

F. No. 04-14/2023-QC Government of Pakistan Drug Regulatory Authority of Pakistan Ministry of National Health Services, Regulation & Coordination

Islamabad, the 03rd November, 2023.

TERMINATION OF DRUG PRODUCT RECALL

M/s. Roche Pakistan Ltd., 1st Floor, 37-B, Block 6. P.E.C.H.S, <u>Karachi.</u>

Subject: <u>CASES OF LOSS OF VISION DUE TO OFF-LABEL USE OF AVASTIN INJECTION IN PUNJAB.</u>

- 1. Reference is made to subject cited "Drug Product Recall" of even No. of this division dated 25-09-2023 wherein it was directed to recall the suspected batches of subject mentioned product i.e., Batch No. H0352B11, B7266B20 and B7266B07.
- 2. Samples of above-mentioned batches were sent to Central Drugs Laboratory (CDL) Karachi for the purpose test/analysis to verify the quality and safety of suspected product. CDL, Karachi vide report No. KQ-9-23-000115.(Final) and No. KQ-9-23-000116.(Final) dated 10-10-2023 (**Reports annexed**) has declared the samples of above-mentioned batches as of standard quality.
- 3. Therefore, keeping in view the reports of CDL, above-mentioned Drug Product Recall is hereby terminated with the approval of competent authority i.e. the Director, QA< Division, DRAP, Islamabad.

(Hafiz Sanaullah Babar)
Deputy Director (QA<)
DRAP, Islamabad.

Copy to:

i. PS to CEO, DRAP, Islamabad.

ii. Additional Director/Office In-charge DRAP Lahore, Karachi, Islamabad, Peshawar & Quetta.

iii. Chief Drugs Controller/Inspector Punjab, Sind, Khyber Pakhtunkhwa, Balochistan, ICT, Gilgit-Baltistan & Azad Jammu & Kashmir.

iv. Office Copy.