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Why do we need Pharmacovigilance?

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In the 1960's, the thalidomide disaster led to limb deformities in the newborns of those mothers who took the drug while pregnant. This implies that premarketing evaluation of drug safety, in animal experiments and in phase 1-3 clinical trials, provides insufficient evidence of safety. Accordingly, it is vital to monitor safety of all medicines throughout their marketed life because adverse drug reaction-related cost to the country may exceed the cost of the medications themselves. The study of ADRs is the concern of the field of pharmacovigilance which is gaining importance as the number of stories of drug recalls increases. The WHO international drug monitoring program started in 1968; it is located in Uppsala, Sweden. In Egypt, the Egyptian PV Centre was established in 2009 and is linked to the global PV system. The program is based on voluntary ADR reporting and monitoring and is vital for maintaining drug safety. Voluntary reporting by physicians and other health providers and consumers may alert the authorities and pharmaceutical companies to possible adverse effects of drugs. It aims in reducing the risks associated with drug prescribing and administration and improving patient care, safety and treatment outcome. The Yellow Card Scheme was founded in 1964 after the thalidomide disaster. It receives more than 20,000 reports of possible side effects each year. To conclude, pharmacovigilance is a dynamic clinical and scientific discipline. It provides reliable, balanced information for the effective assessment of the risk/benefit profile of medicines. Under-reporting remains the corner stone that hinders pharmacovigilance activities.

Biography

Samira Saleh, PhD, Cairo University and Post-doctoral studies from Strathclyde University, UK, is currently the Head of the Department of Pharmacology, Faculty of Pharmaceutical Sciences and Pharmaceutical Industries, Future University. She is a Board member of The Egyptian Society of Pharmacology and Experimental Therapeutics and the Editor-in-Chief of the Egyptian Journal of Basic and Clinical Pharmacology. She makes evaluation of Science and Technology Development Fund (STDF) projects. She has published around 85 papers, supervised more than 50 thesis and gave presentations at more than 60 conferences. She received many awards from the Supreme Council of universities for publishing papers in international journals.

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