



IMPACT OF PHARMACOVIGILANCE ON DRUG SAFETY

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ABSTRACT

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem. Pharmacovigilance has grown significantly in recent years and its importance in the healthcare system has been recognized worldwide. However, there are considerable issues which need to be addressed to ensure the safety of medicines. PV deals with adverse effects of drug, poly-pharmacy, paradoxical reactions, and severe adverse events. The aim and scope of pharmacovigilance is broad and includes multiple components such as medication errors, counterfeit and unauthorized medicines, lack of efficacy, drug interactions, and rational prescription of medicines. Pharmacovigilance systems were developed in most countries after the thalidomide disaster in the 1960s when thousands of children were born with phocomelia as a side effect of the medicine thalidomide, leading to the shortening or absence of limbs. The thalidomide tragedy raised numerous questions about the safety of medicines and raised the challenge of establishing systems to assess and ensure the safety of medicines in all countries. Biosimilars are biologic drugs produced by a different company aiming at imitating the original product. Biosimilars have the same peptide sequence, but may not be identical due to post-transcriptional modification or alterations during the purification process. PV is a flourishing concept which deals with chemical, botanical, and biological medicines including medical devices.

KEYWORDS: Poly-Pharmacy, Paradoxical reaction, Counterfeit, Rational Prescription, Biosimilars.

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