

F. No. r-DNA-11012(12)/180/2025-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 110002,

Dated:

21 AUG 2025

To,

M/s AstraZeneca Pharma India Limited,
Block N1, 12th Floor, Manyata Embassy Business Park,
Rachenahalli, Outer ring road, Bengaluru,
Karnataka (India)- 560045

Subject: Submission of PMS study protocol Study Code: D9106R00007, Version 1.0 Dated 22 Dec 2024 of Durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC) – Regarding

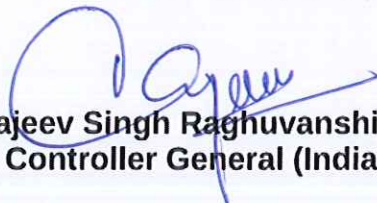
Ref: 1. Your Application Ref. No. REG/2024/DCGI/AK/217 dated 22.12.2024 received vide e-receipt No. 67751 dated 01.10.2024.

2. Recommendations of the SEC (Oncology) meeting dated 08.07.2025 at CDSCO HQ New Delhi

Sir,

With reference to the subject cited above, your application has been reviewed based on the submitted documents and further deliberated in the SEC meeting held on 08.07.2025. As recommended by SEC, this Directorate has no objection for the conduct of PMS study vide Study Code: D9106R00007, Version 1.0 Dated 22 Dec 2024 for the subject drug product under the provisions of Fifth Schedule of New Drugs and Clinical trial rules 2019.

Yours faithfully,


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