F. No. SND/IMP/21/000022 & SND/IMP/21/000090
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Subsequent New Drugs Division

FDA Bhawan, Kotla Road
New Delhi
Dated:

23 OCT 2025

To,

M/s. Eli Lilly and Company (India) Pvt. Ltd.,
Plot No. 92, Sector 32, Industrial Area,
Gurugaon, Haryana (India) – 122001.

Subject: Withdrawal of COVID-19 indications of Baricitinib Tablets 2mg & 4mg- Reg.

Sir,

Please refer to your application on the subject cited above regarding request for withdrawal of COVID-19 indications (additional indications for restricted use in emergency situation) of Baricitinib Tablets 2mg & 4mg.

As per request submitted by you, this office acknowledges withdrawal of following approved indications for Baricitinib Tablets 2mg & 4mg for restricted use in emergency situation and respective permissions:--

1. **Indication approved vide permission no. IMP/FF/SND/69/2021 dated 03-May-2021:**Baricitinib, in combination with Remdesivir, for the treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID 19) in hospitalised adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
2. **Indication approved vide permission no. IMP/SND/21/000104 dated 15-Nov-2021:**Baricitinib for treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

However, Baricitinib Tablets 2mg & 4mg may continue to be marketed for other approved indication i.e. Rheumatoid arthritis.

Yours faithfully,

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy to:
1. Website of CDSCO
2. It-help desk of CDAC to update in Sugam data base.