CONFERENCE ABSTRACT

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PHARMACOVIGILANCE AND DRUG SAFETY: A NEW PARADIGM FOR PHARMACY PRACTICE

Mundokar K. P, Vaidya V. M., Bhajipale N.S.
S.G.S.P.S. Institute of Pharamcy, Kaulkhed, Akola.

ABSTRACT

With the continuous improvement of international Pharmacovigilance technology and methods it becomes the key part of the post marketing evaluation. Adverse drug reaction experienced with use of a medicinal product may result in significant morbidity and mortality. The ultimate goal of Pharmacovigilance is to ensure safe use of medicine, minimizing the risk related to the medical product and maximizing the benefits. Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effect or any other possible drug related drawback , particular, long term and short term adverse effect of medicine. During development of a medicinal product it undergoes animal listing and establishing its safety and efficiency in human before permission to market is granted. However, clinical trials are conducted on a small number of patient, ranging to a few thousand and excluding special population. Ex: children, pregnant and lactating women and geriatric patient. Data generated during clinical trials will provide information about the common adverse events but more rare adverse events may not be encountered. Therefore, it is important to monitor safety during the post approval period and throughout the entire lifecycle of the medicinal product to arrive at the actual risk benefit profile of the medical product and take necessary measures to minimize risks. In addition to analyzing individual care safety reports and aggregate reports, risk managements is undertaken by data mining Pharmacovigilance safety databases, signal detection, and by implementing risk management programmes.

KEYWORDS: Drug safety, Adverse drug reaction, Drug monitoring, Clinical trials.

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