

---

## Ophthalmic biosimilars: Lessons from India

Sir,

India has been on the forefront of biosimilar development for ophthalmic therapeutics by developing and commercially marketing Razumab<sup>®</sup> (Intas Pharmaceuticals, Ahmedabad, India), the first commercially available biosimilar to Ranibizumab (Leucentis<sup>®</sup>), an innovator molecule (Genentech, South San Francisco, CA, USA). Many other similar molecules are in the Reserach and Development (R&D) phase globally.<sup>[1]</sup> Razumab was approved for the Indian market in 2015 for clinical use and has grown its user base rapidly. This is reflected by the fact that the number of units sold in 2018

alone were almost equal to the total sale of Razumab since its launch. (Unpublished data from manufacturer).

Yet, a major hindrance in the success of Razumab is the occurrence of adverse drug reaction (ADR) sterile endophthalmitis, being reported for specific batches of Razumab, putting a question on its safety.<sup>[2]</sup> ADR is an inherent part of any drug administration and has been reported in innovator molecules also.<sup>[3]</sup> However, cluster occurrence in specific batches of Razumab brings the interbatch variability to the limelight, and puts a question on the quality control. To counteract the nocebo about these complex molecules being perceived as generic drugs with lower safety and efficacy, stricter guidelines to validate the postapproval inter batch comparability of biosimilars should be enforced.

There are many potential ophthalmic biosimilar molecules which would be entering the global market in the next few years.<sup>[1]</sup> Manufacturers of these molecules can take the following lessons from India.

1. There is a need of biosimilars especially in developing countries where the presence of compounding pharmacies is rare. It is an opportunity for ophthalmic biosimilar manufacturers globally.
2. Strict pharmacovigilance and the careful choice of immunogenicity testing assay prior to market approval can reduce the nocebo effect around these molecules.<sup>[4]</sup>

#### Financial support and sponsorship

Nil.

#### Conflicts of interest

There are no conflicts of interest.

**Ashish Sharma, Nilesh Kumar,  
Baruch D Kuppermann<sup>1</sup>, Bandello Francesco<sup>2</sup>,  
Anat Lowenstein<sup>3</sup>**

Department of Vitreoretina, Lotus Eye Hospital and Institute, Coimbatore, Tamil Nadu, India, <sup>1</sup>Gavin Herbert Eye Institute, University of California, Irvine, Irvine, CA, USA,

<sup>2</sup>Department of Ophthalmology, University Vita-Salute, Scientific Institute San Raffaele, Milano, Italy,


<sup>3</sup>Division of Ophthalmology, Tel Aviv Sourasky Medical Center and Sackler Faculty of Medicine, Tel Aviv University, Israel

**Correspondence to:** Dr. Ashish Sharma, Department of Vitreoretina, Lotus Eye Hospital and Institute, Coimbatore - 641 014, Tamil Nadu, India.  
E-mail: drashish79@hotmail.com

## References

1. Sharma A, Reddy P, Kuppermann BD, Bandello F, Loewenstein A. Biosimilars in ophthalmology: Is there a big change on the horizon? *Clin Ophthalmol* 2018;12:2137-43.
2. Available from: <https://www.moneycontrol.com/news/business/companies/exclusive-complaints-prompt-intas-to-recall-batch-of-biosimilar-razumab-in-india-2251273.html>. [Last cited on 2019 Mar 03].
3. Souied EH, Dugel PU, Ferreira A, Hashmonay R, Lu J, Kelly SP. Severe ocular inflammation following ranibizumab or aflibercept injections for age-related macular degeneration: A retrospective claims database analysis. *Ophthalmic Epidemiol* 2016;23:71-9.
4. Sharma A, Kumar N, Kuppermann BD, Francesco B, Loewenstein A. Biotherapeutics and immunogenicity: ophthalmic perspective. *Eye* 2019 Apr 09.

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

Access this article online	
<b>Quick Response Code:</b>	<b>Website:</b> www.ijo.in
	<b>DOI:</b> 10.4103/ijo.IJO_430_19
<b>Cite this article as:</b> Sharma A, Kumar N, Kuppermann BD, Francesco B, Lowenstein A. Ophthalmic biosimilars: Lessons from India. <i>Indian J Ophthalmol</i> 2019;67:1384-5.	
© 2019 Indian Journal of Ophthalmology   Published by Wolters Kluwer - Medknow	