Adverse Drug Reactions reporting and pharmacovigilance: its importance

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Abstract

The use of medicines is unavoidable. The use of in vivo and in vitro techniques in drug development is not sufficient for medicine approval. In the development of drugs there are clinical stages that are carried out to ensure the safety and efficacy of medicines. Medicines in preproduction elicit different effects and reactions from those elicited in the post production, as those are influenced by longer treatment exposure, polypharmacy, bioavailability and metabolism. The post marketing surveillance stage ensures the detection of adverse drug reactions (ADRs) which were not detected during clinical stages. The establishment of pharmacovigilance (PV) systems was prompted by the thalidomide disaster, the death of Hannah Greener due to use of chloroform, the Biologics Control Act, the Food and Drug Act, Durham-Humphrey Amendment and the Kefauver-Harris amendments. For a good and efficient PV system it is imperative that ADRs are reported, quantified and documented. Since the inception of PV in South Africa in 1992, the system has progressed from passive regulatory reporting to active surveillance activities. Studies have shown many barriers to passive reporting of ADRs in the health care sector such as poor knowledge by health care providers to completing the reporting form, reporting is time consuming, and when reporting is done, there is no acknowledgement of the submitted forms by the PV authorities. ADRs bring about a financial burden in health budgets, therefore the management of ADRs and more over of preventable ADRs is essential.

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