REG.NO:D7635654-AFINJ JOHP-ISSN: 2348-7704

HEB JOHP

HEB's Journal of Hospital Pharmacy
An Official Publication of Bureau for Health & Education Status Upliftment
(Constitutionally Entitled as Health-Education, Bureau)

Targeted Pharmacovigilance for Biosimilars

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ABSTRACT

Background:

Biosimilars have emerged as cost-effective alternatives to biologic therapies, improving patient access to treatment, particularly in resource-limited settings. However, due to their complex structure and potential immunogenicity, concerns regarding their safety, interchangeability, and pharmacovigilance remain. In addition, limited awareness and understanding among healthcare professionals may influence their optimal utilization in clinical practice.

Objective:

The present study aimed to evaluate adverse drug reactions (ADRs) associated with biosimilars and to assess the knowledge, attitude, and practice (KAP) of healthcare professionals regarding biosimilars in a tertiary care hospital.

Methods:

A prospective observational study was conducted in the departments of oncology, general medicine, and paediatrics at a tertiary care teaching hospital in Dehradun, India. ADRs were collected and analyzed from 105 patients receiving biosimilar therapies using standard reporting formats and causality assessment scales. Simultaneously, a structured and validated KAP questionnaire was administered to 120 healthcare professionals, including physicians, pharmacists, and nurses. Data were analyzed using descriptive statistical methods and expressed as frequencies and percentages.

Results:

A total of 105 ADRs were documented, with the highest incidence observed among oncology patients. The majority of ADRs were classified as mild to moderate in severity, with infusion-related reactions, hypersensitivity reactions, and gastrointestinal disturbances being the most commonly reported. Causality assessment indicated that most reactions were probable or possible. The KAP analysis revealed that a considerable proportion of

healthcare professionals had inadequate knowledge regarding biosimilars, particularly in differentiating them from generic drugs and understanding regulatory pathways. Despite this, attitudes toward biosimilars were generally positive, with most respondents acknowledging their cost-effectiveness and clinical utility. However, pharmacovigilance practices, including ADR reporting, were found to be suboptimal.

Conclusion:

The study highlights that while biosimilars are increasingly utilized in clinical practice, significant gaps persist in knowledge and pharmacovigilance practices among healthcare professionals. Strengthening targeted pharmacovigilance systems and implementing structured educational programs are essential to ensure the safe and effective use of biosimilars.

Keywords:

Biosimilars; Pharmacovigilance; Adverse Drug Reactions; Knowledge Attitude Practice; Healthcare Professionals; India

Access this Article Online	Quick Response Code:
Website: http://www.journalofhospitalpharmacy.in	
Received on 03/05/2026	
Accepted on 14/05/2026 © HEB All rights reserved	