

# Importance of Pharmacovigilance and the Role of Healthcare Professionals

Najafi S\*

Pharmaceutical Sciences, Saint John's University, New York, USA

\*Corresponding author: Sheyda Najafi, Pharmaceutical Sciences, Saint John's University, New York, USA, Tel: +13472209926; E-mail: shayda8466@yahoo.com

Received date: December 27, 2017; Accepted date: January 22, 2018; Published date: January 29, 2018

Copyright: © 2018 Najafi S. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

## Commentary

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.

According to the World Health Organization (WHO), pharmacovigilance also known as the “drug safety” is the science and activity relating to the detection, assessment, and prevention of adverse effects. 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 [1].

On the other hand, adverse drug reactions (ADR) are defined by WHO as “any noxious and unintended response to a medicines which might occur at doses utilized for prophylaxis, diagnosis or treatment.” Globally, the high prevalence of ADRs has increased the morbidity and mortality in both the hospital and community settings. ADR is known as one of the main causes of the patient harm over the world. In numerous countries, ADRs rank among the top leading causes of mortality and morbidity [2].

To prevent or lower the patient hazards, improvements in public health and precise evaluation and monitoring of drug safety are crucial. To achieve this goal, an efficient pharmacovigilance and ADR reporting system should be established in all countries.

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 [3].

It is evident the costs of mortality and morbidity of drugs is much higher than the cost of drug development process. On average, 10 percent of approved medicines are withdrawn from the market due to serious adverse events. Pharmaceutical companies spend approximately one billion dollars to develop a medicine and it may take many years. Though a significant amount of information could be obtained on the product's efficacy during the process of pharmaceutical drug development, it is impossible to determine the complete safety profile of the product in pre-market studies. Yet, some medicines could be withdrawn from the market due to safety issues concerning the emergence of severe adverse events [4].

During the last decade, the widely recognized recall of Vioxx, a non-steroidal anti-inflammatory drug, played a strong role in driving new safety reforms at the FDA rulemaking level. Approved by the FDA in

1999, Vioxx was initially hoped to be safer than previous analgesic medicines, due to its lower risk of GI bleeding. However, it was estimated to have contributed to fatal heart attacks in thousands of patients in the United States. With regards to Vioxx withdrawal, there was a widespread debate for reforms in the U.S FDA's procedures for pre- and post- market medication safety regulation. It is also critical for healthcare professionals and pharmaceutical companies to appropriately monitor drug safety in the post-marketing step [5]. Pre-market Clinical Trials fail to address all safety concerns of the medicines. The defects of clinical trials to identify medication safety consist of small study sample size, limited age groups (excluding children, adolescent, elderly, etc.), short duration of study, and limiting specific indication for use of medicine. Following the introduction of the medicine into the pharmaceutical market, massive populations over the world get exposed to the medicine. Furthermore, information on ADRs is collected over time as the medicine is used for multiple indications or in different subsets of patients, and this limitation modifies the safety profile of the drug. So when a drug is newly marketed, much may be achieved about its efficacy while relatively little could be obtained about its safety. The post-marketing surveillance is vital to identify drug safety issues not detected during the pre-marketing studies. Then, the primary source of safety information for new approved drugs is post-marketing surveillance of adverse experiences in both community and clinical settings [6,7].

Healthcare professionals play a crucial role in the pharmacovigilance system. They require considerable knowledge and expertise in the field of medication safety which will successfully contribute to this area through early recognition, management, and reporting of the medicine safety issues. Furthermore, the healthcare professionals should be well educated about the necessity and procedure of adverse event reporting. They should possess a combination of training and research skills in this area. Despite global concerns against medication safety, there is a lack of awareness and knowledge of pharmacovigilance and ADR reporting among healthcare professionals yet. Moreover, recent studies have indicated that ADRs are poorly reported by healthcare providers, especially in developing countries. It has been reported that only 2-4% of all adverse reactions and 10% of serious ADRs are reported worldwide. It is highly recommended that healthcare professionals including physicians, pharmacists, and nurses report any suspected adverse reaction particularly those suspected reactions to newly authorized medicines and serious events. Therefore the medicine safety assessment must be considered an inseparable part of everyday clinical practice for healthcare professionals [8].

Spontaneous adverse reaction reporting is the main backbone of pharmacovigilance and is required to create hypotheses about potential harms of medicines that need further evaluation. Spontaneous reporting is highly helpful in identification of very rare or delayed

reactions that could not be detected during the short period of the clinical trial. The safety of a medicine could be investigated after its approval and throughout its life cycle by using spontaneous reporting tool [9].

The knowledge and perception of healthcare professionals toward safety profile of medicines is essential. They should be aware of the potential occurrence of unexpected adverse reactions and report suspected adverse reactions to the Medicine Regulatory Authorities to facilitate detection and assessment of drug safety signals. Healthcare professional should notice that no medicinal product is entirely or absolutely safe for all people, in all places, at all times. They must always practice with some measure of uncertainty.

## References

1. World Health Organization (2015) Fast facts on Pharmacovigilance.
2. World Health Organization (2002) The Importance of Pharmacovigilance-Safety Monitoring of Medicinal Products.
3. Kim JH, Scialli AR (2011) Thalidomide: the tragedy of birth defects and the effective treatment of disease. *Toxicol Sci* 122: 1-6.
4. Food and Drug Administration (2005) Guidance for Industry, Premarketing Risk Assessment.
5. Krumholz HM, Hines HH (2007) What have we learnt from Vioxx?. *BMJ* 334: 120-123.
6. Naranjo CA, Busto U, Sellers EM (1982) Difficulties in assessing adverse drug reactions in clinical trials. *Prog Neuropsychopharmacol Biol Psychiatry* 6: 651-657.
7. Berlin JA, Glasser SC, Ellenberg SS (2008) Adverse Event Detection in Drug Development: Recommendations and Obligations Beyond Phase 3. *Am J Public Health* 98: 1366-1371.
8. Almandil NB (2016) Healthcare professionals' awareness and knowledge of adverse drug reactions and pharmacovigilance. *Saudi Med J* 37: 1359-1364.
9. Sharma M, Gupta SK (2011) Postmarketing surveillance. In: Gupta SK. *Textbook of pharmacovigilance*. New Delhi: Jaypee Brothers 75-92.