F. No.12-52/2004-DC(Part I)
Directorate General of Health Services
Office of Drugs Controller General (India)
(Biological Division)

FDA Bhawan, Kotla Road,
New Delhi 110002

Dated: 09.03.2016
11-03-16

Notice

This is in continuation to alert notice issued vide letter no. 12-52/2004-DC (Part-I) dated 21.01.2016 regarding use of Bevacizumab Injection in Ophthalmologic condition. The matter has been examined by the Ministry of Health and Family Welfare based on recommendation of Expert Committee meeting held on 08.02.2016 on this subject.

The Committee examined and deliberated on the use of Bevacizumab Injection in Ophthalmologic conditions as an off-label indication and following observations were made by the Committee:-

1. Bevacizumab Injection is not approved by global regulatory Authorities for intravitreal use due to non-application by the Innovator for this purpose. However, WHO (April 2015) has recommended Bevacizumab Injection by including in the list of essential medicines prepared as anti-vascular endothelial growth factor in ophthalmic section based on recommendation of International Council of Ophthalmology (ICO). Further, regulatory agencies of France and Italy have allowed its off-label use as a Temporary Recommended Use (TRU).
2. The safety and efficacy of Bevacizumab injection in intravitreal use is stated to be proven by various independent studies (over 2500 studies published) conducted globally. It was discussed that rate of endophthalmitis is significantly lower after the injection of Bevacizumab Injection as compared to standard cataract surgery.
3. The Bevacizumab Injection is 40 times cheaper than other available drug (Ranibizumab Injection) for same use and equally effective in India. This would put less financial burden on patients and prevent blindness of many.

Based on the above facts, following recommendations were made by the Committee:

The office of DCG(I) was requested to take necessary measures to withdraw the Alert Notice issued on 21.01.2016 which was primarily issued as a precautionary measure in the light of the incidences of blindness reported in Gujarat. Further, it was proposed that All India Ophthalmological Society (AIOS) and Vitreo Retinal Society of India (VRSI) will formulate guidelines for safe and effective use of Bevacizumab Injection for Ophthalmic purpose based on the written-informed consent as practiced globally for off-label use under appropriate environmental conditions by skilled ophthalmic surgeons based on risk-benefit analysis. They will further ensure that appropriate training and awareness may be imparted to its members.

The Ministry of Health and Family Welfare, Government of India has accepted recommendations of the Committee. Accordingly, this notice is issued.

(Dr. G. N. Singh)
Drugs Controller General (India)

To

All State/UT Drugs Controller

Copy to :

ll Zonal/Sub-Zonal Offices of CDSCO

Copy for information to:

i. **PPS to DGHS**
ii. **PS to JS(R)**