PHARMACOVIGILANCE OF BIOSIMILARS: Challenges & Possible Solutions

Dr J Vijay Venkatraman

MBBS, F. Diab., MBA

Managing Director & CEO

Oviya MedSafe

Coimbatore, India

London, United Kingdom

Introduction

Founded in the year 2012, **Oviya MedSafe** is a Pharmacovigilance Consulting & Drug Safety Services company based out of India and the UK, offering end-to-end global pharmacovigilance support.

Oviya MedSafe consults to emerging pharmaceutical companies to develop and maintain their drug safety systems, which includes advisory and operational support of safety databases.



Biosimilars

Biological medicine that is developed to be similar to an existing medicine (a reference medicine).

Analogues of biopharmaceutical products following patent expiry.

Biosimilars:	EU, Australia
Follow-on Biopharmaceuticals:	USA, Japan
Subsequent Entry Biologics:	Canada
Similar Biotherapeutic Products:	WHO

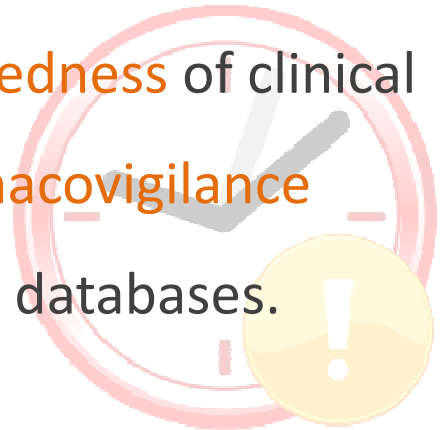


Status quo

- Biopharmaceutical first launched - 1980s
- Manufactured - Recombinant technologies
- Nearing patent expiration – Highest number of biologicals will lose its patent protection by 2020
- Opportunity - Development of biosimilars
- Higher molecular complexity - Technical advancement
- Need for pharmacovigilance - Biosimilars require more rigorous assessment as compared to traditional generic medicines.

Challenges

- Products may differ in the production process from batch to batch
  - This inherent differences may produce dissimilarities in clinical efficacy, safety, and immunogenicity.
- Switching of biosimilars
  - Differences in biological activity can result in adverse outcomes
- Need for tailored pharmacovigilance plan
  - Even with available regulatory guidelines, limitedness of clinical experience with biosimilars at approval, pharmacovigilance programs will be important to establish clinical databases.



EU

- EMA issued guidelines as precautions, many under review.
- Guidelines address pre-clinical and clinical testing prior to market authorization, postmarketing PV plan expected to be included.
- RMP stating the safety data must be submitted by manufacturers to conduct trials and obtain authorization for the product.
- RMP must be submitted as a part of the marketing application for all new chemical and biological drugs, inclusive of biosimilars.
- RMP should include immunogenicity and lack of efficacy as a safety concern



EU

- Approved biosimilars are considered ‘comparables’ to the reference product, but are not ensured to bear therapeutic equivalence.
- Total of 14 biosimilars have been approved by the EMA.
- Adverse event reporting requires the member states to take all measures to identify any biological product dispensed.
- Traceability is improved by commercializing biologics with a brand name or the international nonproprietary name plus the manufacturer’s name.



US

- In accordance with the FDA, biosimilars are products highly similar to a US-licensed reference biological product not withstanding minor differences in clinically inactive components.
- There are no differences between the biological product and the reference product in terms of safety, purity, and potency.
- Till date, the FDA has not approved a biological product as a biosimilar or interchangeable.
- USFDA is currently working on the review and licensure process for biosimilars.



Conclusion

- Pharmacovigilance, as a part of risk management programme, will need to comprehensively include regular monitoring for the consistency, safety, traceability, and the efficacy of the drug.
- Postmarketing surveillance for biosimilars is critical due to the limited spontaneous information available with regard to suspected adverse drug reactions associated with their usage.

Contact Us

Global Delivery Centre (HQ):

Oviya MedSafe Pvt Ltd

2nd Floor, KTVR Gardens

220a-3, Marudha Konar Road

Velandipalayam

Coimbatore - 641 025

India.

Tel: +91-422-2444442

UK Office:

Oviya MedSafe UK Ltd

Suite LP25393

Lower Ground Floor

145-157, St John Street

London, EC1V 4PW

United Kingdom

Tel: +44-8452-733839

E-Mail: info@oviyamedsafe.com

Web: www.oviyamedsafe.com

Stay connected:

www.linkedin.com/company/oviya-medsafe

www.twitter.com/OviyaMedSafe

www.facebook.com/OviyaMedSafe

Oviya MedSafe

Practising Safety

Our Home to Drug Safety



Thank You