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Traceability of Infliximab Reference Medicinal Product and its Biosimilar Products Adverse Drug Events Reports in Saudi Arabia

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Background & Objective

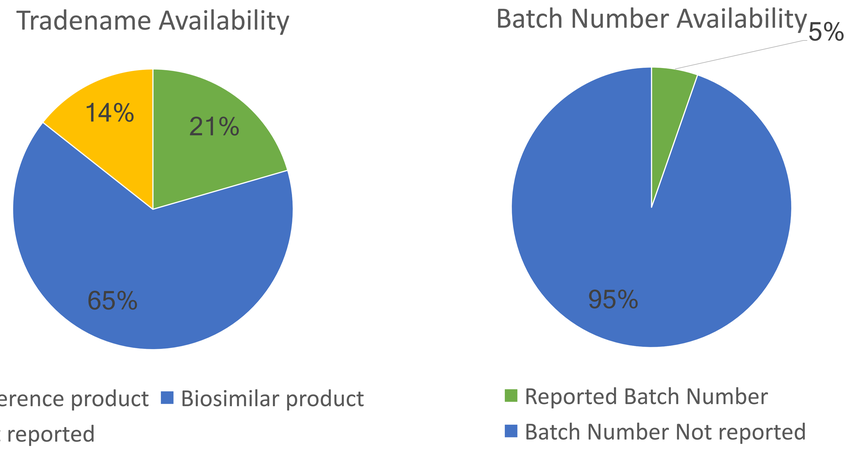
Infliximab reference product and two biosimilar products were approved by the Saudi Food & Drug Authority (SFDA) for treatment of a wide variety of inflammatory conditions such as rheumatoid arthritis, Crohn's disease, and ankylosing spondylitis. Recording both the product trade name and the batch number are essential in spontaneous reporting of adverse drug events (ADEs) of biological medicines due to the variability of the bio-manufacturing process that may cause safety risks such as immunogenicity. This study aims to assess the availability of batch number and trade name in the ADE reports of Infliximab (reference product) and biosimilar products in the National Pharmacovigilance Center (NPC) database at SFDA.

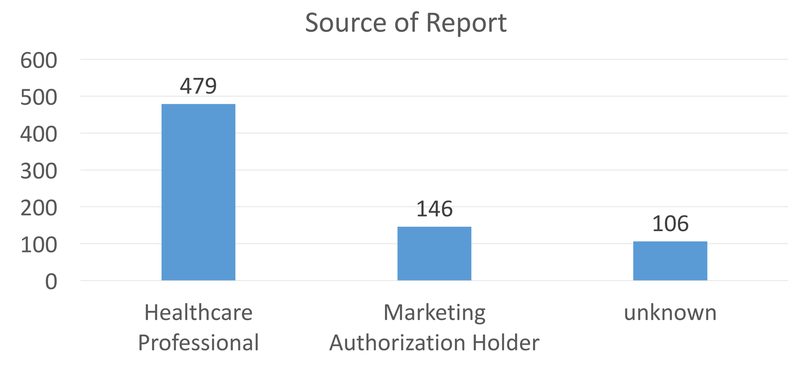
Methods

We performed a descriptive analysis of spontaneous ADE reports of Infliximab (reference and biosimilar products) in Saudi Arabia reported to the NPC from December 1, 2017 to January 03, 2023. The analysis examined the reporting frequency of batch number, and trade name.

Results

Overall, a total of 731 cases were retrieved from the NPC database. We found reported trade name in 626 (85.6%) cases [150 (23.9%) for reference product and 476 (76%) reports for biosimilar products]. However, the batch number identifier was only included in 39 (5.3%) out of 731 cases [7 (17.95%) in reference product and 32 (85.05%) in biosimilar products). 479 (89%) of case reports were received from healthcare professionals (pharmacists), whereas 146 (19.9%) cases have been reported from marketing authorization holders.





Conclusion

Our study shows lack of reporting batch number with Infliximab reference and biosimilar products in the NPC database. It is essential to raise awareness of importance to report trade name and batch number of reference and biosimilar products among healthcare providers and the public to improve data quality of biologic and biosimilar products' ADE reports.