

Shedding Light on the Ethical Dilemma: The Avastin Injection Crisis in Punjab

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The recent uncovering of issues surrounding Avastin (Bevacizumab) injections in Punjab has sparked serious ethical questions and highlighted the urgent need for regulatory changes. More than 70 people losing their sight due to the use of this injection has shaken the public's trust in healthcare providers and regulators.

At the heart of this crisis lies the widespread off-label use of Bevacizumab, driven primarily by its affordability compared to approved alternatives such as Ranibizumab and Aflibercept. Originally meant for cancer treatment, Avastin injections were used in the management of various ocular pathologies as a cheaper option. But the illegal production, storage, and distribution of these injections has caused irreversible harm to many patients, raising concerns about patient safety.

The role of regulatory authorities, such as the Drug Regulatory Authority of Pakistan (DRAP), also comes under scrutiny in light of this debacle. Despite the existence of licensing requirements and quality control measures, the Avastin scandal underscores the inadequacies in enforcement and oversight mechanisms. The failure to identify and prevent the illegal production and distribution by some unauthorized distributors of this injection reflects systemic shortcomings that demand immediate attention and reforms.

Foremost, regulatory agencies must consider licensing Bevacizumab for intravitreal use under controlled conditions. Despite its off-label status, extensive clinical data, alongside endorsements from reputable entities like the National Institute for Health and Care Excellence (NICE) and the International Council of Ophthalmology, underscore its potential efficacy and safety in the management of diseases like diabetic retinopathy, age related macular degeneration and choroidal

neovascularization. Regulatory bodies can ensure stringent oversight while facilitating access to this vital treatment modality by implementation of robust pharmacovigilance mechanisms and enable the generation of comprehensive long-term safety data, assuaging concerns regarding its off-label usage and bolstering confidence among clinicians and patients alike.

Furthermore, healthcare stakeholders, including Ophthalmologists and drug manufacturers, play pivotal roles in safeguarding patient welfare amidst off-label drug utilization. Ophthalmologists must diligently apprise patients of the off-label nature of treatments, thereby empowering them to make informed decisions. Simultaneously, drug manufacturers should rigorously monitor off-label usage and commit to ongoing safety surveillance to uphold their ethical obligations. Collaborative efforts between regulatory bodies, healthcare providers, and pharmaceutical companies are indispensable in navigating the intricate terrain of off-label drug usage, ensuring both patient safety and ethical integrity remain paramount.

In response to these challenges, Ministry of Health, regulatory bodies like drug Regulatory Authority and Healthcare Commission must adopt a multifaceted strategy that balances patient access with stringent safety standards. This entails conducting thorough assessments of Bevacizumab's efficacy and safety for ocular applications, guided by evidence from extensive clinical studies and meta-analyses. By leveraging insights from reputable organizations like NICE and the International Council of Ophthalmology, regulatory agencies can formulate evidence-based guidelines for the controlled licensing of Bevacizumab,

ensuring that its utilization adheres to rigorous standards of safety and efficacy. Additionally, the establishment of robust pharmacovigilance systems is imperative to monitor adverse events and long-term outcomes associated with off-label usage, thereby facilitating the generation of comprehensive safety data and informing future regulatory decisions. One of the most important challenges faced by these regulatory bodies is to strictly ensure the safe distribution of this injection by maintenance of appropriate cold chain and sterility during its distribution.

By fostering collaboration between stakeholders and prioritizing patient safety, the healthcare ecosystem can navigate the complexities of off-label usage of Bevacizumab while upholding ethical principles and regulatory standards.

References:

1. "Pakistan Today". "More than 70 rendered blind as unregulated drug continues to wreak havoc". [Online]. Available: <https://www.pakistantoday.com.pk/2023/09/26/more-than-70-rendered-blind-as-unregulated-drug-continues-to-wreak-havoc/>. [Accessed: 12 October 2023].
2. Kumar A, Tripathy K, Chawla R. Intraocular use of bevacizumab in India: An issue resolved? *Natl Med J India*. 2017;30:345–7.
3. Anothaisintawee T, Leelahavarong P, Ratanapakorn T, Teerawattananon Y. The use of comparative effectiveness research to inform policy decisions on the inclusion of bevacizumab for the treatment of macular diseases in Thailand's pharmaceutical benefit package. *Clinicoecon Outcomes Res*. 2012;4:361–74.