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# Biosimilars: Review of the safety issues and the current Pharmacovigilance methods

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WHO defines biosimilar as "A biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product." They are copy versions of an approved original biologic medicine whose data protection has expired. Recent expiration of patents of the original biologic medicines has created opportunities for the development of biosimilars. Since biosimilars are available in the market at significantly lower costs compared to the conventional drugs, they are very important in developing countries like India. There are various sources of variation among the manufacturing process of original and the biosimilar drugs which can lead to considerable changes in the safety and efficacy of the biosimilar. A unique concern is their potential to induce an immune response. The other challenges related to biosimilars are naming/labelling, substitution and interchangeability and traceability. Moreover, since similar biologics are authorized based on a reduced preclinical and clinical data, clinical safety monitoring of these products should be stringent in post marketing phase to detect any unexpected adverse event at the earliest. Therefore, it has been made mandatory that biosimilar manufacturing companies should submit a Risk Management Plan (RMP) as a part of their marketing authorization process. Periodic Safety Update Reports (PSURs) may play an important role as a pharmacovigilance tool for biosimilars.

## Biography

Aashal B Shah is currently pursuing MD Pharmacology (second year) in Government Medical College, Surat, affiliated to Veer Narmad South Gujarat University. Presently she is working on various projects related to Adverse Drug Reaction detection, monitoring, causality assessment, severity and preventability.

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