs Controllers
2. CDSCO zonal or sub-zonal offices
3. CDSCO Website