DRAP ALERT NO. Nº I/S/9-24-36

DRUG PRODUCT ALERT & RECALL

INCIDENTS OF LOSS AND DAMAGE OF VISION WITH THE OFF-LABEL USE OF AVASTIN 100MG/4ML INJECTION

Date: **24**th September, 2023

Target Audience:

- Ophthalmologists and Endocrinologists
- Healthcare Professionals – Physicians, Pharmacists, and Nurses.
- Regulatory Field Force.
- General Public.

Problem Statement:

Incidents of loss of vision in diabetic patients have been reported following treatment with Altered/Dispensed/Diluted Avastin injection. This product is approved by Drug Regulatory Authority of Pakistan (DRAP) to treat Colorectal and other metastatic carcinomas. The use of this drug product in diabetic retinopathy or other ophthalmic conditions is one of the off-label uses and not approved by DRAP.

The incident is linked with the alteration/dispensing/dilution and sale of Avastin 100mg/4mL Injection under unhygienic/non-sterile conditions illegally and without any Drug Sale/Dispensing License (DSL) from Provincial Health Authority by M/s Genius Advanced Pharmaceutical Services Lahore.

Threats to Public Health: -

Avastin is a registered drug of M/s. Roche Pharma in Pakistan and is available in strength of 100mg/4ml and 400mg/16ml preparations. This drug is indicated for the treatment of colorectal and other metastatic carcinomas as a VGRF (vascular endothelial growth factor) inhibitor. However, the use in diabetic retinopathy is an off-label use to block the growth of abnormal blood vessels in the eye. Since, this drug was being dispensed/diluted/repacked in 1.25mg/0.05ml dose under unhygienic conditions and in an un-approved manner, therefore, its safety cannot be ascertained, which may lead to damage and loss of vision in the patients.

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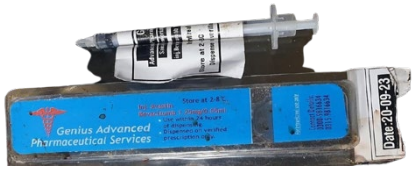
Following is the detail of alleged product:

Product involved	Manufacturer	Picture
Inj. Avastin 1.25 mg/0.05ml **Composition**: Bevacizumab **Registration No.** Nil	Genius Advanced Pharmaceutical Services.	**Un-registered Product** 

Following is the detail of DRAP approved product:

Product	Manufacturer/Importer	Picture
Avastin 100mg/4ml Injection **Composition**: Bevacizumab **Registration No.** 043004 **Suspected Batches:** H0352B11 B7266B20 B7266B07	M/s Roche Diagnostics, Germany **Importer:** M/s Roche Pharma, Karachi.	**Registered Product** 

Action Initiated: -

The Regulatory field force raided the premises of M/s Genius Advanced Pharmaceutical Services, Lahore, involved in the repacking and dispensing of Avastin injection under unhygienic/non-sterile conditions. The premises have been sealed and legal proceedings have been initiated against the personnel involved.

Samples of registered Avastin injection has been taken and sent to Drug Testing Laboratory for test analysis for verification of quality and safety of this registered product. The Importer of registered product i.e. M/s Roche Pakistan Ltd., has been directed to recall above mentioned batches of Avastin injection from the market immediately. The sale/distribution of registered Avastin Injection has been put on halt till verification of its quality and safety to safeguard the public health. Healthcare Professionals, Pharmacists and Chemists have been directed to stop the distribution, dispensing and administration of this product immediately and check their stocks and stop supplying this product. The remaining stocks should be quarantined and returned to the supplier/company.

Advice for Healthcare Professionals:

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities regarding the off-label use of this product. Adverse reactions or quality problems experienced with the use of this product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Advice for Patients/General public: -

Patients should not use this product for any ophthalmic disease and should contact their physician or healthcare provider if they have experienced any problem related to taking or using this drug product, and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

Drug Regulatory Authority of Pakistan
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