PHARMACOVIGILANCE OF BIOSIMILARS: Challenges & Possible Solutions

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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.
• 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.
• 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.
• 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.
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