

## Event of Visual Impairment and Loss with Off-Label Administration of AVASTIN Injection

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In mid-September 2023, a significant number of diabetic patients in Lahore, Pakistan, experienced sudden vision loss or impairment. This led to widespread concern as many individuals suffered irreversible damage to their eyesight.<sup>1</sup> Following an investigation into these cases, the Drug Regulatory Authority of Pakistan (DRAP) discovered that affected patients had been administered Avastin (100mg/4mL inj), a medication intended for cancer treatment, rather than an appropriate drug for diabetic eye conditions.<sup>2</sup>

The misuse of Avastin resulted in at least 65 reported cases across the Punjab province.<sup>1,7</sup> According to the data, Avastin is a registered drug by Roche Pharma Pakistan, which offers it in dosages of 400 mg/16 ml and 100 mg/4 ml. It is advised and suggested for the treatment of colorectal and other metastatic carcinomas, according to the FDA and DRAP.<sup>3, 5, 6</sup> But as an off-label indication, it can be used in the diabetic retinopathy condition, in which there is blockage in the blood vessels of the eye that causes blurred vision. The root of the problem was an unregistered pharmaceutical company called Genius. They illegally procured Avastin, a cancer drug, and dangerously diluted it into much smaller doses under unsanitary circumstances. This contaminated product was then distributed,

resulting in severe vision loss among numerous diabetic patients.<sup>4</sup> The regulatory bodies rapidly raided the premises of its local marketing company in Lahore, which was involved in the repackaging and dispensing as well as the sale of the Avastin injection. The company has been sealed, and legal procedures have been started again for the stakeholders of the company. On the other hand, a registered drug from Avastin's sample was taken and sent to the testing lab for further evaluation to analyze the safety and efficacy of the drug. In light of the situation, Roche Pharma has recalled batches H0352B11, B7266B20, and B7266B07 of Avastin from the market. The distribution and use of Avastin have been halted nationwide until the investigation are complete.<sup>4</sup> Pakistan is facing a critical healthcare crisis due to the proliferation of unregistered pharmaceutical companies and a shortage of qualified healthcare providers. This dangerous combination has led to tragic consequences, including widespread vision loss. This is a public health emergency. We urge all healthcare professionals, including ophthalmologists, diabetologists, and general practitioners, to strictly avoid using locally manufactured or unregistered medications. The lives of the patients depend on it. It is imperative to promptly identify, track, and report any such side effects. To enhance drug safety, the establishment of pharmacovigilance centers is crucial. These centers should provide up-to-date information on medications. The misuse of drugs for unapproved purposes must be strongly discouraged.

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